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Standardisation and the Directive 98/34/EC Historical background

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TECHNICAL REGULATIONS AND STANDARDS IN EUROPE: A HISTORICAL BACKGROUND¹

THE SEARCH FOR THE ABOLITION OF TECHNICAL BARRIERS TO TRADE IN EUROPE

The European Union (EU) is the largest group of independent countries in the world, which has continually made efforts to abolish technical barriers to trade (TBTs). These efforts are based on the very Treaty establishing the EU and they are supported by a legal dispute settlement system (the European Court of Justice), which can be used as a last resort. The dispute settlement system is accessible, in most cases, to individuals as well as to countries and the resulting decisions are directly enforceable.

Efforts for developing technical regulations applicable to the markets of all Member states also started very early. However, it quickly became evident that a new method was needed to advance these development efforts after examining the procedures, the decision making process in relation to laws of similar character, the qualifications of the persons involved in this process, and the large volume of TBTs that needed to be tackled.

On closer examination, it also became apparent that the range of areas covered by each country's technical regulations system did not coincide. Something that was regulated in one Member state was not necessarily regulated in another. Theoretically the (European) technical regulations should cover the totality of areas covered in every single Member state. The volume of questions to be tackled reinforced the need for another solution.

The first breakthrough: the Low Voltage Directive

In 1973, the Council of Ministers adopted the Directive 73/23/EEC better known as the "Low Voltage Directive." It covered the free movement of goods operating between 50 and 1000 Volts AC or between 75 and 1500 Volts DC. Obviously, governments could not imagine subjecting every single electrotechnical product to a special law in such a large trade area. The situation was even more difficult since, at that time, the agreement of nine governments was needed on the technical requirements for these products.

Thanks to the advancement of International standardisation through the International Electrotechnical Commission (IEC), a large number of safety related international standards on electrotechnical products were already available and implemented (in some cases, with minor modifications) in the individual European countries. This made it possible, after numerous meetings with experts, to adopt the directive, which

¹ Based on a yet not published article of Mr Ev.Vardakas

made open reference to these standards, once the standards bodies of the countries of the European Communities had commonly adopted them.

In Article 5, the Directive stipulated that:

“The Member States shall take all appropriate measures to ensure that, in particular, electrical equipment which complies with the safety provisions of harmonized standards shall be regarded by their competent administrative authorities as complying with the provisions of [the present Directive].

Standards shall be regarded as harmonized once they are drawn up by common agreement between the bodies notified by the Member States in accordance with the procedure laid down in Article [...], and published under national procedures. The standards shall be kept up to date in the light of technological progress and the developments in good engineering practice in safety matters.

For purposes of information the list of harmonized standards and their references shall be published in the Official Journal of the European Communities.”

This text introduced several important innovations:

- The notion of “harmonized standards,” which were defined as identical standards for all Member states that conformed to the “safety objectives” of the legislator.
- The elegant solution of “presumption of conformity,” which considered that products designed and produced in accordance with these (harmonized) standards also met the legal requirements. This gave an advantage to these standards without making them mandatory.
- The text also pre-empted and politically supported the establishment of CENELEC as the place to produce “by common agreement” the harmonized standards.

The second breakthrough: the “Cassis de Dijon” ruling

The Treaty establishing the European Union has amongst its principles, at least regarding the free movement of goods, that of “mutual recognition.” This principle remained vague until the Court of Justice of the European Communities (ECJ), in one of the most important of its judgements, concluded in 1979 that:

“Obstacles to movement within the Community resulting from disparities between the national laws relating to the marketing of the products in question must be accepted in so far as those provisions may be recognized as being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer.”

This case was brought before the ECJ because of the legal difficulties encountered when one company attempted to export a French liqueur called “Cassis de Dijon” to Germany.

The repercussions of this ruling were tremendous:

- It would not give any advantage to a certain Member state by allowing it to introduce technical regulations—and therefore, to create technical barriers to trade—if the (national) regulation could not fulfil the conditions imposed by the ruling (i.e. “...*being necessary in order to satisfy mandatory requirements relating in particular to the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer*”).
- All previously adopted national technical regulations imposing requirements on products outside of these areas could not be used to block the marketing of nonconforming products.
- The Community does not need to legislate on the free movement of goods, except when addressing the previously mentioned subjects.
- Any product that does not fall within these areas and is legally circulating in one of the Member states can automatically circulate freely in all of the Member states.

The “transparency” Directive

The 98/34/EC Directive (initially adopted in 1983 as 83/189/EEC) sets up a procedure that imposes an obligation upon the Member states to notify the Commission and each other of all draft technical regulations concerning products and, with its 1998 extension, Information society services before they are adopted into national law. This procedure aims at providing transparency (thus its name in the European Community’s jargon is “the transparency Directive”) and control with regard to those regulations. This transparency procedure is also voluntarily extended to the EFTA countries and (even before their entrance to the European Union) to a large number of acceding countries. As of today, some 26 countries participate in this exchange.

In reality, this Directive imposes limitations on the freedom of national legislators (including Parliaments) to introduce national technical regulations before the other participating countries and the Commission verifies their compatibility with the Treaty principles and the Community legislation. Since they could create unjustified barriers to trade between countries, notification in the draft form and subsequent evaluation of their content during the procedure help to diminish this risk. It should be noted that the national draft laws notification system in the framework of the

WTO/TBT agreement is largely based on the principles and mechanisms of this Directive.

Apart from the technical regulations, this Directive deals with national (voluntary) standards. It creates the basis of the relationship between the European Union and European Standards bodies by listing the “recognized” national and European standards bodies and obliging the national standards bodies to publish not only their draft standards but also their annual standardisation programs in advance. For the time being, it is the basic (yet minimal) legal document covering the activities of the European standards bodies and their relations with the Union.

Its adoption served as a first impetus for strengthening the co-operation between the national standards bodies in the framework of CEN (CENELEC was earlier reinforced through the Low Voltage Directive –“LVD”). ETSI was created much later (in 1988) and included in the list of recognized European bodies.

The “Single Market” project

In June 1985 the Commission President Delors and the Commissioner Lord Cockfield drafted a white paper on the completion of the internal market. It set out a comprehensive list, largely based on the “Cassis de Dijon” ruling, of what needed to be done to abolish borders in Europe and introduced the ambitious deadline for Internal Market completion by the end of 1992.

This project created a major change in the mentality of all actors and put important pressure on the European legislation. The list of measures considered necessary in this white paper was rather long. New methods had to be followed in order to be able to produce the vast legislative body. The Community no longer had the luxury of discussing and negotiating legislative proposals for an infinite number of years.

For the free movement of goods, the “method” had already been invented approximately one month earlier, in May 1985, when the Council of Ministers agreed to the “New Approach to technical harmonization and standards.”

THE “NEW APPROACH”

The new regulatory technique, the “New Approach to technical harmonization and standards” was laid down in a Council Resolution of 7 May 1985. It established that legislative harmonization should be limited to essential requirements that products have to meet in order to freely circulate within the Community. In other words, the legislator should establish in a concise but precise enough form the objectives (regarding, for example, safety) to be satisfied by the products. The laws shall not describe design specifications but specify the performances of the products in a way that they can be uniformly enforced in the Community. They shall also require the

manufacturer to perform a risk analysis and elaborate the design specifications to satisfy the corresponding essential (performance based) requirements. Furthermore, the laws define one or more conformity assessment procedures, which manufacturers have to apply to demonstrate compliance.

The affixing of the CE marking, being obligatory for the free movement of products falling in the field of application of every law (Directive), means the manufacturer declares that the product conforms to the essential requirements and other stipulations of the Directive (including conformity assessment requirements).

The New Approach intends to reduce regulatory intervention to the minimum necessary to protect the public interest whilst maintaining the high standards of safety and legislative quality. However this legislative technique is not easy to develop.

Standardisers within the European Standards bodies were asked to interpret these requirements in a more concrete form. But again, the application of the “harmonized standards” produced in this way remained voluntary.

The essential requirements - the Legislator's objectives

Elaborating on the “essential requirements” presents the most difficult part of the New Approach legislation. As seen in the 20 or so Directives that have followed the pattern of the New Approach so far, the “essential requirements” are not always perfect in their conception and expression. This is because creating concise and concrete descriptions of the legislator's objectives requires a deep knowledge of the sector *and* a distance from the traditional practice for drafting technical specifications in laws. The additional feature requested from well-written essential requirements (i.e., to be uniformly and directly enforceable) presents the most difficulties, as they must enable direct assessment of the product conformity.

The Council Resolution introducing the New Approach took care to give the enterprises a valid, more detailed interpretation of these requirements. This was especially helpful to small and medium-sized enterprises, which do not usually possess the technical capacity for designing their products “*ex ovo*.” The Council gave a privileged position to European standardisation by assigning the non-exclusive task of interpreting these essential requirements in their standards to the European standards bodies.

The interpretative function of harmonised European standards

As stated before, New Approach directives do not contain the definitive technical detail needed to make a product; they contain broad safety requirements. Manufacturers therefore need to translate these essential requirements into technical solutions. One of the best ways to achieve this translation or “interpretation” is

through European standards. To this end, mandates (i.e., official requests) are issued by the European Commission to the relevant European Standards bodies for the development of necessary standards including, where necessary, guidance from public authorities on specific aspects of these standards.

European standards allow technical solutions to be developed by all those with an interest in the product sector—they are open, transparent, and lead to the sharing of innovation and best practices. Most importantly, European standards ensure that different manufacturers have a uniform interpretation of the essential requirements in the Directives and, therefore, a level playing field is ensured.

Something that is very often forgotten by those who do not know the legal situation well and, therefore, is necessary to repeat here is the fact that they are not obligatory. If a manufacturer wishes, it may use its own solution. The only burden it then faces is the obligation to prove that his solution conforms to the essential requirements of the law. In other words, the introduction of the standards in the New Approach only inverts the burden of the proof. If a manufacturer has produced according to the relevant standards, the public authority controlling the market has to prove that the product is not in conformity.

The success

The New Approach has been praised often for its success at the European level. It has already been used as a basis for creating an international model for WTO/TBT's conforming technical regulations in the framework of the United Nations Economic Commission for Europe (UNECE). It has provided a common basis for nearly 30 countries that enables the free trade of sensitive products with a volume of some thousands of billions of Euros, providing a fair place for those directly involved to influence the system under a transparent, cost-efficient, politically credible, and democratic route such as the standardisation process.

In a recent reflection document, which the Enterprise Directorate General of the European Commission presented at a Seminar in 2003, important possibilities for expanding the New Approach (including areas outside of the free movement of goods) were identified:

“The implicit conclusion of the Council Resolution of 1985 is that any industrial or entrepreneurial activity operating within the Internal market could adopt the New Approach as it is currently applied, as long as the public interest is adequately protected. Such activities could range throughout the product cycle, from research and innovation to market.”

The “New Approach” brought a tremendous tension to the standardisation system in Europe. No legislator would naturally agree to give a blank check to the standardisers without a minimum degree of confidence in them and their system. The case was relatively easy in Europe—in practically every country one (and only one) national standardisation system was recognized. In some countries (like Germany) this recognition was based on a contractual relation, called “Normenvertrag”, between the government and the standards body. In other countries, the recognition was more direct since it was included in or based on a law (this was, for example, the case in Greece, Portugal, France, and, in a similar way, a royal charter in the UK).

At the European level, recognition was made without significant problems through the “transparency Directive.”

Learning to” work together”

The national standards bodies in Europe, among them some of the strongest in the world such as AFNOR, BSI and DIN, had a tradition of working independently and competing in the world market. Over the years, different philosophies were developed on several aspects including the way standards are written and presented. For example, the German philosophy emphasizes “thin” content for each standard to allow for easy revisions while the British prefer self-standing documents that provide the maximum amount of possible information to their users.

Franco-German standards disputes at the end of the 1970s and efforts to diminish them, supported by top-level politicians of both countries at the time, led to the experiment of recognizing equivalence between them. The fruits of these efforts were mediocre. It became evident that the only solution was to work together and jointly develop standards. This belief arrived at the same moment that the New Approach was being prepared at the Community level.

The most difficult part of the agreements was the requirement for every national standards organization to adopt the agreed upon European Standard—even if an organization voted against it—and to withdraw all conflicting standards from its standards collection. The experience in CENELEC, which had implemented such a rule about a decade before, made its acceptance easier.

The arrival of mandates (i.e., official requests) from the Community for joint development of European Standards made necessary, especially between 1985 and 1990, the massive establishment of European Technical Committees for a large number of sectors. Their encouraging results stimulated further stakeholder interest in entirely voluntary standardisation efforts (i.e., work not having a connection with the

European Union's mandates or legislation). Today, according to statistics made available by the European Standards Bodies, about two-thirds of their work are initiated and adopted independently of the European Union's mandates.

This change is not only quantitative. It contains a deep qualitative change in the approach for standardisation by the national industry and other stakeholders' associations. They are abolishing the old-fashioned approach to work alone in their own corner. The internal market in Europe as well as the world market does not offer serious opportunities for "own" solutions. Politically seen, this change of behaviour is the genuine implementation of the European ideal at the level of standardisation. From the trade point of view, it can also be considered the result of what is now more visible through surveys and other means in Europe (i.e., that national standards are potential—if not already real—technical barriers to trade).

This also explains the position of Europeans regarding the international standards bodies (ISO, IEC, and ITU). They have traditionally supported international standards bodies loyally, seriously and consistently implemented the results of their work to their fullest potential, and continue to support them.

As a result, the European Union now has the privilege and advantage of having all of its national standards bodies, including those being traditionally recognized as "big powers" in their area and those from co-operating nations (EFTA), working together. They represent one-fifth of ISO's membership and a very important part of the world in terms of trade.

Accelerating the "production" of Standards

After the first difficult years of adaptation to the new situation, European standardisation is now at a cruising speed. The European collection already serves as a "critical mass" and it is unlikely that European standardisation is vulnerable from the point of view of standards content. However, risks exist and new challenges are faced daily.

Current efforts to improve the efficiency of the European standardisation system must consider conflicting factors. On one hand, the quality of consensus building and the requirements of openness and transparency imply that there is a minimum amount of time needed. On the other hand, ever-decreasing product life cycles demand speedier standards production. This is why there is a need to focus efforts on applying sound project management to the development of each standard, and the bits that are controllable should be well managed. For example, from the start one needs to think carefully about the impact, users, and purpose of the standard; planning and thinking about problems that may occur during development is needed (for example, will there be a laboratory validation needed of the test method). Only when this is done will we

have standards that are needed, reflect market needs, and are within the timescales desired by the market.

The “selling less and influencing more” paradox

The major source of the national standards bodies’ income is the sale of their documents. Since all European standards have to be implemented as national standards with identical content, European Standardisation has, by definition, resulted in the creation of fewer standards overall. With the exception of the need for translations (something extremely important in Europe for the accessibility of small and medium size enterprises), the national standards bodies, as the sole distributors of their standards, obviously sell less. On the other hand, the adoption of a European standard in a given subject brings with it the possibility of more broadly influencing not only intra-European but also international trade.

A paradox is therefore created: the volume of the standards sold is decreasing while their influence (and through them that of the relevant technology) is increasing significantly. But the (national) standards bodies cannot live on influence; they have to sell in order to stay alive and continue to serve their constituencies. The added influence of the resulting standards does not seem to be transformed into an additional financial contribution from their (qualitatively) better-served constituencies.

A similar situation, although caused by different reasons, also exists elsewhere. The Standards Developing Organizations (SDOs) in the USA also survive on their sales. Their standards are, very often, of high quality and serve as “carriers” of important technologies. However, in cases where their standards are considered appropriate to become International standards (and logically, to be exposed to broader “ownership”), the SDOs hesitate because of the risk sales losses. The paradox here is that in an effort to prevent some income loss, they limit the potential for the technologies represented in the standards to become more influential. In order to stay alive, they have to limit the influence of the technologies embedded by their constituencies in their standards.

It is obvious that in both cases we are facing a serious problem—the standardisers are obliged, in order to survive, to avoid loyally serve their constituencies. A way has to be found to transform this influence into resources and someone has to provide them.

REFERENCE TO STANDARDS IN “TRADITIONAL” EUROPEAN LEGISLATION

Standards are not only used in the framework of the “New Approach-based” legislation. Hundreds of references to standards are made in the European legislative corpus. Ironically, very few of them are European standards. Most of them are

national standards that are often superseded or withdrawn. Furthermore, a large number of cases even refer to standards that do not originate in Europe.

The most important problem for these references is the constant need for updating. A recent document published by the Enterprise Directorate General exemplifies this problem clearly.

It is obvious that the European Commission must still do important work to develop a more organized system and monitoring technique for this extra “New Approach” use of standards. This would not only help the quality of the legislation but also facilitate its synchronization with technology.