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**LENGTH:** 14612 words**COMMENT:** Creating Consumer Confidence or Confusion? The Role of Product Certification Marks in the Market Today**NAME:** MARK R. BARRON\***BIO:** \* J.D. Candidate 2007, Marquette University Law School; B.S. in Electrical Engineering 1990, Marquette University. The author would like to thank Professor Irene Calboli and the editors and staff of the Marquette Intellectual Property Law Review for their guidance and assistance in publishing this Comment. The author extends special thanks to his wife, Thuy, and children, Jack and Sam, for their patience and support through the law school years.**SUMMARY:**

... Certification marks have played and continue to play an important role in the product safety conformity assessment process. ... The development of the NRTL program has had a significant impact on the U.S. conformity assessment system and the use of product certification marks because it established mandatory requirements for products used in the workplace and designated certifiers to participate in the process. ... For example, there is no governmental regulation requiring that a typical electrical household appliance obtain a third-party certification mark before it may be sold at a retail store. ... And, where there is not a strong consumer or seller interest, the manufacturer typically decides whether to pursue product certification and, if so, the types of certification marks that would be most beneficial to the sale of the product. ... Both of those allow the manufacturer to "self-declare" compliance with the essential requirements and affix the CE marking without third-party intervention. ... At the very minimum, and absent any accreditation path or partnership, the certifier of choice will need to be able to help the manufacturer submit the product to the desired entity and obtain the desired certification mark. ...

**TEXT:**

[\*414]

## Introduction

Certification marks have played and continue to play an important role in the product safety conformity assessment process. These marks are often the end result of extensive product testing and evaluation, and they serve to demonstrate to a consumer or user that the product complies, for example, with industry standards, as determined by the owner of the certification mark. n1

The process of demonstrating that a product complies with applicable, specified requirements is known as conformity assessment. n2 The standards or requirements involved in the conformity assessment process may be product specific or may pertain to specific phenomena and cover many types of products. n3 Ongoing changes that have occurred in product conformity assessment systems in various countries throughout the world have impacted the role of certification marks. As a result, use of certification marks has changed and the number and types of marks has increased. It remains to be seen, however, whether multiple certification marks displayed on a product will lead to consumer confidence or confusion. Ultimately, the perceived value of these product certification marks may not sustain the high costs of obtaining them.

This Comment explores the changes that have occurred in product certification marks as a result of new regulations that govern their use. Part I outlines the definition of certification marks provided in the Lanham Act. Part II

describes the nature of conformity assessment regulations and explores the role of certification marks. Part III focuses on how changes to conformity assessment regulations in the United States and Europe have impacted the role of certification marks.

[\*415] Part IV continues to examine some of the pros and cons of the increased number of different certification marks in use from the perspectives of product manufacturers and users. Part V then suggests that regulatory legislation and market preferences will continue to drive the importance of certification marks on products and that the increased number of certification marks may not necessarily benefit manufacturers or consumers.

It is certain, however, that manufacturers will face new regulations governing how products are designed, produced, and discarded. Products must meet these regulations before they are allowed to be put up for sale in any given country. From both an economic and legal perspective, it will become even more imperative for manufacturers to have a global compliance strategy in place to ensure compliance with applicable regulations, selection of the "right" certification marks, and an efficient path through the entire conformity assessment process.

#### I. Certification Marks Defined

Certification marks in the United States are a unique type of mark and perform a different function from that of traditional trademarks. n4 They have even been described as "special creatures" of trademark law. n5 In fact, certification marks and trademarks are mutually exclusive, and if a mark is used as a certification symbol, it cannot be registered as a trademark. n6 The Lanham Act defines the term "certification mark" as follows:

Any word, name, symbol, or device, or any combination thereof [that is]

(1) used by a person other than its owner, or

(2) which its owner has a bona fide intention to permit a person other than the owner to use in commerce and files an application to register on the principal register established by this chapter, to certify regional or other origin, material, mode of manufacture, quality, accuracy, or other characteristics of such person's goods or services or that the work or labor on the goods or services was performed by members of a union or other organization. n7

[\*416] Certification marks are different from trademarks in that they are not used by the owner and not used to identify and distinguish goods or services of any one party. n8 They are instead used on the goods and services of others to provide a visible guarantee that those goods and services meet standards set by the owner of the certification mark. n9 This function of certification marks carries with it the responsibility of strict control of the use of the mark. n10 A certification mark owner must comply with strict standards of enforcement and control - failure to do so can affect the registration process and the owner's rights in the mark. n11

Certification marks are able to be registered

in the same manner and with the same effect as are trademarks, by persons, and nations, States, municipalities, and the like, exercising legitimate control over the use of the marks sought to be registered, even though not possessing an industrial or commercial establishment. n12

Subject to limited exceptions, when registered, certification marks are entitled to the protection provided for trademarks. n13

#### A. The UL Mark

Certification marks used to certify a characteristic or characteristics of a product are the focus of this Comment. An example of such a mark is the UL mark of Underwriters Laboratories, Inc. (UL). n14 For many years, U.S. consumers have relied on the assurance of UL that, among other things, electrical equipment complies with the safety standards that UL sets. n15 The process for obtaining authorization to use the UL mark on a product is determined by UL and involves product testing and follow-up surveillance. n16

A manufacturer that desires to use the UL mark on a product must submit representative samples of the product to UL for evaluation and [\*417] testing. n17 When the evaluation and testing are completed and UL concludes

that the samples comply with its standards, the product is eligible for listing with UL and able to display the UL mark. n18 By affixing the UL mark to its products, a manufacturer agrees to ensure that the products continue to be manufactured in compliance with the applicable standards and that the UL mark will not be displayed on products not in compliance. n19

In order to control use of the mark and ensure that future manufactured products also conform to the applicable safety standards, UL requires that the manufacturer enter into a follow-up service agreement with UL. n20 The follow-up service agreement provides for a periodic inspection program whereby UL's field inspectors will visit manufacturers that produce UL listed products. n21 When an inspector discovers a product bearing the UL mark that does not comply with the requirements, the inspector has authorization to hold shipment of the product until the issue is resolved with UL or to remove the UL mark from the product. n22

For many years, the UL mark of safety on products was, for the most part, the primary choice for manufacturers wishing to have products tested and certified to safety standards for the U.S. market. n23 For reasons discussed in Part III of this Comment, that is no longer the case.

#### B. Competition from New Certification Marks

Today, manufacturers desiring to obtain certification for products to be marketed in the United States have many choices for certifiers, and UL has many competitors. n24 Moreover, certifiers today issue marks not [\*418] only for product safety, but also for other phenomena such as emissions and immunity, functional safety, and compliance with the standards of other countries. n25 Examples of other product certification marks include the marks of FM Global's FM Approvals unit, Intertek's ETL SEMKO division, Canadian Standards Association (CSA), NSF International, and TUV Rheinland of North America, Inc. n26 Each organization offers several types of certification marks that signify compliance with various phenomena and standards used in other countries. n27

The increase in the number, type, and uses of certification marks can be attributed in part to changes in global product safety and conformity assessment regulations. n28 These regulations generally dictate the steps a product must go through to be used or sold in a certain market. n29 In turn, certifiers that participate in these steps to support manufacturers of products who desire to place products on the market have had to adjust the procedures for issuing their certification marks and for controlling the use of the marks. n30

[\*419] Changes in product regulations have, in some cases, given rise to many new certification marks. n31 While certifiers and manufacturers are challenged with the new regulations and competition from new certification marks, consumers are now confronted with understanding the meaning and intent of the marks on the products that they purchase. Manufacturers and consumers alike may benefit from a better understanding of the general concept of conformity assessment.

#### II. Conformity Assessment Regulations in General

"Conformity assessment is defined as a "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled." n32 In other words, it is the process that helps to verify that a product is in compliance with a given set of requirements. The definition seems straightforward, but it can involve many steps and can vary depending on the type and intended use of a product. n33 Granting use of a certification mark is typically the final action of a certifier once the steps in the process have been completed. n34

At its most basic level, conformity assessment involves evaluating a product's construction, testing the product in relation to applicable requirements, and ensuring through proper follow-up that the product continues to comply with those requirements throughout its life. n35 On a more complex level, conformity assessment can involve mandatory reviews by a specific group of third-party certifiers and an approved quality production system for the product being certified. n36

[\*420] The flexibility of the process with respect to manufacturers' options varies with the type of product involved and nature of the regulatory system in the target country. n37 For example, the process for medical products may be significantly more involved than the process for a typical household electrical appliance. n38 Such distinctions, as in this example, are generally due to the nature of the application; the nature of the medical application, where medical products are often in direct contact with patients or even used on patients invasively, dictates a more involved assessment process.

With respect to the nature of the regulatory system, some countries have chosen to allow for a system that is largely voluntary, while others have chosen to impose strict regulations on certain types of products. The U.S. regulatory system, for example, is largely voluntary with the U.S. government intervening primarily when the nature of the product demands it or when the product is used in certain environments, such as the workplace. n39 The regulatory system in the European Union, in contrast, is regulated by directives that impose requirements on products being placed in the European Union market. n40 This Comment will explore the impact of the U.S. and European Union regulatory systems on certification marks in Part III.

Manufacturers today are faced with often complex regulations that affect their products, and they have a wide range of certification marks to consider. Choosing the "right" mark or marks for a product involves analyzing the applicable regulations and customer needs of each market sought and applying the most efficient, cost-effective means of obtaining the desired marks without, hopefully, repeating steps in the process. n41 For certifiers, careful monitoring of conformity assessment systems is [\*421] necessary to ensure that they meet the requirements for participating in the process and issuing the certification mark. n42

In today's global market, manufacturers and certifiers face difficult challenges in interpreting regulations and determining market desires in order to participate successfully in the process with desired product certification marks. Many of the certification marks available today are a result of the changes that have occurred in this process. Part III of this Comment will explore the specific changes in product certification marks in the United States and the European Union.

### III. Use of Certification Marks and the Impact of Changes in Conformity Assessment Regulations

#### A. Focus on the United States

Product certification in the United States is largely voluntary in that it involves voluntary standards. n43 In other words, demand for certification in the United States is largely driven by the private sector; this would include, for example, the consumer, user, or seller of a piece of equipment. n44 There are, however, product categories and environments that the U.S. government has chosen to regulate through a mandatory process involving mandatory standards and certification. n45 For products not covered by these areas of interest, the systems and standards remain largely voluntary. n46

Two primary areas where product certification is relevant are the focus here: the workplace and the U.S. marketplace.

#### 1. Product Certification in the Workplace

Products used in the workplace in the United States are generally subject to Occupational Safety and Health Administration (OSHA) regulations and certification. n47 To help regulate products that are used [\*422] in the workplace, OSHA established a program on April 12, 1988, to accredit "nationally recognized testing laboratories" (NRTLs). n48 The program, which is part of OSHA's Directorate of Science, Technology, and Medicine, recognizes private sector institutions as NRTLs. n49 An NRTL essentially determines whether specific products meet applicable safety standards to provide assurance that the products are safe for use in the U.S. workplace. n50 Certain product categories, including electrical equipment, have been designated by OSHA as requiring NRTL approval before they may be used in the workplace. n51

The development of the NRTL program has had a significant impact on the U.S. conformity assessment system and the use of product certification marks because it established mandatory requirements for products used in the workplace and designated certifiers to participate in the process. n52 In fact, the establishment of NRTLs by OSHA, under the direction of the Department of Labor (DOL), was essentially "pushed along" by a claim brought by the certifier, Met Laboratories, Inc. (MET), against the then Secretary of Labor, Robert B. Reich. n53 MET filed the claim seeking to enforce the terms of an agreement between it and the DOL that involved establishing NRTL accreditation procedures and eliminating provisions that suggested two of MET's competitors, Underwriters Laboratories (UL) and Factory Mutual (FM), were uniquely qualified as NRTLs. n54

In 1973, the DOL developed regulations pursuant to the Occupational Safety and Health Act intended to establish procedures for the certification of NRTLs. n55 The regulations were not implemented immediately but the DOL did issue standards for testing of equipment and suggested that the work could only be completed by UL and FM. n56 As a competitor of UL and FM, MET found this appearance of governmental preference unacceptable. n57 UL was already one of the [\*423] oldest and largest testing institutions in the United States as well as likely being

the most widely recognized. n58 The implications regarding UL's unique status under the DOL regulations would only help strengthen UL's reputation among its customers.

After several more attempts to enforce the agreement, MET succeeded in 1987, and the court directed the DOL to complete the work within 120 days. n59 The DOL deleted the references to UL and FM and created the framework for certifying labs as NRTLs in 29 C.F.R. §1910. n60

OSHA's NRTL accreditation program allowed certification institutions to compete free from governmental preference. n61 As a result, new players in the certification system, including foreign-based testing and certification organizations, applied and were granted NRTL status. n62 Today, there are eighteen NRTLs that have been accredited by OSHA, n63 and manufacturers of products used in the workplace have many options when seeking to certify products to meet OSHA requirements. Moreover, manufacturers now have more certification mark options to help meet consumer demands. n64

## 2. Product Certification in the Marketplace

Certification of products for consumer purchase in the United States is generally voluntary from a governmental perspective because it involves voluntary standards. n65 For example, there is no governmental regulation requiring that a typical electrical household appliance obtain a third-party certification mark before it may be sold at a retail store. n66 Rather, the retail store and consumer are typically the driving force [\*424] behind the demand for certification marks in the U.S. marketplace. n67 And, where there is not a strong consumer or seller interest, the manufacturer typically decides whether to pursue product certification and, if so, the types of certification marks that would be most beneficial to the sale of the product. n68

Prior to the advent of the NRTL program, the UL mark was probably the certification mark most widely used and recognized by manufacturers and consumers of electrical products. n69 With the advent of the NRTL program, new certifiers, including foreign-based certifiers, became able to apply for NRTL status from OSHA to test products for use in the United States. n70 As a result, manufacturers of electrical products now have many more options for certifiers and certification marks. n71

### B. Focus on the European Union

The conformity assessment system in the European Union has undergone major changes over the past twenty years that have impacted the use of certification marks. n72 The now well-recognized CE marking affixed to products sold within the European Union was born out of efforts to create a single internal market in Europe. n73 Along with the development of the CE marking, new legislation has further changed [\*425] the status and use of certification marks throughout the European Union. n74

Prior to 1957, the countries of Europe were divided by barriers that not only slowed the economic and social progress of the region, but did not allow for balanced trade and fair competition. n75 In acknowledgment of these issues, six countries formed the European Economic Community under the 1957 Treaty Establishing the European Community to encourage the development of a single internal market. n76 The differences that existed among these European countries gave way to shared laws designed to promote harmonization, the free movement of goods, and the removal of barriers to trade. n77 By 1985, however, this internal market concept had still not yet been fully realized. n78

Recognizing that barriers still existed, the European Commission drafted a White Paper in 1985 entitled *Completing the Internal Market*. n79 This document essentially called for further progress by outlining several hundred legislative proposals, identifying time frames for completion of those proposals, and setting a goal of completing implementation of the single market by December 31, 1992. n80 The Single European Act of 1987, amending the Treaty Establishing the European Community, committed Members to the White Paper goals and to the 1992 deadline. n81

[\*426]

### 1. The New Approach

A major element of the single internal market effort was ensuring that the technical harmonization governing products adequately addressed diverging national technical standards and regulations within the European Commu-

nity. n82 As such, the European Community adopted the Council Resolution of 1985 on a New Approach to Technical Harmonization and Standardization (New Approach). n83

The New Approach established four key principles: (1) products placed in the European Community market need to meet a minimum set of essential requirements set out in the directives to benefit from free movement within the European Community, (2) technical specifications interpreting essential requirements are provided for in harmonized standards, (3) application of the harmonized or other standards is voluntary, and (4) products in compliance with the harmonized standards benefit from a presumption of conformity with the corresponding essential requirements. n84

Essential requirements are based on the principle of protection of the health and safety of users of products including consumers and workers. n85 The requirements may pertain to specific hazards associated with a product, such as flammability or electrical and mechanical malfunctioning, or may refer to the product or its performance, including design, construction, and manufacturing processes. n86 The harmonized standards contain particular technical specifications to aid in meeting the essential requirements of the directives. n87 Overall, the standards offer a "guaranteed level of protection with regard to the essential requirements established by the directives." n88 With respect to conformity assessment, the New Approach provided "flexibility ... over the entire manufacturing process" so that it could be "adapted to the needs of each individual operation." n89

[\*427]

## 2. The Global Approach

Following the establishment of the New Approach, and to address the needed specific conditions for conformity assessment, the European Community completed the Council Resolution of 1989 on a Global Approach to Conformity Assessment (Global Approach). n90 This established modules for the various phases of conformity assessment and criteria for applying the modules and for designating bodies that operate within the modules. n91 The modules vary depending on a product's state in the development process (whether in the design, prototype, or full production stage), the type of assessment involved, including both the type of approval and quality assurance, and the entity responsible for the assessment, such as the manufacturer or a third party. n92 The various levels of conformity assessment are as follows: (1) manufacturers' internal design and production control; (2) third-party type examination combined with manufacturers' internal production control activities; (3) third-party type or design examination combined with third-party approval of product or production quality assurance systems, or third-party product verification; (4) third-party unit verification of design and production; and (5) third-party approval of full quality assurance systems. n93 Significantly, the Global Approach also established and called for use of the CE marking. n94

## 3. The CE Marking

The CE marking is essentially the end visible result and symbol of the New and Global Approaches in action within the single internal market of the European Union. n95 A CE marking placed on a product symbolizes that the product conforms to all applicable Community provisions and that conformity assessment procedures have been applied and completed. n96

[\*428] With respect to Community provisions, the CE marking indicates that the product complies with the essential requirements of applicable New Approach directives. n97 With respect to conformity assessment procedures, the CE marking indicates that the product complies with the procedures provided for in the applicable New Approach directives as governed by the modules set forth by the Global Approach. n98 In other words, the New Approach directives set out the minimum essential requirements a product must meet to benefit from free movement within the Community as well as the options for conformity assessment as provided by the Global Approach. n99

Because the CE marking ensures to products the freedom to move within the Community, Member States may not restrict the placing on the market or putting into service CE marked products. n100 In turn, manufacturers are obligated to place the CE marking on products covered by directives before placing the products on the market or putting the products into service within the Community. n101

Application of the CE marking to a product also generally involves developing a declaration of conformity stating the manufacturer's name and location, description of the product, applicable directives applied, technical standards applied to demonstrate compliance with the essential requirements of the applicable directives, and signatures of the manufacturer and a designated authority that resides within the Community. n102 Technical documentation in support of the declaration of conformity also must be developed and maintained by the manufacturer. n103

For many types of products, the Global Approach conformity assessment modules require intervention of a Notified Body at certain stages in the process before the CE marking may be applied. n104 Notified Bodies are responsible for carrying out the third-party tasks mandated by the procedures. n105 Notified Bodies are assessed by the Member [\*429] States to confirm technical competence, independence, impartiality, and integrity, and are subject to regular surveillance in accordance with these principles. n106 Manufacturers have the choice of which Notified Body to select so long as the Notified Body has been designated to operate under the specific procedures applicable to the given product. n107

Notified Bodies are assigned an identification number for use when involved in the process. n108 For example, where the module involves third-party assessment of production quality, the manufacturer chooses a Notified Body from a list of designated Notified Bodies for this task and is required to place on the product the identification number of the chosen Notified Body after the CE marking. n109 Manufacturers are also permitted to affix subsequent marks on the product, such as certification marks, provided that the additional marks do not create confusion with the CE marking and do not reduce the legibility and visibility of the CE marking. n110

Prior to the development of the New Approach and the CE marking, national legislation in Europe generally dictated the conformity assessment rules for a given product. n111 It was difficult and costly to sell products within the European Community because different national requirements for product certification frequently required duplication of tests and compliance with different standards that often necessitated product design changes and the need for multiple certification marks. By focusing on technical harmonization and standardization and allowing for flexibility in the process, the New Approach, complemented by the Global Approach, allows products free movement within the European Union while still mandating that those [\*430] products meet basic essential requirements related to matters of health, safety, consumer protection, and environmental protection. n112

Manufacturers now have access to the European market by demonstrating that their products comply with the essential requirements of the directives and placing the CE marking on their products. n113 Where technical requirements once varied from country to country, the New Approach mandates development of harmonized standards that are presumed to conform to the essential requirements. n114 Compliance with the harmonized standards is voluntary; however, the presumption of conformity with the essential requirements element is encouragement to do so. n115 In addition, under the Global Approach manufacturers have a choice as to the method of conformity assessment specified in the applicable directives. n116 The resulting CE marking allows products to move freely within the European Union without the need - from a regulatory as opposed to market perspective - to obtain multiple national certification marks. n117

#### 4. Reflections on the New and Global Approaches

Europe recently celebrated the twentieth anniversary of the New Approach in an international conference held on November 30, 2005. n118 In his closing speech to the delegation, Gunter Verheugen, Vice-President of the European Commission responsible for Enterprise and Industry, described the successes of the New Approach and commitment to continue to use it as a role model to be extended into areas beyond the safety of industrial products. n119 He also acknowledged existing deficiencies in the New Approach. n120 Namely, it has not assured a consistent visible level of confidence in the marketplace that has led to [\*431] unequal implementation in the Member States. n121 In some industry sectors, the New Approach has left consumers and users doubting the validity and value of the CE marking. n122 Believing that the basic tenants of the New Approach still stand, the Commission committed itself to review the areas where the New Approach has been deficient and ensure that it is properly implemented in the future. n123

For many types of products, demonstrating compliance with the essential requirements and methods of conformity assessment may be completed exclusively by the manufacturer. n124 For certain products that, for example, have greater hazards associated with them, a third-party Notified Body is required to intervene in the process. n125 In such cases, the identification number of the Notified Body is placed after the CE marking on the product. n126 Even where Notified Body participation is required, manufacturers need choose only one Notified Body for the particular product or hazard covered. n127 In other words, it is not necessary to involve a Notified Body from each country where the product will be sold. n128

In addition to the regulatory requirements mandated by the directives, manufacturers must also address market pressures from sources that include, for example, consumers or users concerned with [\*432] national certification marks. n129 Similar to the desire exhibited by the market in the United States for the UL mark, national markets within the European Union may desire certification marks from local testing and certification organizations.

n130 For example, even with the New Approach and the CE marking in place, there may still be a strong local desire for particular regional certification marks that were likely in existence prior to the New Approach and CE marking. n131 However, even where national certification marks remain, the formerly divergent national technical standards have been replaced by harmonized standards mandated by the New Approach. n132 In other words, to the extent that manufacturers may still need to seek national certification marks to satisfy market requirements, they can obtain those marks using harmonized technical standards and, therefore, one product design. n133

#### IV. Pros and Cons to the Resulting Changes in the Use of Certification Marks

In the United States, OSHA's NRTL program has allowed certification institutions to compete without the hint of governmental preference to UL that existed previously. n134 As a result, many new certifiers, including those that are foreign-based, have pursued NRTL status. n135 Manufacturers today can choose certifiers other than UL to, for example, obtain better service, lower costs, or to satisfy a market need. In addition, foreign-based NRTLs can often provide certification for other countries of interest as well as for the United States. n136 With the addition of the new NRTLs, manufacturers may find differences in areas of expertise that might influence the decision to choose a certifier. Indeed, because new certifiers with different capabilities, expertise, and accreditations, have become available locally in the United States, the [\*433] process of choosing a certifier has now become significantly more complex to the extent that a global strategy is needed.

Such a strategy should include consideration of the markets of interest, the conformity assessment requirements in those desired markets, and whether a third-party certifier is needed. Consideration of the certifiers' capabilities and areas of expertise is also important and certification from several certifiers may be required to satisfy both regulatory and market demands of the countries of interest. OSHA's accreditation of NRTLs provides new certification options for U.S. manufacturers that need to meet requirements in the United States as well as in other countries. n137 As a result, manufacturers will need to develop proper strategies to help choose the "right" certification marks and obtain those marks in the most efficient manner.

In the European Union, changes in the conformity assessment process have also led to many more certification options and the need for a comprehensive strategy. n138 The strategy will need to address the New Approach regulatory requirements, including the applicable directives, available conformity assessment options, and whether Notified Body participation is required. In addition, manufacturers must be mindful of market desires to determine whether additional national certification marks are needed. Finally, manufacturers will need to determine which certifiers can offer needed Notified Body assistance as well as any desired local certification marks to satisfy both regulatory and market requirements.

The New Approach drastically changed the certification landscape in the European Union offering products free market access throughout the European Union based on compliance with a minimum level of essential requirements. n139 But with the increased flexibility provided by the New Approach comes increased responsibility on the part of manufacturers to accurately apply the legislation that covers their products. Conformity assessment strategies will need to account for new legislation as well. The goal is the same as for those selling products in the United States: to choose and obtain the "right" certification marks in the most efficient manner while complying with all applicable regulatory requirements and satisfying market demands.

[\*434]

#### V. The Future of Certification Marks

The future of certification marks will be influenced by both regulatory legislation and market preferences, depending on the country of interest and the conformity assessment environment operating in that country or region. In the United States, competition between the NRTLs will increase as certifiers position their companies to provide global certification marks through local service. New NRTLs with new certification marks may continue to appear for some time, particularly if foreign-based certifiers are to provide U.S. certifications to their local customers. As a result, manufacturers and consumers located in the United States will be faced with an increasing number of certification mark options with consumers and users deciding what marks, if any, are important to them in the purchase of a particular product.

In the European Union, even with the creation of the CE marking as the certification passport to the European market, certification institutions will remain in the form of legislative-based Notified Bodies that help in the CE cer-



tification process as well as issuers of certification marks of national origin that help manufacturers meet market demands.

In many other parts of the world, certification marks already have a strong presence either as mandatory regulatory-type marks similar to the CE marking or as voluntary and more market-driven marks that are viewed by local consumers and users as necessary if the product is to be well-received. For example, China has formalized a safety license system requiring manufacturers to obtain the China Compulsory Certification (CCC) mark before products may be sold in China. n140 Products that are regulated but that do not have the CCC mark may be held by customs in China and manufacturers may be subject to penalties. n141

#### A. Choosing the "Right" Certification Mark

Choosing the "right" certification mark for a given product in the future will involve many factors and will call for a comprehensive strategy. Some certification marks will be required before the product may be legally sold, while others will be required to satisfy the market. Studying applicable legislation like the OSHA requirements, European Union directives, or China's safety license system will help to reveal what certification marks are required by law to sell products.

[\*435] Conformity assessment may require a third-party certifier to participate in the process for the purpose of such things as testing the product, assessing the manufacturer's quality assurance system, or inspecting the product in a routine follow-up examination.

Once the regulatory requirements have been examined, the market demands need to be considered because certification marks driven by regulatory requirements will allow legal access to a market of interest, but may not necessarily help sell the products. The UL mark is voluntary from a regulatory perspective for consumer products sold in the United States. n142 Nevertheless, many retail entities and consumers continue to look for the UL mark on products before they purchase. n143 With competition from the many new NRTL certification marks, however, the demand for the UL mark may ultimately be diluted. As an example, Wal-Mart recently added MET and ETL SEMKO to its list of approved certification marks and alternatives to the UL mark. n144

In the European Union, the CE marking is required on most products in order to place the product on the market. However, consumers may still look for more established, local marks, such as the VDE mark in Germany, the BSI mark in the United Kingdom, or the IMQ mark in Italy. n145 Continued demand for local marks in the European Union may be particularly true for product categories where the CE marking may be applied without any intervention from a third party.

To illustrate, under the New Approach, the available conformity assessment options generally depend on the type of product or hazard being regulated. n146 For example, a typical household electrical appliance is generally covered by the Low Voltage and EMC Directives. n147 Both of those allow the manufacturer to "self-declare" compliance with the essential requirements and affix the CE marking without third-party intervention. n148 This practice allows the greatest flexibility in conformity assessment. However, in such cases, the consumer has no real proof [\*436] from an objective source that the product was truly evaluated and tested, leaving a rather empty impression of the meaning of the CE marking on that product. Where a CE marking on this household appliance is accompanied by a VDE, BSI or IMQ mark, for example, the consumer has proof from an objective third party that the product has been evaluated, tested, and deemed to comply with applicable standards. n149

Conversely, where greater hazards are associated with a particular product either by its nature or intended use, the available conformity assessment options typically mandate third-party intervention, for example, to initially examine the product's construction or to test the product. n150 An electrical medical device covered by the Medical Devices Directive typically must be evaluated by a third party before being sold. n151 In such cases, the CE marking is followed by the designated number of the Notified Body that performed the evaluation. n152 The purchaser of the equipment has visible proof by virtue of the Notified Body number that the medical product has been tested by an objective third party. The fact, however, that the CE marking is merely accompanied by a number will likely leave the purchaser wondering which Notified Body performed the testing. Therefore, the demand for local certification marks on products with elevated hazards may continue with the visible end result being a CE marking ubiquitously accompanied by a Notified Body number and desired local certification marks.

With the regulatory and market dimensions fully examined, the next step in the strategy is to obtain the desired certification marks in the most efficient manner. Practically speaking, this involves choosing a certifier based on a number of factors: (1) the location of the certifier in proximity to the manufacturer's engineering functions, (2) ca-

pability of issuing a large portfolio of certification marks, (3) expertise in a given product type, (4) cost for testing and certification, and (5) project evaluation completion times.

From the certifiers' perspective, meeting customer demands will involve creating a strategy equal in complexity to that of the manufacturers. Often certifiers can participate in a regulatory scheme [\*437] by obtaining proper accreditations. However, when customers desire other private certification marks, the certifiers will need to develop strong partnerships with other certifiers whereby each organization's test data is accepted by the other for issuance of the other's certification mark. The goal of the certifier is to be able to transparently provide all desired certifications. At the very minimum, and absent any accreditation path or partnership, the certifier of choice will need to be able to help the manufacturer submit the product to the desired entity and obtain the desired certification mark.

#### B. Standards Harmonization

Two additional noteworthy issues will also impact the future of certification marks: standards harmonization and mutual recognition agreements (MRAs). First, standards harmonization activities continue to prosper throughout the world with the goal of producing one standard that is accepted everywhere for a given product. n153 This goal is highly desirable to manufacturers because it is often impossible to have one product design where standards from different countries technically conflict.

However, where a harmonized global standard does exist, do multiple certification marks representing compliance with the same harmonized standard add any real value to the product? Should there be one global certification mark for all products? However desirable such a scheme may seem to some, it is not likely in the near future for several reasons.

From a regulatory perspective, governments continue to create new mandatory marks, such as the CE marking in Europe and the CCC mark in China. For electrical products, both marks can be used to indicate compliance with IEC-based harmonized standards that are used elsewhere in the world. n154 Yet manufacturers must go through each [\*438] conformity assessment process and affix each mark even where, for example, the product has been certified to the same harmonized standard and carries a third-party certification mark from another country.

From a voluntary perspective, local certification marks like the UL mark continue to be desired in some markets by entities, such as local inspectors, retailers, and consumers. In cases where the manufacturer has chosen to pursue certification to a harmonized standard from another NRTL, for example, ETL SEMKO, the customer still may demand the UL mark even though UL would apply the same harmonized standard.

As an example, a laptop computer is covered by the harmonized standard IEC 60950: Safety of Information Technology Equipment. n155 This standard is used throughout the world to test and evaluate information technology equipment. Certainly, there are national deviations in this standard to account for, such as the differences in a given country's electrical infrastructure; however, the overall requirements for product construction and performance are the same and any national deviations may be applied by a single test laboratory. Nevertheless, a typical laptop computer today has dozens of certification marks on its product nameplate, all certifying to basically the same standard.

As more standards become harmonized, countries nevertheless continue to concurrently mandate use of their own certification marks and markets continue to demand local certification marks; thus, manufacturers are left chasing certification marks that essentially mean the same thing and are paying high annual fees to maintain the use of those marks. Regulatory marks will likely survive unless legislation is otherwise revised. Voluntary marks driven by market influence will continue so long as consumers and users see value. However, where a product nameplate has dozens of certification marks, will consumers and users continue to see a distinction? Will manufacturers continue to pursue multiple marks?

[\*439] It is likely that industry sectors will push for continued standards harmonization activities, and market forces will drive the reduction of the number of certifiers whose certification marks are seen as merely redundant. Time will tell as to whether, for example, the perceived value of the UL mark will sustain the high costs of obtaining it.

#### C. Mutual Recognition Agreements

The second noteworthy issue is the fairly recent development of MRAs between nations to promote international trade in regulated products. n156 MRAs facilitate market access by providing easier access to other countries' con-

formity assessment procedures. n157 This is accomplished by each country designating Conformity Assessment Bodies (CABs) that can test and certify according to the other country's requirements. n158 For example, the MRA between the United States and European Community covers specific product sectors, one of which is electrical safety. n159

In Europe, electrical products are generally covered by the Low Voltage Directive (LVD). n160 In the United States, electrical products used in the workplace are covered by subpart S of 29 C.F.R. §1910. n161 Under the MRA, manufacturers in the United States that wish to have local access to the conformity assessment procedures under the European LVD may seek the help of local certifiers that have established CAB status under the MRA. n162 Under the electrical safety annex, CABs in the United States may act in the same manner as designated Notified Bodies under the LVD. n163 Conversely, manufacturers in Europe may seek the help of local CABs that have obtained OSHA NRTL status. n164 CABs in Europe can test according to U.S. requirements and issue a certification mark as an NRTL. n165

[\*440] While local access to another country's conformity assessment procedures may provide some benefit, MRAs do not address differences in regulatory climates between the partnering countries. In the United States, product certification is governed by OSHA through the NRTL program that addresses products used in the workplace. n166 Products may be sold in the United States without any certification at all, and customer demand will often dictate what certification marks are needed. A European CAB may obtain NRTL status and issue its own NRTL mark to allow a European-based manufacturer to gain entry to the U.S. market. n167 However, if the U.S. market demands to see a UL mark on the product, gaining legal entry to the United States does little for the manufacturer.

Conversely, electrical products in the European Union are governed by the LVD, which allows manufacturers to self-declare that the essential requirements have been met and affix the CE marking to the product. n168 Thus, the manufacturer in the United States, unlike the manufacturer in Europe, does not generally need to seek out a third party to gain access to the European market. True, the U.S. manufacturer may be confronted with similar market issues should the European market desire certification marks in addition to the CE marking. However, because the regulatory climates between the United States and Europe are different, the CABs in Europe appear to have more obstacles to confront than do the CABs in the United States. The MRAs ultimately may increase the available list of certifiers and certification marks, but it is questionable as to whether those marks will become desirable.

### Conclusion

Manufacturers and consumers today are faced with an increasing number of certification mark choices primarily because of changes in product conformity assessment systems in countries throughout the world. New regulations have produced new certification marks, and market forces have continued to demand familiar marks. As a result, products often display a dozen or more certification marks, and consumers are faced with having to decipher this growing number of marks. In facilitating and informing consumer decisions about product selection, the increasing array of certification marks potentially creates [\*441] more questions and confusion among consumers, rather than fostering consumer confidence.

Is product certification an important factor to today's consumer? As the UL mark that once stood alone on products becomes lost in the sea of new certification marks, how long will it or any other mark hold any individual strength in meaning for the consumer? Moreover, as the meaning of individual certification marks becomes diluted, how will this impact the manufacturer that is forced to do more with less in today's "lean-driven" environment?

Product testing and certification organizations do not have a history of providing a fast, customer-friendly, reasonable cost path through the certification process. These organizations have also not had a sound understanding of how manufacturers view the role of product certification within the product design and development process. Perhaps competition from new certifiers that work with manufacturers will drive some certification marks away. Consumers will ultimately decide what is important to them and manufacturers will choose certifiers that position themselves under the regulatory regime to meet the demands.

Standards harmonization is a positive initiative for manufacturers because having one product design that can be used throughout the world is critical in today's cost-driven, value-conscious environment. However, more and more products may soon carry dozens of certification marks that essentially mean the same thing. Private relationships between certifiers and public MRAs may help reduce repetition of certain aspects in the conformity assessment process, such as product testing. This, too, can be a cost and time saving benefit to manufacturers. However, it

is not likely that MRAs will help reduce the number of certification marks manufacturers need to sell products. On the contrary, MRAs will probably increase the number of designated certifiers and certification marks.

The increase in the number and use of certification marks will continue to cost manufacturers and confuse consumers. Manufacturers will need to be ever more diligent in creating a global strategy to monitor regulations that govern how a product is designed, produced, and disposed, wherever it is sold. The strategy will also need to account for market pressures that mandate voluntary, local certification marks if the product is to be sold successfully.

Finally, manufacturers will need to find an efficient path, from both a cost and time perspective, to obtain the certification marks of value that satisfy both the regulatory and market requirements. Competition [\*442] among new certifiers may help pave the way but not without additional pressure from manufacturers. While reduction in the number of certification marks may not be a reality any time soon, a comprehensive conformity assessment strategy will help in choosing the "right" marks for now.

### Legal Topics:

For related research and practice materials, see the following legal topics:

International Law Authority to Regulate General Overview Trademark Law Conveyances General Overview Trademark Law Special Marks Certification Marks

### FOOTNOTES:

n1. Underwriters Laboratories, Inc. issues the UL mark after products successfully undergo an evaluation according to UL standards. See Underwriters Laboratories, Inc., *Frequently Asked Questions: Submitting Products*, <http://www.ul.com/faq/submitting.html> (last visited Apr. 5, 2007).

n2. See American National Standards Institute, *Accreditation Services Overview*, [http://www.ansi.org/conformity assessment/overview/overview.asp?menuid=4](http://www.ansi.org/conformity%20assessment/overview/overview.asp?menuid=4) (last visited Apr. 5, 2007).

n3. The European Union Directive on Electrical Equipment Designed for Use Within Certain Voltage Limits has a list of associated product standards related to electrical safety (Low Voltage Directive). Council Directive 2006/95, 2006 O.J. (L 374) 10; Commission Communication in the Framework of the Implementation of Council Directive 73/23, 2005 O.J. (C 284) 1. The European Union Directive on Electromagnetic Compatibility has a list of associated standards that relate to such phenomena. Commission Communication in the Framework of the Implementation of Council Directive 89/336, 2005 O.J. (C 246) 1.

n4. See 3 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* §19:91 (4th ed. 2005).

n5. See *id.*

n6. See *id.* §19:94.

n7. Lanham Act §45, 15 U.S.C. §1127 (2000).

n8. See Terry E. Holtzman, *Tips from the Trademark Examining Operation*, 81 *Trademark Rep.* 180 (1991).

n9. See *id.*

n10. See *id.*

n11. See *id.*

n12. 15 U.S.C. §1054.

n13. *Id.*

n14. See Holtzman, *supra* note 8, at 182. See generally Underwriters Laboratories, Inc. Homepage, <http://www.ul.com/> (last visited Apr. 5, 2007).

n15. See sources cited *supra* note 14.

n16. See Underwriters Laboratories, Inc., Frequently Asked Questions: Submitting Products, *supra* note 1 (describing the UL product submittal process).

n17. See *id.*

n18. See *id.*

n19. For a description of what happens after testing at UL, see the overview of UL follow-up services provided on the UL Web site. Underwriters Laboratories, Inc., Frequently Asked Questions: Follow-Up Services, <http://www.ul.com/faq/followup.html> (last visited Apr. 5, 2007).

n20. See *id.*

n21. See *id.*

n22. See *id.*

n23. UL has been testing products since 1894, and today over twenty billion UL marks appear on products. See Underwriters Laboratories, Inc. Newsroom: About UL, <http://www.ul.com/media/backgrounders.html> (last visited Apr. 5, 2007) [hereinafter UL Newsroom]. For a detailed historical perspective on the origin of Underwriters Laboratories, Inc., see Harry Chase Brearley, *A Symbol of Safety 1-23* (1923).

n24. UL's competitors include, for example, FM Global, Intertek (ETL SEMKO), Met Laboratories, Inc. (MET), and the Canadian Standards Association (CSA).

n25. For example, the certification organization, TUV Rheinland of North America, has a portfolio of testing services that includes testing for electromagnetic compatibility (emissions and immunity) and functional safety as well as testing for general product safety. See TUV Rheinland of North America: Product Testing, [http://www.us.tuv.com/product\\_testing/index.html](http://www.us.tuv.com/product_testing/index.html) (last visited Apr. 5, 2007).

n26. See CSA, <http://www.csa.ca/Default.asp?language=English> (last visited Apr. 5, 2007); FM Global, FM Approvals, <http://www.fmglobal.com/approvals/default.asp> (last visited Apr. 5, 2007); Intertek ETL SEMKO, <http://www.intertek-etlsemko.com/> (last visited Apr. 5, 2007); NSF International, [http://www.nsf.org/international/about\\_en.asp](http://www.nsf.org/international/about_en.asp) (last visited Apr. 5, 2007); TUV Rheinland of North America: Certification Services, [http://www.us.tuv.com/certification\\_services/index.html](http://www.us.tuv.com/certification_services/index.html) (last visited Apr. 5, 2007).

n27. For a comprehensive description of the services and marks offered by each organization, see sources cited *supra* note 26.

n28. For example, in the United States, the Occupational Safety and Health Administration (OSHA) created the Nationally Recognized Testing Laboratory (NRTL) program, which paved the way for new certifiers to become accredited to test products for use in the workplace. See OSHA Directorate of Science, Technology, and Medicine: Nationally Recognized Testing Laboratory, <http://www.osha.gov/dts/otpca/nrtl/index.html> (last visited Apr. 5, 2007) [hereinafter NRTL].

n29. See Am. Nat'l Standards Inst., National Conformity Assessment Principles for the United States (2002), available at <http://public.ansi.org/ansi-online/Documents/News%20and%20Publications/Links%20Within%20Stories/NCAP.pdf>. The American National Standards Institute (ANSI) is a private, nonprofit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system. ANSI Overview, <http://www.ansi.org/about/ansi/overview/overview.aspx?menuid=1> (last visited Apr. 5, 2007). ANSI's mission is to enhance both the global competitiveness of U.S. businesses and the quality of life in the United States by promoting and facilitating voluntary consensus standards and conformity assessment systems and safeguarding their integrity. See *id.*

n30. For example, in the United States, the NRTL program has specific requirements that an applicant for NRTL status must meet before NRTL status may be granted. 29 C.F.R. §1910.7 app. A (2005).

n31. See NRTL, *supra* note 28.

n32. See ANSI: Understanding the Benefits of Accreditation, <http://www.ansi.org/conformity-assessment/accreditation-programs/benefits.aspx?menuid=4> (last visited Apr. 5, 2007).

n33. The conformity assessment system in the European Union, for example, is based on a set of modules that represent the various phases of the conformity assessment process. The modules applicable to a given product vary with the type of product and associated hazards involved. Generally, when a product is considered to be more hazardous, the complexity of the conformity assessment process increases. See Council Decision 93/465, 1993 O.J. (L 220) 23.

n34. See Underwriters Laboratories, Inc., Frequently Asked Questions: Submitting Products, *supra* note 1.

n35. See *id.*

n36. See Council Decision 93/465, *supra* note 33. As a working example, the European Union Directive for Equipment Designed for Use in Potentially Explosive Atmospheres requires that the product be submitted for review to a competent third party, known as a Notified Body. In some cases, the Directive also requires that the manufacturer maintain an approved quality production system. See Council Directive 94/9, 1994 O.J. (L 100) 1.

n37. See Council Decision 93/465, *supra* note 33.

n38. In the European Union, for example, medical products are covered by a number of directives that have complex conformity assessment procedures involving third-party Notified Bodies. See, e.g., Council Directive 93/42, 1993 O.J. (L 169) 1. Conversely, household electrical appliances are covered by the Low

Voltage Directive (LVD) that has less complex conformity assessment procedures because it does not mandate intervention in the process by a Notified Body. See Council Directive 2006/95, *supra* note 3.

n39. For example, OSHA mandates that certain products, when used in the workplace, must meet standards of safety as determined by an NRTL. 29 C.F.R. §1910.303 (2005).

n40. For a general overview of the new and global approaches to conformity assessment in the European Union, see Enterprise and Industry: New Approach & Global Approach, Conformity Assessment, Legislation & Standardization, [http://europa.eu.int/comm/enterprise/newapproach/index\\_en.htm](http://europa.eu.int/comm/enterprise/newapproach/index_en.htm) (last visited Apr. 5, 2007).

n41. Repeating steps in the conformity assessment process, such as having to perform the same or similar tests on a product twice, can lead to excessive and unnecessary costs and lengthy delays in getting the product to market.

n42. OSHA, for example, has many criteria for accrediting NRTLs. See *supra* note 30 and accompanying text.

n43. See Geraint G. Howells, *The Relationship Between Product Liability and Product Safety - Understanding a Necessary Element in European Product Liability Through a Comparison with the U.S. Position*, 39 Washburn L.J. 305, 309-10 (2000) (discussing the role of voluntary standards in the United States).

n44. *Id.*

n45. For example, the federal government regulates through entities such as the Food and Drug Administration (FDA), which regulates medical products, and the Federal Communications Commission (FCC), which regulates electromagnetic emissions of products.

n46. See Howells, *supra* note 43.

n47. See *supra* note 39 and accompanying text.

n48. See 29 C.F.R. §1910.303 (2005); NRTL, *supra* note 28. Note that OSHA has three options to demonstrate that electrical equipment is acceptable in the workplace. Obtaining NRTL approval is one option under the definition of "acceptable." See 29 C.F.R. §1910.399.

n49. See 29 C.F.R. §1910.7 app. A; NRTL, *supra* note 28.

n50. See NRTL, *supra* note 28.

n51. Electrical equipment is included within the scope of OSHA's mandate. See 29 C.F.R. §1910.303; see also *supra* note 39 and accompanying text.

n52. See *supra* notes 30, 39 and accompanying text.

n53. *Met Labs., Inc. v. Reich*, 875 F. Supp. 304, 308 (D. Md. 1995).

n54. *Id.* at 306.

n55. Id.

n56. Id.

n57. See id.

n58. UL has been testing products since 1894, and today over twenty billion UL marks appear on products. See UL Newsroom, *supra* note 23.

n59. See *Met Labs., Inc.*, 875 F. Supp. at 306.

n60. Id.

n61. By deleting the names of UL and FM in the OSHA standards and establishing workable NRTL accreditation procedures, NRTLs were able to participate equally in the NRTL program. See generally id.

n62. For example, both the CSA and the multiple TUV entities have foreign-based company headquarters. See OSHA: Current List of NRTLs, <http://www.osha.gov/dts/otpca/nrtl/nrtllist.html> (last visited Apr. 5, 2007).

n63. Id.

n64. Each NRTL issues its own certification mark giving customers many certification mark options. Id.

n65. See Howells, *supra* note 43.

n66. This is provided that the product is not regulated by government entities, such as the FDA or FCC. The NRTL requirements cover products intended for use in the workplace. See 29 C.F.R. §1910.303 (2005).

n67. Industry often complies with voluntary standards to, in part, help defend product liability claims and to use as a marketing tool. See Howells, *supra* note 43. Wal-Mart, for example, recently added MET and ETL SEMKO to its list of approved certification marks. See Intertek ETL SEMKO: Retail Acceptance, [http://www.intertek-etlsemko.com/portal/page?pageid=34,79564&dad=cust\\_portal&schema=CUST\\_PORTAL](http://www.intertek-etlsemko.com/portal/page?pageid=34,79564&dad=cust_portal&schema=CUST_PORTAL) (last visited Apr. 5, 2007); Met Laboratories, Inc.: Retail Acceptance, <http://www.metlabs.com/pages/safety.html#WALMART> (last visited Apr. 5, 2007).

n68. See Howells, *supra* note 43.

n69. See UL Newsroom, *supra* note 23.

n70. See OSHA: Current List of NRTLs, *supra* note 62.

n71. Id.



n72. See Commission Guide to the Implementation of Directives Based on the New Approach and the Global Approach, 7-8 (2000) [hereinafter EC Guide], available at [http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999\\_1282\\_en.pdf](http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/document/1999_1282_en.pdf) (describing the goal of creating a single internal market by Dec. 31, 1992).

n73. *Id.* Some would argue that the CE marking is not a certification mark because it is affixed by the manufacturer through a process of self-declaration of conformity with the applicable European directives. Others would argue that the CE marking is, in fact, a certification mark. This Comment's conclusions are not impacted by the issue regarding the classification of the CE marking so the matter is not addressed in any depth for purposes of this analysis.

n74. See Council Decision 93/465, *supra* note 33 (concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives); Council Resolution of 21 December 1981 on a Global Approach to Conformity Assessment, 1990 O.J. (C 10) 1 [hereinafter Global Approach Resolution]; Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards, 1985 O.J. (C 136) 1 [hereinafter New Approach Resolution].

n75. Treaty Establishing the European Community, arts. 1-3, Nov. 10, 1997, 1997 O.J. (C 340) 3.

n76. See *id.*

n77. See Case 120/78, *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)*, 1979 E.C.R. 649 (holding that products legally sold in one country should be able to move freely throughout the European Community).

n78. See Commission White Paper on Completing the Internal Market, at 1-2, COM (1985) 310 final (June 14, 1985), available at [http://europa.eu.int/comm/off/pdf/1985\\_0310\\_f\\_en.pdf](http://europa.eu.int/comm/off/pdf/1985_0310_f_en.pdf).

n79. See *id.*

n80. See *id.*

n81. Single European Act, Feb. 17, 1986, 1987 O.J. (L 169) 1.

n82. See EC Guide, *supra* note 72, at 7.

n83. New Approach Resolution, *supra* note 74.

n84. See EC Guide, *supra* note 72, at 7.

n85. See *id.* at 27.

n86. *Id.*

n87. See *id.* at 28.

n88. *Id.* at 7.

n89. *Id.* at 8.

n90. Global Approach Resolution, *supra* note 74. The global approach was eventually completed by Council Decision 90/683, which was amended by Council Decision 93/465. Council Decision 93/465, *supra* note 33; Council Decision 90/683, 1990 O.J. (L 380) 13.

n91. Council Decision 93/465, *supra* note 33 (concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives).

n92. *See id.*

n93. *Id.*

n94. *See id.*; Council Decision 90/683, *supra* note 90; Global Approach Resolution, *supra* note 74.

n95. *See* EC Guide, *supra* note 72, at 44.

n96. *See id.*

n97. *See id.*

n98. *See id.*

n99. *See* Council Directive 2006/95, *supra* note 3; Council Directive 94/9, *supra* note 36; Council Directive 93/42, *supra* note 38.

n100. *See* Council Decision 93/465, *supra* note 33, at 27.

n101. *Id.*

n102. *See id.* at 26-27; Council Directive 93/68, arts. 2-13, 1993 O.J. (L 220) 1, 2-22 [hereinafter CE Marking Directive].

n103. *See* Council Decision 93/465, *supra* note 33; Council Decision 90/683, *supra* note 90; Global Approach Resolution, *supra* note 74.

n104. *See* sources cited *supra* note 103.

n105. *See* EC Guide, *supra* note 72, at 36.

n106. *Id.*

n107. *Id.* at 41.

n108. See Council Decision 93/465, supra note 33, at 28; EC Guide, supra note 72, at 46.

n109. The Medical Devices Directive (MDD), for example, may require that a Notified Body assess and monitor the manufacturer's production quality system. Council Directive 93/42, supra note 38. The manufacturer may choose to work with an appropriate Notified Body designated under the MDD. See id.; List of Notified Bodies Under Directive 93/42: Medical Devices, <http://www.obelis.net/Services/MDD/MDD-notified%20body.pdf> (last visited Apr. 5, 2007) [hereinafter List of Notified Bodies: Medical Devices].

n110. See Council Decision 93/465, supra note 33, at 27.

n111. As an example, compliance with the now updated German Appliances Safety Act (GSG) was mandatory prior to the New Approach. The GSG has now been replaced by the Appliances and Product Safety Act (GPSG) and brought into line with the New Approach legislation. See VDE, The New Act on Technical Work Equipment and Consumer Products (GPSG), <http://www.vde.com/Allgemein/en/Informationen/News/Testing+and+ Certification/2004-Oeffentlich/GPSG.htm?SmartNavigation=c3a8e5c5-b552-4810-9a55-c9bcf9207ea3> (last visited Apr. 5, 2007).

n112. See EC Guide, supra note 72, at 7.

n113. Id. at 44.

n114. Id. at 27-28.

n115. Id. at 29.

n116. Id. at 31-34.

n117. See Council Decision 93/465, supra note 33, at 26-27.

n118. See European Conference on the 20th Anniversary of the New Approach, [http://europa.eu.int/comm/enterprise/newapproach/new\\_approach\\_conference\\_en.htm](http://europa.eu.int/comm/enterprise/newapproach/new_approach_conference_en.htm) (last visited Apr. 5, 2007).

n119. Gunter Verheugen, Vice-President, European Comm'n Responsible for Enter. & Indus., Closing Speech at the European Conference on the 20th Anniversary of the New Approach 6 (Nov. 30, 2005), <http://europa.eu.int/comm/enterprise/newapproach/pdf/verheugen%20speech%20anniversary%20naga.pdf>.

n120. Id. at 4.

n121. Id.

n122. Id.

n123. The Commission issued a communication on Enhancing the Implementation of the New Approach Directives on May 7, 2003. That communication stated the Commission's determination to "strengthen the

foundations of the system of free movement of goods in anticipation of an enlarged European Union." Communication from the Commission to the Council and the European Parliament Enhancing the Implementation of the New Approach Directives, at 3-4, COM (2003) 240 final (May 7, 2003). The Commission called for an initiative to clarify the meaning of the CE marking and to promote its accurate representation to consumers and users. *Id.* at 13. Following that communication, the Council issued a resolution inviting the Commission to propose appropriate initiatives in the fields of conformity assessment and market surveillance. Council Resolution of 10 November 2003 on the Communication of the European Commission "Enhancing the Implementation of the New Approach Directives," 2003 O.J. (C 282) 3.

n124. In such cases, the manufacturer is responsible for evaluating and testing the product in accordance with the applicable requirements, assembling the technical documentation, preparing a declaration of conformity, and affixing the CE marking. See Council Directive 2006/95, *supra* note 3; Council Directive 89/336, art. 10, 1989 O.J. (L 139) 19 (regarding the harmonization of the laws of Member States relating to electromagnetic compatibility).

n125. See Council Decision 93/465, *supra* note 33, at 27.

n126. See *supra* note 109 and accompanying text.

n127. See *supra* note 126.

n128. See *supra* note 126.

n129. Examples of national certification marks include the marks of VDE in Germany, BSI in the United Kingdom, and IMQ in Italy. See BSI, <http://www.bsi-global.com/en/> (last visited Apr. 5, 2007); IMQ, <http://www.imq.it/portale/index.jsp?code=513> (last visited Apr. 5, 2007); VDE, [http://www.vde.com/vde\\_pi\\_en/](http://www.vde.com/vde_pi_en/) (last visited Apr. 5, 2007).

n130. See sources cited *supra* note 129.

n131. See *supra* note 129.

n132. See New Approach Resolution, *supra* note 74, annex II.

n133. *Id.*

n134. See *Met Labs., Inc. v. Reich*, 875 F. Supp. 304, 306 (D. Md. 1995).

n135. See OSHA: Current List of NRTLs, *supra* note 62.

n136. The German-based TUV Rheinland of North America can issue certification for the United States under its NRTL status as well as the TUV mark that is well-recognized throughout Germany. See TUV Rheinland of North America: Certification Services, *supra* note 26.

n137. See OSHA: Current List of NRTLs, *supra* note 62.

n138. See EC Guide, *supra* note 72, at 7-8.

n139. Id.

n140. See China's CCC Mark: A Guide for U.S. Exporters, <http://www.mac.doc.gov/China/Docs/BusinessGuides/cccguid2.htm> (last visited Apr. 5, 2007).

n141. Id.

n142. See Howells, *supra* note 43.

n143. See *supra* note 67 and accompanying text.

n144. See *supra* note 67 and accompanying text.

n145. See BSI, *supra* note 129; IMQ, *supra* note 129; VDE, *supra* note 129.

n146. See Council Decision 93/465, *supra* note 33, at 27.

n147. See Council Directive 2006/95, *supra* note 3; Council Directive 93/42, *supra* note 38; Council Directive 89/336, *supra* note 124, art. 10; see also *supra* text accompanying notes 38, 124.

n148. See Council Directive 2006/95, *supra* note 3; Council Directive 93/42, *supra* note 38; Council Directive 89/336, *supra* note 124.

n149. See BSI, *supra* note 129; IMQ, *supra* note 129; VDE, *supra* note 129.

n150. See Council Directive 93/42, *supra* note 38; see also List of Notified Bodies: Medical Devices, *supra* note 109.

n151. See sources cited *supra* note 150.

n152. See EC Guide, *supra* note 72, at 41.

n153. For example, the International Electrotechnical Commission (IEC) is a global standards writing organization that develops technical standards for electrical and electronic products. The standards serve as a basis for developing national standards. The harmonized standards under Europe's New Approach are IEC-based, and in the United States many UL standards have already been harmonized with IEC standards. See IEC: Mission and Objectives, <http://www.iec.ch/about/mission-e.htm> (last visited Apr. 5, 2007); see also Commission Communication in the Framework of the Implementation of Council Directive 73/23, *supra* note 3; UL's Standards for Safety Standards Catalog, <http://ulstandardsinfontet.ul.com/catalog/stdscat-frame.html> (last visited Apr. 5, 2007).

n154. See Commission Communication in the Framework of the Implementation of Council Directive 73/23, *supra* note 3; IEC: Mission and Objectives, *supra* note 153; UL's Standards for Safety Standards Catalog, *supra* note 153. Chinese GB standards used in the CCC mark system are and will continue to be based on IEC standards. See U.S. Government Export Portal, Exporting to China: Frequently Asked Questions on CCC Mark Issues, [http://www.export.gov/china/exporting to china/CCC FAQ.asp#q2](http://www.export.gov/china/exporting%20to%20china/CCC%20FAQ.asp#q2) (last visited Apr. 5, 2007).

n155. See Int'l Electrotechnical Comm'n, International Standard: Information Technology Equipment - Safety (2005), available at [http://domino.iec.ch/preview/info\\_iec60950-1\[ed2.0\]b.pdf](http://domino.iec.ch/preview/info_iec60950-1[ed2.0]b.pdf).

n156. See, e.g., Agreement on Mutual Recognition Between the European Community and the United States of America, U.S.-EU, Dec. 1, 1998, Hein's No. KAV 5464 [hereinafter Agreement on Mutual Recognition], available at [http://ts.nist.gov/Standards/Global/upload/US-EU MRA Final Version 1998.pdf](http://ts.nist.gov/Standards/Global/upload/US-EU_MRA_Final_Version_1998.pdf); Council Decision 1999/78, 1999 O.J. (L 31) 1.

n157. See Agreement on Mutual Recognition, art. 2.

n158. See *id.* art. 7.

n159. See *id.* at 33 (outlining the Electrical Safety Annex).

n160. See Council Directive 2006/95, *supra* note 3.

n161. See 29 C.F.R. §1910.303 (2005); see also *supra* text accompanying note 39.

n162. See EC Guide, *supra* note 72, at 36.

n163. *Id.*

n164. *Id.*

n165. *Id.*

n166. *Id.*

n167. *Id.*

n168. See *supra* note 153 and accompanying text.