## The Origins of CE Marking: Standards, Business, and the European Market in the 1980s-1990s

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Figure 1: The CE Mark<sup>1</sup>

Its contours are widely recognizable, but the "CE Mark" appears with such ubiquity and is so deeply embedded within our collective visual memories that we think little about its significance. By indicating conformité européenne to regional standards for health and safety, the symbol serves several important functions: equally a source of consumer confidence in a product's regulatory compliance and a mechanism for a kind of regional "nation branding," a logo "in the promotion of [the EC's] interests in the global marketplace" and a visual reminder of the far reaching influence of Brussels and its rule makers.<sup>2</sup> Most importantly, marks of conformity like the CE dually function as vectors for the circulation of goods within and among markets on the one hand and as non-tariff barriers restricting market access on the other. In the case of European markets, the small emblem of the CE effectively determines what products in key categories like electronics and machinery can legally be sold within the European Economic Area (EEA) – the trading bloc formed between the European Union (EU) and European Free Trade Association (EFTA) in 1994. As a result, this seemingly mundane icon of technocracy is actually at the center of the relationship between business and governance in Europe and represents the most fundamental building blocks of political economy, shaping everything from the macroeconomy of international trade to the microeconomy of household goods.

For all of its contemporary consequence, relatively little scholarly attention has been paid to the origins of CE Marking, the system of conformity assessment and certification that includes affixing the emblem of the CE Mark. Yet, its centrality to the free movement of goods across the EU's Single European Market and the EEA, as well as its ability to restrict the market access of goods and their manufacturers, underscore the importance of historicizing its development and examining the stakeholders involved in shaping its procedures.<sup>3</sup> The European Commission's "New Approach" to

<sup>&</sup>lt;sup>1</sup> European Commission, Directorate General for Internal Market, Industry, Entrepreneurship, and SMEs: https://ec.europa.eu/growth/single-market/ce-marking\_en. Accessed May 2021.

<sup>&</sup>lt;sup>2</sup> Mads Mordhorst, "Nation Branding and Nationalism," in Stefan Berger and Thomas Fetzer, eds. *Nationalism and the Economy: Explorations into a Neglected Relationship.* (Budapest: Central European University Press, 2019): 191. For more on the ability of EU institutions to exert global influence, see: Anu Bradford, *The Brussels Effect: How the European Union Rules the World.* (New York: Oxford University Press, 2020). Importantly, the CE Mark is not intended to serve as an indicator of quality, just of regulatory compliance.

<sup>&</sup>lt;sup>3</sup> International efforts to organize standards began in the early twentieth century, but it was only in the context of the intensifying global competition of the 1980s that the Commission turned to standardization and harmonization as the way to relaunch the integration process. See: Carol Cosgrove Twitchett, ed. *Harmonization in the EEC*. (London: MacMillan Press, 1981); Michelle Egan, *Constructing a European Market: Standards, Regulation, and Governance*. (New York: Oxford University Press, 2001); Yates and Murphy, *The International Organization for Standardization (ISO): Global Governance through Voluntary Consensus*. (London: Routledge, 2009); Stefano Ponte, Peter Gibbon, Jakob Vestergaard, eds. *Governing through Standards: Origins, Drivers and Limitations*. (New York: Palgrave Macmillan, 2011).

standardization – launched in 1985 amid hurried efforts to relaunch integration and complete the Single Market – streamlined the process of removing technical barriers to trade by focusing only on "essential requirements" outlined by directives drafted by the European Commission and approved by the Council, delegating the development of standards to European standards bodies, keeping the use of standards voluntary, and granting presumed legal conformity to products manufactured according to European standards.<sup>4</sup> While the New Approach lacked comprehensive procedures for testing and certifying conformity, subsequent Commission directives for pressure vessels, toys, and construction products issued in 1987 and 1988 implemented a common "EC Mark" of conformity, although they did not address the persistent patchwork of heterogeneous national systems. In 1989, after consultation with industry and business groups, the Commission's "confusingly named" "Global Approach" to Certification and Testing provided three major reforms: it created comprehensive operational categories called "modules" for conformity assessment (the set of processes that demonstrate a product has met the requirements of a standard), consolidated the certification of conformity (verification that the legal requirements have been met), and required a universal mark of conformity for all products covered by New Approach directives: the "CE Mark."

How did businesses respond to the development of regional standards, essential requirements, and various systems of conformity assessment and certification? Did companies based in the EC express different interests than their counterparts headquartered elsewhere? How does the history of the CE Marking and its wide application inform our understanding of the business experience of integration by standardization, and what does it tell us about the dynamics of business-government relations across the European region? Motivated by such questions, this working paper examines the origin, implementation, and reform of the CE Marking process and considers the perspectives of both policymakers and companies in developing a common system of testing and certification. Archival documents from European institutions make it possible to reconstruct exchanges between business groups and the European Commission and Parliament and reveal that the EC solicited business feedback as it worked to develop and refine its Global Approach. Because CE Marking shaped the regional business environment and was the result of a public-private effort, this dialogue between

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<sup>&</sup>lt;sup>4</sup> Commission of the European Communities, "Technical Harmonization and Standards: A New Approach," COM(85) 19 final, Brussels, 31 January 1985. Jacques Pelkmans has published extensively on the New Approach and standardization in the European Community and Union. See, for example: Pelkmans, The New Approach to Technical Harmonization and Standardization," *Journal of Common Market Studies*, Vol. 25, no. 3 (1987): 249-269.

<sup>&</sup>lt;sup>5</sup> That even the Commission acknowledged the potential for confusion in naming this reform warrants some explanation: reflecting other EC efforts to take "global approaches" to economic affairs and regulation, the Global Approach to Testing and Certification was not global in its geographic scope, but rather in the comprehensiveness of its methods and in the flexibility of its applications. Commission of the European Communities, "Re-Examined Proposal for a Council Decision – concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives," COM(90) 606 final – SYN 208. Brussels, 7 December 1990. PE3-21885, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>6</sup> European Commission, "Guide to the Implementation of Directives Based on New Approach and Global Approach (1999)." (Luxembourg: Office for Official Publications of the European Communities, 2000.)

<sup>&</sup>lt;sup>7</sup> European Council, "Council Directive 93/68/EEC of 22 July 1993 on Amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384 / EEC (nonautomatic weighing instruments), 90/385 / EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits)." Official Journal of the European Communities.

<sup>&</sup>lt;sup>8</sup> These sources were consulted at the Historical Archive of the European Union in Fiesole, Italy, through the Archive of European Integration, and from the Official Journal of the European Communities.

business and policymakers is an essential, but understudied chapter in the history of European standardization and market integration. And because of its application beyond the borders of EC member states, the development of CE Marking occupies a central place in the wider economic history of European integration, from the EC to the EEA.<sup>9</sup>

This working paper makes three main contributions. First, it considers the role of CE Marking in European economic integration. In doing so, it finds that the process of conformity assessment and certification was crucial to internal market integration in the EC, advanced the competitiveness of European firms, and compelled extra-EC companies to adopt European standards in order to gain access to the large Single Market. 10 But common standards also presented challenges to firms operating in Europe. 11 As a second contribution, then, this paper examines the ways standards and regulations shaped business environments, especially for firms producing and selling products in the key categories for which the EC issued directives. Essential requirements and rules for conformity assessment and certification had the potential to facilitate economies of scale just as much as they had the potential to create new barriers to trade. 12 Third, this paper analyzes the ways business groups shaped the regulatory environment in which they operated by contributing to the development of the Global Approach to Testing and Certification. Interpretations of this history need not sensationalize the influence of business on policy in order to acknowledge that the increasing, global "privatization of regulation" augmented the "power of standards" and certification and only made firms more committed to close involvement in the standards process, motivating European multinationals and exporters to the EC to advocate for Europe's adoption of international norms.<sup>13</sup> Filling the gap in scholarship on both CE Marking and business responses to it, this public-private history gives us purchase on the evolution of business-government relations in Europe and on the ways conformity assessment and certification shaped production, consumption, and regulation across the region.<sup>14</sup>

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<sup>&</sup>lt;sup>9</sup> Taken together, the EFTA's inception as a rival intergovernmental organization to challenge the EEC and the eventual economic alliance between the two entities lay bare the ultimate prioritization of open trade within a regionally coordinated policy framework. The timing of the EEA agreement is also of consequence: it was in May 1992, before the completion of the 1992 Program, that the member states of the EC and those of the EFTA agreed to form an internal market among them. Notably, Switzerland withdrew from the agreement by popular referendum just a few months later.

<sup>&</sup>lt;sup>10</sup> Jacques Pelkman's extensive work on standardization and market integration laid the foundation for research on CE Marking. Also, in his study on the contributions of the European Parliament to the making of the Single Market, Laurent Warlouzet surveyed the importance of the New and Global Approaches to market integration. See: Laurent Warlouzet, "Completing the Single Market: The European Parliament and Economic Integration, 1979-1989," *European Parliament History Series*, PE 646.120 (2020): 66.

<sup>&</sup>lt;sup>11</sup> On the topic of businesses responding to the challenge of European economic integration, this working paper builds on work by Geoffrey Jones and Peter Miskell, "European Integration and Corporate Restructuring: The Strategy of Unilever, c. 1957-1990," *Economic History Review* Vol. 58, no. 1 (2005): 113-139.

<sup>&</sup>lt;sup>12</sup> Michelle Egan's 1997 paper on European standards raised the important question of whether standards better facilitate trade or serve as impediments to it. See: Michelle Egan, "Bandwagon or Barriers? The Role of Standards in the European and American Marketplace," Center for West European Studies: European Union Center Working Paper no. 1, December 1997.

<sup>&</sup>lt;sup>13</sup> Tim Büthe and Walter Mattli, *The New Global Rulers: The Privatization of Regulation in the World Economy.* (Princeton University Press, 2011). Jean-Christophe Graz, *The Power of Standards: Hybrid Authority and the Globalization of Services.* (London: Cambridge University Press, 2019).

<sup>&</sup>lt;sup>14</sup> Neil Rollings and Marine Moguen-Toursel, "European Organized Business and European Integration in the Post-Second World War Period," *Jahrbuch für Wirtschaftsgeschichte/Economic History Yearbook*, Vol. 53, no. 1 (2012), 103-123; Matthias Kipping and Neil Rollings, "Private transnational governance in the heyday of the nation-state: The Council of European Industrial Federations (CEIF)," *Economic History Review*, Vol. 61, no. 2. (2008): 409-431; David Coen, Wyn Grant, and Graham Wilson, *The Oxford Handbook of Business and Government*. (Oxford: Oxford University Press, 2010).

To contextualize its interventions, this paper begins by historicizing the foundations of European standardization and surveying the achievements and shortcomings of the Commission's "old approach" to technical regulation in use from the 1960s to 1980s. In its second section, this paper discusses the New Approach and its role in relaunching the process of market integration among EC member states in 1985. The weaknesses of the New Approach and the need for reform are discussed in the third section, along with the Commission directives from 1987 and 1988, which introduced the EC Mark. The fourth section turns to the drafting of the Global Approach and the contributions of business to developing its modules and CE Marking procedures. The fifth section connects the development of CE Marking to the completion of the Single Market and the creation of the EEA. The conclusion reflects on the implications of this history for conceptions of European integration and of the ways business related to the rules of the Single Market and the broader European Area.

#### I. Early European Standardization and the "Old Approach"

The roots of European standardization lie in the late nineteenth and early twentieth century globalization of ideas, trade, and norms. World War I shocked the trend of increasing global interconnectedness and creation of international standards, 15 but by the interwar period, the League of Nations imagined new frameworks for economic cooperation, and organizations like the International Chamber of Commerce (ICC) advocated for trade liberalization with common rules. Such internationalist aspirations were soon stymied again, as much by the uneven development of the Second Industrial Revolution and the failed management of the peace as by the outbreak of another World War. 16 Yet, early proposals for international economic coordination paved the way for postwar designs for a new world order in which economic integration could finally guarantee stability.<sup>17</sup> As wartime nationalism gave way to intensive international cooperation after the Second World War, new organizations emerged with improved plans for widespread social and economic coordination. 18 These proposed "internationalisms" required institutions to facilitate their objectives, and so sprung up a vast network of organizations like the United Nations (UN) and its economic commissions, the Council of Europe, the Organization for Economic Cooperation and Development (OECD), and, out of the European Coal and Steel Community (ECSC), the European Economic Community (EEC), the early predecessor of the EC and EU.<sup>19</sup>

The many and diverse iterations of integration, ranging from cultural essentialism to political federalism to economic unification, shared a core element: the need for common norms and standards and the demand for an apparatus to coordinate harmonization. While "globalists" saw standards at the intersection of the worlds of *dominium* and *imperium*, capable of forging a world economy through the use of uniform technical specifications for goods on an international market, international

As JoAnne Yates and Craig Murphy explain, engineers played a central role in advancing international standards. See: Yates and Murphy, Engineering Rules: Global Standard Setting since 1880. (Baltimore: Johns Hopkins University Press, 2019).
 Craig Murphy, International Organization and Industrial Change: Global Governance since 1850. (New York: Oxford University Press, 1994): 136-152.

<sup>&</sup>lt;sup>17</sup> Glenda Sluga, Internationalism in the Age of Nationalism. (Philadelphia: University of Pennsylvania Press, 2013); Patricia Clavin, Securing the World Economy: The Reinvention of the League of Nations, 1920-1946. (Oxford: Oxford University, 2013); Thomas David and Pierre Eichenberger, Businessmen of the World, Unite!' The International Chamber of Commerce and the Rise of Global Capitalism in the Twentieth Century. (Project in progress, 2020).

<sup>&</sup>lt;sup>18</sup> Craig Murphy explained how the interwar depression had finally convinced European officials to forsake their punitive and imperial approach to the peace and focus instead on development assistance, inclusive social orders, institutional frameworks, industrial growth, and welfare support. See: Murphy, *International Organization and Industrial Change*, 153-218.

<sup>19</sup> Patricia Clavin and Glenda Sluga, eds., *Internationalisms: A Twentieth Century History*. (Cambridge University Press, 2016); Kiran Klaus Patel, *Project Europe: A History*. (Cambridge University Press, 2020).

standards garnered widespread support from those with regional and even national interests who saw standards as engines of widespread economic growth, the means by which producers could achieve economies of scale.<sup>20</sup> That the International Organization for Standardization (ISO) was established in parallel with the UN and EC in the mid-1940s and came to occupy a prominent place within the concentration of international organizations in Geneva and provide standards documents to its fellow intergovernmental organizations proves just how central standardization was to the global project of economic integration.<sup>21</sup>

As the European project took shape in the 1950s and Western European countries developed their own more insular internationalism, standards acquired a new importance. They became mechanisms for integration through the removal of barriers to trade and, equally, for reinforcing the exclusivity of the EEC agreement for a common market made between France, Germany, Italy, and the Benelux countries in the 1957 Treaty of Rome. Articles 30 and 100 of the EEC Treaty focused on the legal and policy regimes for legislative harmonization, the purpose of which was to overcome national differences impeding cross-border trade: Article 30 allowed for restrictions on imports, exports, and goods for reasons of security, morality, and human health and safety; Article 100 gave the Council the power, after receiving a proposal from the Commission and consulting the Economic and Social Committee of the Parliament, to issue directives for the approximation of legislation across member states. High quality standards offered the promise of expedient legislative harmonization. But the EEC lacked an effective apparatus to utilize voluntary standards as a means of technical harmonization. Meanwhile, several European countries interested in free trade but not in the EEC's uniform tariff – namely, Austria, Denmark, Norway, Portugal, Sweden, Switzerland, and the United Kingdom – formed the European Free Trade Association (EFTA) in January 1960.<sup>24</sup>

It was in this dual context of the EEC on one side and the EFTA on the other that "standards entrepreneur" Olle Sturén, a Swedish engineer, spearheaded the creation of the Comité Européen de Coordination des Norms (CEN) in 1961, an organization that could unite the "inner six and outer seven" around the shared goal of free trade in the region.<sup>25</sup> CEN's mission was, from the outset, to promote open trade across the continent through the development of common standards.<sup>26</sup> It was designed to receive input from a variety of stakeholder groups, including European companies, governments, and, most importantly, the national standards bodies on whose cooperation the

<sup>&</sup>lt;sup>20</sup> Although Quinn Slobodian does not himself make this argument about standardization, the framework he provides for understanding the economic thought of twentieth century neoliberals aligns closely with documentary evidence on the rationale used to support the formation of a global system of standards. See: *Globalists: The End of Empire and the Birth of Neoliberalism.* (Harvard University Press, 2018). For more on the wide appeal of international standards in the postwar period, see: Yates and Murphy, *Engineering Rules*.

<sup>&</sup>lt;sup>21</sup> Mark Mazower, Governing the World: The History of an Idea, 1815 to the Present. (New York: Penguin Books, 2012), 102.

<sup>&</sup>lt;sup>22</sup> See: *Treaty Establishing the European Economic Community*, Rome, 25 March 1957. Article 100 outlined the process by which the Global Approach was reformed in 1989/1990: text drafted by the Commission was considered by the Parliament's Economic and Social Committee, which consulted business groups, and then a revised version was approved by the Council.

<sup>&</sup>lt;sup>23</sup> In contrast, the increasingly robust infrastructure of the ISO was actively drafting standards for widespread adoption, many of which informed national legislation.

<sup>&</sup>lt;sup>24</sup> Theirs was a free trade agreement, but without the obligations of the Treaty of Rome.

<sup>&</sup>lt;sup>25</sup> Yates and Murphy, *Engineering Rules*, 11; 121. From the outset, the EFTA funded the budget of CEN, and later CENELEC and ETSI, along with the EC.

<sup>&</sup>lt;sup>26</sup> In his subsequent position as head of the ISO from 1968 to 1986, Sturén worked to internationalize the organization beyond Europe as much as possible, an effort that sent him to China, India, Japan, Mexico and beyond. See: Olle Sturén, "The Expansion of ISO: Decade by Decade," in International Organization for Standardization, *Friendship among Equals: Recollections from ISO's First 50 Years.* (Genève: ISO Central Secretariat, 1997): 65-66.

organization relied. In fact, the regional body acted as something of a clearing house for national standards, as well as a forum for discussion and negotiation between national bodies like the Deutches Institut fur Normung (DIN), the Association Française de Normalisaton (Afnor), and the British Standards Institution (BSI).<sup>27</sup>

In 1966, the French government proposed a partnership with the Federal Republic of Germany (BRD) to create a Franco-German committee on standardization. <sup>28</sup> The Germans agreed, with the caveat that the United Kingdom be included as well, thus forming the Tripartite Committee on Standardization, a sub-group of CEN aimed at accelerating the larger group's progress toward harmonization. <sup>29</sup> Meeting two to three times per year, the Committee tackled such topics as auto safety standards and juridical frameworks for standards enforcement, and it made agreements about norms for key items like office equipment and machine tools. <sup>30</sup> In 1971, on the eve of the EC's first enlargement to include Britain, Ireland, and Denmark, the UK Delegation to the Tripartite Committee urged that "it was now essential to get the CENEL harmonized system into full operation (in the sense of putting components on the market) as quickly as possible." <sup>31</sup> In addition to the "preparation of harmonized specifications," this objective required "the establishment of an internal Mark of Conformity." <sup>32</sup> A mark would indicate to consumers across the enlarged common market that a product had met the EEC's specifications. While the Committee failed to advance the idea of a conformity mark any further at the time, this early proposal for a certification of conformity to regional standards laid the first layer of a foundation for what would eventually become the CE Marking.

Despite these supplementary initiatives to accelerate regional normalization and despite early calls to formalize conformity assessment to regional standards, CEN made only modest progress during the 1960s and 1970s. A few achievements do stand out, though. Amid the global race in computing of the early 1970s and building on early predecessor organizations for electrotechnical standards,<sup>33</sup> the highly strategic electrotechnical sector developed a more cohesive regional standards organization called CENELEC (December 1972). Similar to CEN, membership in this expanding genealogy of electrotechnical standards organizations included EFTA members from the start, and the objectives were to promote intra-regional trade and cooperation among European tech firms, who were increasingly feeling pressure from their American and Asian rivals. CENELEC benefitted from being focused on fewer, more specific objectives than CEN, and it provided the first opportunity for

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<sup>&</sup>lt;sup>27</sup> Joseph B. Donovan, "European Harmonization of Technical Standards: Implications for the US Automobile Sector," SAE Transactions, Vol. 99 (1990), 1202.

<sup>&</sup>lt;sup>28</sup> "Tripartite Committee on Standardization," 1972. EFTA-1185, HAEU: Florence, Italy. The hand-written notes in this file, a special reward of archival research, offer granular details about the Committee's founding and activities.

<sup>&</sup>lt;sup>29</sup> Progress toward standardization in this period is just one among many bodies of evidence that challenge the conventional narrative of the 1960s-1980s as a period of "Eurosclerosis," as are the many institutional reforms of the Council and Commission made during the 1970s. The strength of the Tripartite Committee originated in the fact that these three states had the most national standards. Furthermore, they recognized the benefit to their industries for new regional standards to be based on their preexisting ones.

<sup>&</sup>lt;sup>30</sup> "Confidential Letter from the United Kingdom Mission (M.A. Wacker) to the Finnish Mission (M.K.Yrjo-Kockinen)," 5 July 1967. EFTA-1185, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>31</sup> "Tripartite Committee for Standardization Meeting in Paris: 14th and 15th October 1971: Note by the United Kingdom Delegation." EFTA/CTE W /1/72 (7 January 1972), Distribution B.2. EFTA-1185, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>32</sup> While this paper focuses on the CE Marking, established by the European Commission in the 1980s, it is also important to note that CEN (together with CENELEC) owns the Keymark, a voluntary quality mark for products and services, which demonstrates conformity to European Standards. As such, it is not connected to the process established for conformity to the "essential requirements" laid out by EC directives, but it does draw from the same standard setting process to which the Commission delegated the development of its "essential requirements."

<sup>&</sup>lt;sup>33</sup> CENEL and CENELCOM were the predecessors of CENELEC.

centralized European interests to set the standards agenda for the ISO and the International Electrotechnical Commission (IEC).<sup>34</sup> Fueled by the momentum generated by the creation of CENELEC, the most significant breakthrough in regional standardization came just a few months later when the European Commission issued the Low Voltage Directive (73/23/EEC) of 1973.<sup>35</sup> This 'ancestor of regional directives for technical specifications,' paved the way for it to take the lead on standardization for the entire region in the years that followed, although nearly a decade would pass before the next major milestone.<sup>36</sup>

During this period of the 1960s and 1970s, the Commission's approach to technical regulation in the EC proved inefficient. It strove to remedy the heterogeneity of requirements among member states through harmonization, replacing of national rules with European ones. But its efforts to independently determine what specifications were needed to harmonize goods across member states was hierarchical, fastidious, and arbitrary.<sup>37</sup> Furthermore, its preoccupation with matters internal to the EC precluded closer collaboration with CEN, which was committed to broad regional cooperation. Because the Commission included very detailed prescriptions in proposed EC legislation, the Council found it difficult to reach any agreements at all. 38 This "old approach" was 'cumbersome, unrealistic, redundant in its disjointedness from standards, slow, poorly implemented, of low priority to the Council, out of touch with the realities of global trade, and, crucially, had utterly neglected issues of conformity assessment and testing.'39 National bodies, each with their own unique assessment criteria and procedures, were responsible for testing product conformity to the new European norms, which they did with wide variation. As a result, the old approach represented a great deal of work with dismal results. Not only were proposed common regulations already outdated by the time member states finished fighting over them, but economic pressures motivated national governments to develop economic policies designed to isolate and protect firms in their own markets, widening the chasm between member state legislations even more and further obscuring the promise of market integration in the EC.

#### II. A New Approach to Market Integration

When the crises of the 1970s gave way to the increasing challenge of globalization in the early 1980s, national governments, who had agreed to increased liberalization through the General Agreement on Tariffs and Trade (GATT) as a means of ensuring economic growth, also implemented protectionist measures to shore up their economies from competition. Liberal trade agreements prohibited the erection of tariff barriers, but states like France and Italy initially erected non-tariff barriers (NTBs)

<sup>&</sup>lt;sup>34</sup> By the twenty-first century, European standard setting was so effectively centralized relative to its fragmented American and Canadian counterparts, that it dominated international standardization. The specifications developed by CEN and CENELEC increasingly set the standards for the ISO and IEC, positioning the European system of standardization at the forefront of global efforts toward harmonization.

<sup>&</sup>lt;sup>35</sup> Commission of the European Communities, "Low Voltage Directive," 73/23/EEC. Brussels, 19 February 1973.

<sup>&</sup>lt;sup>36</sup> Florence Nicholas, *Common Standards for Enterprises*. (Luxembourg City: Office for Official Publications of the European Communities, 1995): 86.

<sup>&</sup>lt;sup>37</sup> The Commission, comprised mostly of civil servants, also lacked the technical expertise required for such a task.

<sup>&</sup>lt;sup>38</sup> "Environmental Policy at 1992," United Kingdom. HW-37, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>39</sup> Jacques Pelkmans, 1986. See also: Jacques Pelkmans, 1986. See also: Jacques Pelkmans and A. Vollebergh, "The Traditional Approach to Technical Harmonisation: Accomplishments and Deficiences," in Jacques Pelkmans and M. Vanheukelen, eds., *Coming to Grips with the Internal Market*. (Maastricht, EIPA, Working Document, 1986).

like voluntary export restraints (VERs) to exclude foreign firms from their market. 40 Such measures both impeded cross-border European business and reversed the Commission's efforts to integrate EC member states by eliminating NTBs. It became clear to both the business community and regional policymakers that Europe's economic survival required the elimination of internal barriers as much as as increased economic growth. The European Court of Justice's ruling in the Cassis de Dijon case in 1979 had set the legal precedent for mutual recognition of standards, allowing goods produced according to the regulatory guidelines of one member state to circulate lawfully through the others. 41 Yet, even if the narratives of 'Eurosclerosis' neglect some progress made during the 1970s, 42 it is true that in the realm of standards quite little had been accomplished within the EC since the customs union was completed in 1968. Non-tariff barriers to trade persisted, impeding the realization of the original goal of an internal market.

In the early 1980s, the Commission proposed that the Community should establish a procedure to coordinate standards and regulations on a regional level to prevent the rise of new technical barriers. The Mutual Information Directive (83/189/EEC), passed in March 1983 and implemented on 1 January 1985, became the primary mechanism by which the EC could coordinate national legislative developments among member states. With this directive, the Commission began to view the regional standards bodies CEN and CENELEC as partners in the harmonization process with the information on national technical specifications the Commission so desperately needed in order to eliminate barriers to trade. Notably, just like the Commission, the Secretariat of the EFTA also agreed to cooperate with CEN/ELEC in 1983. Also, in April 1984, the EC and EFTA signed the Declaration of Luxembourg agreement, providing for the free circulation of goods among the two groups. In junction with this agreement, the EFTA developed its Committee on Technical Barriers to Trade (TBT Committee), which began meeting regularly with the Commission on matters of harmonization and standards in industrial policy.

Building on this momentum, the Commission produced a White Paper in May 1985, which enumerated concrete proposals for "completing the internal market" through a 'New Approach to Technical Harmonization and Standardization.'<sup>45</sup> The Commission recognized that "the practice of incorporating detailed technical specifications in Directives ha[d] given rise to long delays because of the unanimity required in Council decision making."<sup>46</sup> Going forward, in sectors where barriers to

<sup>&</sup>lt;sup>40</sup> Helen Milner, "Resisting the Protectionist Temptation: Industry and the Making of Trade Policy in France and the United States During the 1970s," *International Organization*, Vol. 41, no. 4 (1987): 640. Milner explains how these NTBs were gradually reduced over the course of the decade, when liberalization offered more gains than protectionism.

<sup>&</sup>lt;sup>41</sup> European Court of Justice, Judgement of 20 February 1979: Case 120/78. By establishing the legal precedent for the mutual recognition of standards across member states, this ruling removed barriers to inter-European trade.

<sup>&</sup>lt;sup>42</sup> Richard T. Griffiths, "Under the Shadow of Stagflation: European Integration in the 1970s," in Desmond Dinan, ed. Origins and Evolution in the European Union, 2<sup>nd</sup> ed. (New York: Oxford University Press, 2014); Anil Awesti, "The Myth of Eurosclerosis: European Integration in the 1970s," *L'Europe en Formation* (2009) 3-4, no. 353-354: 39-53. In this decade, sluggish growth and institutional mobility were paired with the development of new case law from the ECJ and the EC's response to the breakup of the international monetary system with its creation of the European Monetary System (EMS). For more on this, see: Emmanuel Mourlon-Druol, A Europe Made of Money: The Emergence of the European Monetary System. (Ithaca: Cornell University Press, 2012).

<sup>&</sup>lt;sup>43</sup> Commission of the European Communities, Directive 83/189/EEC.

<sup>&</sup>lt;sup>44</sup> "Joint Declaration: Ministerial Meeting between EFTA Countries and the EC and Its Member States." Luxembourg, 9 April 1984.

<sup>&</sup>lt;sup>45</sup> Jacques Pelkmans, "The New Approach to Technical Harmonization and Standardization," *Journal of Common Market Studies*, Vol. 25, no. 3 (1987), 259-262; Arthur Cockfield, *The European Union: Creating the Single Market*. (Wiley, 1994).

<sup>&</sup>lt;sup>46</sup> This unanimity requirement, which originated in Article 100 of the EEC Treaty, was also addressed by Article 100-A of the Single European Act and its provision for the institutional reform of qualified majority voting.

trade are created "justified divergent national regulations concerning the health and safety of citizens and consumer and environmental protection, legislative harmonization will be confined to laying down only the *essential requirements*, conformity with which will entitle a product to free movement within the Community." Instead of setting detailed technical specifications, the Commission would only require conformity to a short list of essential requirements, which would then form the basis of new directives in key sectors – similar to that of the Low Voltage Directive of 1973 – requiring that goods meet certain specifications before entering the EC market. Consumer health and safety, along with the estimated risk posed by products and services, determined which sectors required Commission directives. National level technical regulations and standards were also replaced by regional ones, elaborated by CEN, CENELEC, or other bodies, thereby relieving the Commission of the generative tasks for which it was comparatively ill-equipped.<sup>48</sup>

In addition to the narrowed range of essential requirements to which firms bringing goods to the European market were required to adhere, the New Approach also established a new system for the harmonization of voluntary standards. CEN, CENELEC, and ETSI, and not public authorities, became responsible for developing regional standards. The working groups of these standards bodies included "technical experts" from a wide range of stakeholders, including business, which helped to ensure the wide acceptance of the standards they developed. The Commission resolved to align its legislative aims in "reference to standards," by "combining the total harmonization of the objectives at issue (safety, etc.) with a flexible approach of the means (standardization)." As was the case with the principle of mutual recognition, national public authorities were asked to recognize that all products in accordance with harmonized standards presume to conform to the essential requirements defined by EC legislation.

Just months after the Commission's 1985 White Paper had initiated the New Approach, EC member states agreed to the first major institutional reform of the Community since the founding Treaty of Rome signed in 1957. The text of this Single European Act (SEA) described a Europe "at a crossroads:" "we either go ahead – with resolution and determination – or we drop back into mediocrity. We can now either resolve to complete the integration of the economies of Europe; or, through lack of political will to face the immense problems involved, we can simply allow Europe to develop into no more than a free trade area," like, although it was not explicitly named, the EFTA.<sup>51</sup>

<sup>&</sup>lt;sup>47</sup> Commission of the European Communities, "Completing the Internal Market," Article 68, page 19. In this text, the Commission made a clear distinction between the mandatory nature of essential requirements and the voluntary nature of

<sup>&</sup>lt;sup>48</sup> Commission of the European Communities, "Completing the Internal Market," Article 68, page 20.

<sup>&</sup>lt;sup>49</sup> While archival documents maintained by the Historical Archives of the European Union do not include the composition of CEN and CENELEC working groups at the time of their founding, they do make frequent reference to the "technical experts" on those working groups and describe their membership as "including industry." CEN/CENELEC currently describes its network as including "business federations, commercial and consumer organizations, environmental groups and other societal stakeholders. More than 60,000 technical experts from industry, research, academia and other backgrounds are directly involved in our work." CEN/ELEC, "About Us," accessed 2 February 2021: https://www.cencenelec.eu/aboutus/pages/default.aspx

<sup>&</sup>lt;sup>50</sup> Pelkmans, "The New Approach," 253, 257.

<sup>&</sup>lt;sup>51</sup> Single European Act. (Luxembourg, Office for the Official Publication of the European Communities, 1986): 55. The Commission's juxtaposition of its internal market ambitions and a free trade area reveal how the EC saw itself in relation to other regional agreements like the EFTA. In the same excerpt from the SEA quoted above, the Commission said a free trade area, while better than nothing, "would fail and fail dismally to release the energies of the people of Europe; it would fail to deploy Europe's immense economic resources to the maximum advantage; and it would fail to satisfy the aspirations of the people of Europe," albeit undefined. Yet, as this history demonstrates, there were considerable points of intersection

This first amendment to the Treaty of Rome, ratified in February 1986, was designed to facilitate the completion of an internal market in each of three "pillars" – the removal of physical, technical, and fiscal barriers – across nearly 300 agenda items. It allowed the Council to act "by a qualified majority on a proposal from the Commission, in cooperation with the European Parliament and after consulting the Economic and Social Committee" to adopt, "by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States." Such changes to the previous methods of unanimity and direct legislation were essential if the EC was to have any hope of completing its internal market by the aggressive "steeplechase" of a deadline on 31 December 1992, inspired, at least in part, by the urgings of those like Philips CEO Wisse Dekker and his even more ambitious 'Europe 1990' plan. 53

Perhaps the strongest articulation of the position of business on the matter came from the European Roundtable of Industrialists (ERT), a group of business leaders who supported market integration in general and the development of common standards in particular.<sup>54</sup> In June 1985, the ERT, which met bi-annually with the Commission, issued a memorandum on the "Foundations for the Future of European Industry." In order to stimulate the technical harmonization and cooperation needed for European firms to rise to the challenge of foreign rivals on scale, price, and productivity, they argued, the EC needed to develop "common European technical standards." Claims that the ERT "set the agenda" for the Commission's subsequent relaunching of the integration process may overstate the contribution of business, but a close reading of the ERT position papers and Commission documents from the early 1980s verifies the synergy among industry and the Commission on the need for a true internal market in light of global competition. <sup>56</sup>

The ERT's position on regional standards did diverge from those of the Commission, however, in the proposed scope of application: standards should be "EEC-inspired," but these "new specific policies aiming at European industrial and technological cooperation" ought to be open to non-EEC Europeans and must be framed to allow for flexibility in developing Europe's links with the rest of the world." While the Commission remained focused on the potential for standards to remove trade barriers between EC member states and achieve an insular internal market as a defense against globalization, business leaders on the ERT saw them as a way of reinforcing Europe's global trade connections. Not only did the New Approach establish a single set of requirements for goods in the markets across the EC and EFTA to the great advantage of firms from both inside and outside Europe, but the prospect of harmonizing European standards with those from other parts of the globe promised global economies of scale. <sup>58</sup>

between the EC and EFTA, even on issues of economic policy oriented around market integration beyond mere free trade.

<sup>&</sup>lt;sup>52</sup> Single European Act. Article 118A, no. 2.

<sup>&</sup>lt;sup>53</sup> Jacques Pelkmans, "The Significance of EC-1992," *The Annals of the American Academy of Political Science*, Vol. 531 (1994): 95; Wisse Dekker, "Europe 1990," (1985).

<sup>&</sup>lt;sup>54</sup> This group, founded in 1983, was forged in large part by the charisma and rolodex of Swedish Volvo CEO Pehr Gyllenhammar with the support of Commissioners Etienne Davignon and François-Xavier Ortoli and CEOs of 15 other leading European industrial companies.

<sup>&</sup>lt;sup>55</sup> European Roundtable of Industrialists (ERT), "Foundations for the Future of European Industry," June 1985. PSP-385: HAEU: Florence, Italy.

<sup>&</sup>lt;sup>56</sup> Maria Green Cowles, "Setting the Agenda for a New Europe: The ERT and EC 1992," *Journal of Common Market Studies*, Vol. 33, no. 4 (1995): 501-526.

<sup>&</sup>lt;sup>57</sup> ERT, "Foundations for the Future of European Industry," 8.

<sup>&</sup>lt;sup>58</sup> The position of firms whose parent companies were located outside the EC comes into sharper focus in the correspondence between the Commission and the American Chamber of Commerce.

#### III. Problems with the New Approach and the "EC Mark"

In sharp contrast to the inefficiencies and incrementalism of the Commission's earlier strategies, the New Approach and the SEA synergized the policy and legal regimes working to eliminate technical barriers. Speed was the driving motivation behind the impetus to streamline the regional process of standardization, especially in light of the fact that the Commission aimed to double the usual rate of progress toward setting international standards at the ISO and to produce exponentially more specifications in just seven years than CEN had in its two and a half decades. In addition to making haste, the introduction of qualified majority voting and other democratic instruments through Article 100-A of the SEA agreement also lent credibility to the process of harmonization in Europe. Shortly after the SEA was ratified, the EFTA resolved to incorporate the Commission's latest initiatives into its own Convention, obligating its members to adhere to the regulations of Directive 83/189/EEC and paving the way for the synchronous development of common standards, conformity assessment, and certification across countries in the region, regardless of EEC membership.<sup>59</sup> On 19 December 1989, the EFTA agreed further to exchange information and reciprocity in detailed decisions with the EC, tightening the bond between the two groups, at least as far as standards were concerned.<sup>60</sup>

What the New Approach delivered in expediency and credibility, it lacked in strong enforcement. Its "gravest omission" was "that it required certification "without offering any concrete proposal or initiative to deal with it at the European level." The EC had long promised the formalization of certification to regional standards, beginning with the "General Programme" proposed by the First Council Directive of 1968 and the Colonna Report on Industrial Policy in 1970. 14 had discussed certification with the Parliament in 1980, prompting M. Vincent Ansquer, member of the European Parliament from France, to ask in a session the following year when, exactly, the Council intended to introduce a special "EEC Mark." There was some talk about the possibility of making the CENELEC Certification Agreement of 1984 more widespread to homogenize certification across other sectors.

Furthermore, the New Approach failed to address the heterogeneity of national systems for conformity assessment. When the European Council delivered its Resolution on the New Approach on 7 May 1985, it clearly stated that the "approach will have to be accompanied by a policy on the assessment of conformity." Section VIII of the Commission's text had addressed the means of attestation of conformity, including certificates and marks of conformity, results of tests, and manufacturers' declarations. But rather than developing a comprehensive system, it relied on 'specific directives to determine the best means of attestation for the specific requirements of their scope." The Commission's first major directive following the New Approach – the 1987 directive regarding

<sup>&</sup>lt;sup>59</sup> It was in 1987 that the EFTA formally adopted the EEC Directive into its Convention. See: Article 12a of EFTA Convention.

<sup>&</sup>lt;sup>60</sup> This agreement entered into force on 1 November 1990.

<sup>61</sup> Pelkmans, "The New Approach," 265.

<sup>&</sup>lt;sup>62</sup> First Council Directive of 9 March 1968, 68/151/EEC: Official Journal of the European Communities (OJC); Speech by Ambassador Guido Colonna di Paliano to the International Study Convention organized by CISMEC in Milan on the subject 'The Industrial Policy of the European Community,' Brussels, 19 June 1969.

<sup>63</sup> European Parliament: Oral Questions, 9 and 11 February 1981. 26 January 1981. PE1-20241, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>64</sup> European Council, "Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards," 85/C 136/01. Official Journal of the European Communities: 1.

<sup>65</sup> European Council, "New Approach," 16.

simple pressure vessels – implemented a single Community mark, then called the "EC Mark." This mark, "consisting of the symbol "CE," the last two digits of the year in which the mark was affixed, and the distinguishing number...of the approved inspection body," was be used to indicate a product's compliance with the essential requirements set forward by the Commission. <sup>66</sup> Subsequent directives on toys and construction products applied the use of the EC Mark to indicate compliance to the essential requirements established for their respective product categories as well. Still, these directives, focused narrowly on specifications for particular products, offered no remedies for the patchwork of national systems for testing and certification. <sup>67</sup>

The EC mark shall consist of the symbol  $\mathcal{E}$ , the last two digits of the year in which the mark was affixed, and the distinguishing number referred to in Article 9 (1) of the approved inspection body responsible for EC verification or EC surveillance.

Figure 2: The "EC Mark" in the 1987 Directive on Simple Pressure Vessels<sup>68</sup>

Industry responses to the New Approach and EC Mark were mixed. Some firms, especially large companies with the resources required for the conformity assessment and certification process, welcomed what they saw as a 'market passport' for their goods.<sup>69</sup> Similar to indications of geographic origin (IGOs) and trademarks, the EC mark promised a means of securing "reputation and market share," a way to differentiate their products and convince consumers of their quality in an increasingly crowded global market.<sup>70</sup> As a result, compliant companies typically wanted to shore up their investment in the mark by articulating a middling position in their discussions with policymakers: they wanted the mark to remain in use as a way to differentiate their products, but were wary of the requirements being either too stringent so as to constrain their market advantage or too lax so as to increase competition. Other companies, often smaller and medium sized firms, were anxious about the high costs of implementation. For businesses without the capital required to submit prototypes for testing and make production changes before entering the market, a mark of conformity presented a major obstacle.

As a market symbol, the EC Mark promised to indicate to consumers and regulators alike which goods had met the essential requirements. Yet as a policy instrument, it lacked concrete procedures for assessing conformity beyond a disparate network of national testing centers. Without a coherent

<sup>&</sup>lt;sup>66</sup> European Council, "Council Directive of 25 June 1987 on the Harmonization of the Laws of Member States Relating to Simple Pressure Vessels," 87/404/EEC. Official Journal of the European Communities, Article 16; Annex II.

<sup>&</sup>lt;sup>67</sup> Commission of the European Communities, "Council Directive on the Approximation of Laws, Regulations, and Administrative Provisions of the Member States Relating to Toys," 88/387/EEC. 3 May 1988; Commission of the European Communities, "Council Directive on the Approximation of Laws, Regulations, and Administrative Provisions of the Member States Relating to Construction Products," 89/106/EEC. 21 December 1988.

<sup>&</sup>lt;sup>68</sup> See: Council Directive 87/404/EEC on Pressure Vessels, Article 16.

<sup>&</sup>lt;sup>69</sup> Pelkmans, "The New Approach," 260.

<sup>&</sup>lt;sup>70</sup> David Higgins, Brands, Geographical Origin, and the Global Economy: A History from the Nineteenth Century to the Present. (Cambridge: Cambridge University Press, 2018), 3, 7. Higgins also cites Mira Wilkins' work on "The Neglected Intangible Asset" – and its constructive critique by Teresa da Silva Lopes – in describing the ways multinationals have often viewed the advantages of trademarks. See: Higgins, 15; Wilkins, "The Neglected Intangible Asset: The Influence of the Trade Mark on the Rise of the Modern Corporation," Business History, Vol. 34 (1992); da Silva Lopes, Global Brands: The Evolution of Multinationals in Alcoholic Beverages. (Cambridge: Cambridge University Press, 2007).

certification scheme, the New Approach and its corresponding new certification mark were, in large part, rendered toothless. That the lines of text on conformity assessment and certification in the White Paper of 1985 were added as an afterthought during the Council meeting proves just how egregiously the EC had neglected these central elements of the process. Alongside the text of a Commission note on the proposal to create a European Center for Control and Certification to solve these problems, someone scrawled "bonne idée ou pas?", summing up the general ambivalence and/or uncertainty about how to proceed with assessing and certifying conformity.

### IV. A Global Approach to Testing and Certification and the "CE Mark"

As the Commission worked on the numerous agenda items required to complete the Single Market by 1992, it recognized the need for a more flexible policy instrument and clearer protocols for conformity assessment to remove non-tariff barriers to trade between member states. Following a Symposium on Testing and Certification held in Brussels in June 1988, which was well attended by industry representatives, and in light of questions from others of the EC institutions about how, exactly, "the concept of the 'EC Mark' should be understood," the Commission submitted its proposal for a Council decision concerning a "Global Approach to Conformity Assessment and Certification." This proposal was predicated on findings from Commission reports that revealed the cracks in the EC's conformity assessment process and the urgent need for reform if the internal market was going to be completed by the 1992 deadline. It attempted "to bring together all the different elements [of conformity assessment, quality systems, certification, and accreditation] which, when carefully and properly assembled, will give the Community as a whole a comprehensive quality policy which is an indispensable part of any industrial policy and fundamental to the very concept of an Internal Market."

The Global Approach was comprised of two core elements: "The Proposal for a Council Decision concerning the Modules for the Various Phases of the Conformity Assessment Procedures intended to be used in the Technical Harmonization Directives," and the accompanying "Communication on a Global Approach to Certification." The first established an eight-part "modular system," outlined below, which 'subdivided conformity assessment procedures into a number of operations (modules), which differ according to the stage of development of the product, the type of assessment involved, and who carries out the assessment." The second element laid out plans for a comprehensive scheme for conformity assessment and certification. Notified bodies, already operating in the apparatus of member state regulatory regimes, would be entrusted with assessing conformity to EC directives as

<sup>&</sup>lt;sup>71</sup> Pelkmans, "The New Approach," 265.

<sup>&</sup>lt;sup>72</sup> "Note for Mr. Caudron – the rapporteur assigned by the European Parliament's Committee on Economic and Monetary Affairs and Industrial Policy." PE3-21885, HAEU: Florence Italy. Translation: "Good idea, or not?" In the end, the Council deleted the text regarding the Parliament's recommendation to create such a Center. See also: European Parliament, "Draft Recommendation of the Committee of Economic and Monetary Affairs and Industrial Policy concerning the Common Position," 25 July 1990. PE3-21908, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>73</sup> M. Christian de la Malene (RDE), "Written Question No. 3041/91 to the Commission." 11 February 1989. The answer provided by the Commission in this case came on 27 February 1992 from Mr. Martin Bangemann, Commissioner for Industry, in which he referred "the Honorable Member" to the answer to Written Question No. 1685/91 by M. Lamassoure. PE3-7056, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>74</sup> Commission of the European Communities, "A Global Approach to Certification and Testing," COM(89) 209 final – SYN 208; OJC 89/C/231/3. Brussels, 24 July 1989. PE3-21885, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>75</sup> Commission, "Global Approach," Annex I: 5

<sup>&</sup>lt;sup>76</sup> Commission, "Global Approach," Objectives; Commission "Re-Examined Proposal for a Council Decision," 11.

well, and, depending on the module, to affix the renamed mark of *conformité europeenne* – the "CE Mark" -- to verified products, along with their own identification numbers.

#### Global Approach Modules<sup>77</sup>

- **A EC declaration of conformity:** covers design and production; manufacturer establishes technical documentation and affixes CE Mark; tests may be carried out by a third party and Directives provide for random checks
- **B EC type examination:** covers design and must be followed by a module for assessment of production; EC-type examination certificate issued by notified body
- **C EC declaration of conformity to type:** covers production and requires a module B certificate; does not require action by a notified body; manufacturer is responsible for testing and affixing the CE Mark
- **D EC declaration of conformity to type (production quality assurance):** covers production and requires a module B certificate; manufacturer attests to product conformity and affixes the CE Mark and symbol of notified body; subject to EC surveillance
- **E EC declaration of conformity (product quality assurance):** covers production and is often but not always followed by a module B certificate; manufacturer attests to product conformity and affixes the CE Mark and symbol of notified body; subject to EC surveillance
- **F EC verification:** covers production and is often but not always followed by a module B certificate; manufacturer may choose statistical verification if he can guarantee the homogeneity of production and conformity to type; either the notified body or the manufacturer can affix the CE Mark along with the identification of the notified body
- **G EC unit verification:** covers design and production; notified bodies test products issue certificates of conformity and affix the CE Mark together with the identification of the notified body
- H EC declaration to conformity (Full Quality Assurance): covers design and production; manufacturer attests to product conformity with Directives and with approved quality system (like EN 29001) and affixes the CE Mark together with the identification of the notified body

At the behest of M. Gerard Caudron, the rapporteur assigned by the European Parliament's Committee on Economic and Monetary Affairs and Industrial Policy (CEMAIP) to coordinate the Parliament's response to the Council's request to deliver an opinion on the Global Approach, the Commission agreed to delay the submission of the resolution to the Council until the Parliament had sufficient time to consider this "very important matter." Parliamentary deliberation required public feedback on the functioning of the existing system and possible suggestions for reform. In this case, the "public" concerned with conformity assessment and certification was comprised not of individual citizens, but of the firms operating within the European market. On 22 December 1989, Caudron circulated a solicitation of industry feedback on the proposal for a Global Approach to 15 European-based organizations, many of them business interest associations (BIAs), asking the following:<sup>79</sup>

1. Is the proposal for a Council Decision setting out the permitted modules for future directives necessary at this stage?

<sup>&</sup>lt;sup>77</sup> Commission, "Global Approach," Chapter 4, Section 2: "New Legislative Techniques for Conformity Assessment," 21. These modules were revised further during the 1990s. See the Commission's 1999 Guide to the Global Approach for comparison.

<sup>&</sup>lt;sup>78</sup> "Note à l'attention de Monsieur Gérard Caudron." PE3-21885, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>79</sup> Commission of the European Communities, "Re-Examined Proposal for a Council Decision – concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives," COM(90) 606 final – SYN 208. Brussels, 7 December 1990. PE3-21885, HAEU: Florence, Italy. There is a vast literature on business interest associations relevant to this history. For a primer, see: Luca Lanzalaco, "Business Interest Associations," in Jones, G. and Zeitlin, J., eds. *The Oxford Handbook of Business History*. (Oxford University Press, 2018).

- 2. Are the modules adequate in their present form? If not, do any of them need to be modified, or do they need to be supplemented by further modules?
- 3. Do you have any other suggestions for improving the Commission text?
- 4. Do you support the establishment of a European organization for testing and certification?
- 5. Do you have any comments on the criteria for the use of the CE Mark?<sup>80</sup>

The repository of position papers submitted back to the Parliament – from groups like the Committee for Common Market Automobile Constructors (CCMC), the Union des industries de la communauté européenne (UNICE), and the American Chamber of Commerce (AMCHAM) – attests to the high priority industry placed on reforming conformity assessment and certification in the EC.

Their sectoral diversity notwithstanding, the majority of these associations expressed broad support for the proposals contained in the Global Approach but continued frustrations with the redundancies of assessing and certifying conformity, which continued to be plagued by "too many possible methods and undue confusion and legal ambiguity."<sup>81</sup> First, industry representatives noted that even the two components of the Global Approach 'lacked coordination between them, with the proposal for rationalizing the use of the Community mark varying considerably from one directive to the next.'<sup>82</sup> Second, the Commission's ad hoc approach to developing its directives meant that many key products fell under the guidelines of more than one directive. Firms producing home cooking appliances, for example, had no idea whether their product should adhere to the directive on simple pressure vessels, machines, appliances burning gaseous fuels, or hot water boilers.

Additionally, as pointed out by the Italian Confindustria ANIE, "[i]f a product has to conform to a number of different directives, most notified certification bodies will not be competent to check conformity in all these areas." In light of these problems and echoing the position of Europe's technology business association ORGALIME, ANIE argued that manufacturers responsible for their own products should always affix the CE Mark regardless of the method used to verify conformity (first, second, or third party assessment), and that notified bodies should then affix their own stamps of certification alongside the curvature of the CE Mark." The French Conseil National du Patronat Français (CNPF), dually representing the position of the CCMC, suggested that the harmonization process would benefit from the creation of a consultative body, and, since the New Approach had introduced standards into the process, clarification on the differences between obligatory and voluntary conformity was necessary. 85

For its part, AMCHAM expressed concern about mechanisms for the accreditation of testing laboratories located in third countries (outside the EC), both because the manufacturing of its members often occurred in third countries, and because the new EC certification requirements would

<sup>&</sup>lt;sup>80</sup> "Letter from the EC Committee of the American Chamber of Commerce to M. Gérard Caudron, Committee on Economic and Monetary Affairs and Industrial Policy, European Parliament." 15 January 1990. PE3-21885, HAEU: Florence, Italy.

<sup>81</sup> Commission, "Re-Examined Proposal for a Council Decision," 12.

<sup>82</sup> ibid, 12.

<sup>&</sup>lt;sup>83</sup> "ANIE Position Paper on The EC Global Approach to Testing and Certification, Draft Decision on Modules, 25 January 1990." PE3-21885, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>84</sup> ANIE Position Paper, 2.

<sup>&</sup>lt;sup>85</sup> "CNPF Position Paper on the EC Global Approach to Testing and Certification." Paris, 5 October 1989. PE3-21885, HAEU: Florence, Italy; CCMC Letter to M. Caudron. Brussels, 26 January 1990. PE3-21885, HAEU: Florence, Italy.

likely cause a backlog of work for notified bodies and their laboratories in the EC.<sup>86</sup> EFTA members shared similar concerns. After quibbling over the nomenclature of "marks" vs. "initials," UNICE, compelled by a unique set of interests relative to the other BIAs consulted, took substantive aim at the certification procedures supporting the affixing of the mark, the testing for which, it argued, was prohibitively expensive for many of its small and medium sized constituents. Not surprisingly, many of the BIAs that submitted position papers encouraged the use of international ISO standards by regional standards bodies and the Commission wherever possible. Such convergence with global standards would allow European firms to achieve the scale and scope required to compete. <sup>88</sup> Overall, the diverse groups of firms consulted argued that the Global Approach's lack of clarity impeded economic development in the region since businesses were unsure of how to confirm their products' conformity to the essential requirements stipulated by the EC's directives. <sup>89</sup>

The European Parliament made quick work of synthesizing industry feedback and submitted several amendments to the Commission at its May 1990 session, ranging from the insurance of severe penalties for abuse of the new standardization system (Amendment 3) to clarifying the conditions of compliance required for the affixing of the CE Mark (Amendment 9). 90 As rapporteur, Caudron made four sets of general recommendations on "the need to avoid too much bureaucracy in the process of ensuring conformity with essential requirements, the need for certain accompanying measures to be taken, and finally the issue of whether the existing modules should be modified." In October 1990, the Commission authored a "Green Paper on the Development of European Standardization: Actions for Faster Technological Integration in Europe," in which it stressed the need for a common marking system to remedy "the large degree of confusion on the question of marking, underlined by different three regimes existing within CEN/CENELEC circles," and described a common mark of conformity as "a logical consequence of self-standing European standards," which would save manufacturers time and increase consumer confidence in the entire European market. 92 By December, the Commission had drafted a "Re-examined Proposal for a Council Decision," in which it adopted three amendments into its revised proposal for a Council decision on modules and sub-contracting. The Parliament's recommendations on amending the application of the CE Mark, however, were not accepted. "The Council took the view that, pending examination and adoption of a directive on the CE Mark, it would be inappropriate to prejudge the details thereof, and it opted therefore for the simple deletion of the provision of the CE Mark, confining itself to a straight factual reference to the future CE Mark in

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<sup>&</sup>lt;sup>86</sup> "Letter from the EC Committee of AMCHAM to M. Gérard Caudron." 15 January 1990; AMCHAM, "EC Committee Position Paper on Guiding Principles for Subcontracting by 'Notified Bodies' Pursuant to the Council Decision of 13 December 1990 Concerning the Modules for the Various Phases of the Conformity Assessment Procedures," 31 July 1991. PE321885, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>87</sup> "UNICE Position Paper: The Internal Market and Product Certification," 30 November 1988. PE3-21885, HAEU: Florence, Italy.

<sup>88 &</sup>quot;Memorandum from the Roundtable of Industrialists," June 1985. PSP-385, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>89</sup> UNICE membership is comprised of national business associations, which represent all forms of business from their respective countries of origin. As such, it is one of the only transnational business associations representing small and medium enterprises (SMEs). When consulted on the Global Approach, UNICE noted the concerns of smaller firms about the greater ease of large corporations to influence the standards and directives through their channels of elite access, to have the funds to pay for expensive testing, and to incorporate the CE Marking into their products.

<sup>&</sup>lt;sup>91</sup> European Parliament, "Report Drawn up on Behalf of the Committee on Economic and Monetary Affairs and Industrial Policy," Session Documents: Document A3-97/90 SYN 208. 27 April 1990. "Re-Examined Proposal for a Council Decision," PE3-21885, HAEU: Florence, Italy.

<sup>&</sup>lt;sup>92</sup> Commission of the European Communities, "Commission Green Paper on the Development of European Standardization: Actions for Faster Technological Integration in Europe," COM(90) 456 final. (Brussels, 8 October 1990): 45; Article 85, 43.

modules."<sup>93</sup> The Parliament wrote back, seemingly dismayed by the Council's dropping of Amendments 9 and 11 on the use of the Mark, asking for the Commission to submit its proposed directive on certification and marks of conformity as rapidly as possible, since it had neglected to do so in the 1990 Annual Legislative Program.<sup>94</sup>

#### V. "CE Marking" for the EU and EEA

Finally, in May 1991, the Commission proposed a Council Regulation on the CE Mark.<sup>95</sup> The Economic and Social Committee and Parliamentary Committee on Economic and Monetary Affairs and Industrial Policy were again asked to consult on the proposal. 96 The subsequent drafting of the Maastricht Treaty on the European Union in December 1991 and its signing in February 1992 offered a boost of momentum to the Commission to finalize this previously fraught element of the harmonization process. 97 Amid the frenzied rush to complete the last of the agenda items to complete the Single Market by the December 1992 deadline, the Commission penned its final "Amendment to the Proposal for a Council Regulation (EEC) concerning the affixing and use of the CE Mark of conformity on industrial products."98 This amendment articulated a much more flexible approach to the CE Mark, recognizing the full legal validity of marked products irrespective of the date on which the product entered the market, rendering optional the identification of the notified body, and allowing a ten year grace period for manufacturers legally using a mark resembling the CE Mark to attain full compliance. As the business associations had requested, the Commission also warned that deliberate improper affixing of the Mark would have serious consequences including the withdrawal of that product from the market.<sup>99</sup> The flurry of Parliamentary documents on the Mark and its reform from the sessions of 1991-1993 highlight the challenge of arriving at an implementation of the Mark that met the wide-ranging needs and interests of industry, consumers, and policymakers intent on completing the internal market.

In its final form, even though the EC Council declared that "the Community endeavors to promote international trade in products subject to regulation," the Global Approach on modules for

<sup>&</sup>lt;sup>93</sup> Commission of the European Communities, Session Documents: "Common Position Adopted by the Council on 20 June 1990 with a View to the Adoption of a Decision Concerning the Modules for the Various Phases of Conformity Assessment Procedures which are Intended to be Used in the Technical Harmonization Directives: The Council's Reasons," 7067 /90 ADD1, 18 July 1990.

<sup>94</sup> Parliament, "Draft Recommendation," 25 July 1990.

<sup>&</sup>lt;sup>95</sup> Commission of the European Communities, COM(91) 145 final. 17 May 1991.

<sup>&</sup>lt;sup>96</sup> Council of the European Communities, "Common Position Adopted by the Council on 14 June 1993 with a View to the Adoption of a Council Decision Amending the Council Decision of 13 December 1990 (90/683/EEC) Concerning the Modules for the Various Phases of Conformity Assessment Procedures, Supplementing it with Provisions Relating to the Arrangements for Affixing and Using the CE Conformity Marking," Brussels, 15 June 1993.

<sup>&</sup>lt;sup>97</sup> The Maastricht Treaty did little to modify the provisions laid down through this process during the 1980s and 1990s. The EC's Global Approach to harmonization remained largely intact, save for the revision of Article 100A, which provided for joint decision making by the Council and European Parliament in response to the critiques of the EC's democratic deficit. Importantly, Commission Document COM(91) 521, also drafted in December 1991, explicitly opened channels of communication with industry and recognized its vital role in the standardization process.

<sup>&</sup>lt;sup>98</sup> Commission of the European Communities, "Amendment to the Proposal for a Council Regulation (EEC) concerning the affixing and use of the CE Mark of conformity on industrial products," COM(92) 293 final – SYN 336; 92/C/195/11. 10 July 1992.

<sup>&</sup>lt;sup>99</sup> Commission, "Amendment to the CE Mark," Article 6a, no. 5. Again, David Higgins' work is useful here for thinking about the wide range of circumstances in which firms advocated for the enforcement of IGOs, trademarks, and marks of conformity. For more on this, see: Higgins, *Brands, Geographical Origin, and the Global Economy*, 16.

<sup>100</sup> Nicholas, *Common Standards for Enterprises*, 147.

conformity assessment and certification did not allow notified bodies to subcontract work to bodies located in third countries, nor those for direct recognition of third country body assessment and certification aligned with Community legislation. Because the EC had no way to guarantee that third country bodies would prioritize the health and safety of European consumers and because third countries were unwilling to promise reciprocal access to European enterprises in third markets, the EC rejected the largest multilateral scope of the Global Approach's application. As the EU evolved its position further in the 1990s, it agreed to favor the signatory countries of the GATT code on technical barriers to trade. But EFTA member states, already committed to the New Approach and corresponding directives, were exempt from these exclusions and were treated as members of the internal market already, at least where standards, conformity assessment, and certification were concerned.

Just months after the CE Mark Amendment was accepted, with only a relative few of the original agenda items remaining on the Commission's 1992 Program docket, the Single Market was declared complete, paving a new road ahead for the EU, its continued objective of economic and monetary integration, and its external trade and economic coordination agreements. One of the most important economic agreements made by the new EU was with the EFTA. In March 1994, these two organizations, despite their member states' differences in desired degrees of integration, signed an agreement creating the European Economic Area. 102 Their collective aim was not "ever closer union," as had been the case with the formation of the EEC/EC in the Treaty of Rome. 103 Rather, "[d]etermined to contribute, on the basis of market economy, to world-wide trade liberalization and cooperation, in particular in accordance with the provisions of the General Agreement on Tariffs and Trade and the Convention on the Organisation for Economic Cooperation and Development," the EC and EFTA agreed to form an association "to promote a continuous and balanced strengthening of trade and economic relations between the Contracting Parties with equal conditions of competition, and the respect of the same rules, with a view to creating a homogeneous European Economic Area, hereinafter referred to as the EEA."104 A central component of this agreement was the mutual commitment to the system of conformity assessment and certification developed by the New and Global Approaches, to which the 1993 reform Directive gave the name "CE Marking." Although they were not members of the EC/EU, EFTA countries and their businesses overwhelmingly embraced the Commission's consolidated system of directives, essential requirements, conformity assessment and certification as a means of accessing the large Single European Market and all of its attendant advantages.

#### Conclusion

The history of CE Marking highlights the centrality of standardization, conformity assessment, and certification to market integration, not just in the European Community and European Union, but throughout the European region. The standardization necessary to complete the Single European Market required the EC's cooperation with several other intergovernmental organizations, including regional standards bodies like CEN, CENELEC, global frameworks like the GATT and global organizations like ISO, and other regional trade groups like the EFTA. Even if the Commission's New

<sup>&</sup>lt;sup>101</sup> *ibid*, 147.

<sup>&</sup>lt;sup>102</sup> This agreement rested on the foundation of the many that came before (1984, 1987, 1989), as well as the Memorandum of Understanding signed between CEN, CENELEC, and the EFTA in 1990.

<sup>&</sup>lt;sup>103</sup> Preamble to the text of the Treaty of Rome.

<sup>&</sup>lt;sup>104</sup> Agreement on the European Economic Area – OJ No. L, 1.3.1.1994: 3, 5, 7.

Approach was developed as a defensive way to shore up the EC and its market against the challenges of globalization, it also paved the way for closer cooperation with the European region beyond the EC. From 1994 on, CE Marking defined not only the EU's Single Market, but the wider transcontinental market from Britain to the Peloponnese, Scandinavia to Sicily. That more than half of the original EFTA countries became EU members by the mid 1990s provides insight into their willingness to accept the Commission's standards regime even before accession and highlights the degree of market integration that had already occurred before the EEA agreement was signed.

In addition to expanding the narrative of European market integration, the history of CE Marking also sheds light on the relationship between business and regulation in Europe during this crucial period of the 1980s and 1990s. Correspondence between business associations and the institutions of the EC and EU reveals that firms largely supported the New and Global Approaches out of a desire for access to a large internal market. What is more, the modularity and flexibility of the Global Approach made business conformity much more straightforward than the cumbersome "old approach" and incentivized firms to use voluntary standards and embrace the new conformity and certification processes of CE Marking. Business groups also provided crucial feedback for reforming the assessment and certification process to make it more cohesive and less restrictive. When consulted on the Global Approach, big businesses – especially multinational corporations with operations inside and outside of Europe - wanted to ensure that European standardization would facilitate economies of scale beyond the EC and EU and asked the EC to align its directives as much as possible with standards set by the ISO and other international bodies. Companies with fewer resources and more restricted access to European testing and certification sites appealed for a less stringent testing system, lest CE Marking become a barrier to market entry. Pared down essential requirements and voluntary standards reduced the burden of company compliance, and the clarification of modules and greater flexibility on conformity assessment and certification enabled even smaller enterprises to bring their goods to the European market. Beyond compliance with the essential requirements, increasing use of the CE Mark by businesses indicated the perceived advantages of the mark as a form of "European branding" and product differentiation on both European and global markets.

Finally, the history of CE Marking poses several new research questions, especially relating to the EFTA. Building on the foundation of this working paper, scholars could ask: what were the positions of individual EFTA member states on the introduction of CE Marking? Do EFTA archives reveal further participation by business in – or perhaps differing perspectives on – the integration of European markets through standardization? Additional research is needed to mine historical documents of the EFTA, the archives of national standards bodies, and the personal papers of leading figures involved in the development of CE Marking for answers to these and other questions. More scholarship on the subject using those materials would continue to expand histories of regional market integration and further explain the complex ways businesses related to and, in turn, shaped the European business environment.

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