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CURRENT PRINCIPLES AND IMPORTANCE OF TECHNICAL
HARMONIZATION IN THE EU FOR TECHNICAL STANDARDIZATION

TECHNICKÁ HARMONIZACE V EU, SOUČASNÉ PRINCIPY A JEJÍ VÝZNAM
PRO TECHNICKOU NORMALIZACI

Abstract

The basic principle of the technical standardization is to ensure market development via formation of unified technical rules for all the concerned subjects. The information and communication technology industry is characteristic by certain specific features as opposed to the traditional industry. These features impose new demands on the standardization domain, mainly the flexibility, i.e. ability to react to the rapidly developing ICT market very flexibly. The goal of this paper consists in presenting a comprehensive overview of the current system of technical harmonization and standardization in the European Union and impact on the member states.

Abstrakt

Základním principem technické normalizace je zajistit rozvoj trhu vytvořením jednotných technických pravidel pro všechny zainteresované strany. Průmysl informačních a komunikačních technologií (ICT) má ve srovnání s tradičním průmyslem svá specifika, která kladou na oblast normalizace nové nároky. Jedná se především o flexibilitu, schopnost pružně reagovat na velmi rychle se rozvíjející trh ICT. Dalším výrazným aspektem ICT je prostředí, v němž se uplatňuje. Internet vytváří prostředí bez hranic jak z hlediska prostorového, tak časového. Zde vize jednotného neomezeného trhu nabývají postupně konkrétních podob a jeho rozvoj je těžké až nemožné předvídat. Co však je dnes zřejmé a obecně platné, je potřeba otevřené, široké, transparentní, konsensuální a globální normalizace. Cílem autorky je předložit stručný ale ucelený pohled na současný proces technické harmonizace a normalizace v EU a její dopady na členské státy.

Key words: standard, standardization, ISO, CEN

1 INTRODUCTION

Technical harmonization means unification of legal regulations, technical standards and procedures for assessing compliance of properties of products and services that are regulated by these regulations or standards. The harmonization is supposed to be ensured to such an extent to remove technical barriers of business existing due to different national requirements [19].

The harmonization of technical legal regulations and technical standards within the European Union is considered a pillar of the industrial and economic development of

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the company. Its main role consists in supporting and creating conditions for establishing a unified free market based on the freedom of movement of goods, people, capital and services. The principles for removing technical barriers of trade were founded in the European community already by so-called Treaty of Rome in 1957 (Contract of Establishing the European Economic Community). The concept of a unified internal market was carried through in the Single European Act in 198. The achievement of free movement is one of the principles and goals of the first EU pillar [12].

The European Union has been developing as the largest integrated commercial community in the world. The process of creating a unified market within the EU involves not only the creation of the new bodies, tools, processes and procedures, but also the replacement of already established and accepted national processes and procedures. Technical barriers represented by the regulations, standards and compliance assessment have become an integral part of the industrial structure of the states and may be replaced only by acceptable alternatives, not just by their simple removal. The trading within the unified market is therefore conditioned by establishment of common and universally acceptable regulations and standards. This is a very extensive and time-demanding process, as the common unforced standards must be created on the basis of a wide consensus.

2 CURRENT PRINCIPLES OF TECHNICAL HARMONIZATION AND EUROPEAN LAW

Technical harmonization would not be possible without harmonizing legal systems of the member states, unifying legal orders in a single *acquis communautaire* and mutual acknowledgement of national regulations. The utilized means are mainly the primary European Community law, Secondary European Community law (mainly the directives, regulations) and decisions of the European Court of Justice. The EC constitutes a legal frame both for asserting the harmonization of technical regulations in the EU, and for ensuring the unified system of technical standardization in the entire EU. The following text therefore reports information on legal acts, which regulate the area of technical regulations and standards. Shortly are mentioned the types of legal acts, which have the most extensive impact on the EU member countries in terms of asserting the European law.

The European law represents an independent legal system comprising two subsystems:

1. **Law of the European Communities** (so called. **acquis communautaire**, or **supranational law**),
2. **European Union Law** (so called **Union Law**), i.e. the law originated within the frame of intergovernmental cooperation of the member states of the European Union [22].

The main source of information relating to the EC law is the EUR-Lex portal. This portal published all the EU regulations, decisions and directives. Major part of the valid EU legislation is already translated into Czech and is gradually published on EUR-Lex [8].

Law of the European Communities – *acquis communautaire*

The legal basis of the European integration consists in the EC law, so called *Acquis communautaire*.

Acquis communautaire constitutes as a whole a special, separate system of law. It is an autonomous legal system. One of the significant features of the *acquis communautaire* is its precedence before national law including the national systems of the EU member states [21]. It is immediately utilizable, that means without necessity to accept any transformation act (it applies to the binding legal regulations of the European Community except for the directives, as mentioned below).

The EC law – *acquis communautaire* is classified in the specialized literature according to the origin of the legal standards within primary and secondary law.

Primary law is considered a so-called EC constitutional law. It includes legal standards contained mainly in the constituent agreements of the European Community. They usually further include contracts between the EU and third states, internal agreements between the EU members, but also the decisions of the European Court of Justice. The decisive fact is that this system of contracts forms a certain “Constitution of the European Integration”. They include definitions of basic integration principles, bases of individual policies, composition, authorities and decision-making procedures of common institutions. The common bodies can act only on the basis of these agreements, i.e. create so called secondary EC law and to try to develop the integrated policies via this law.

Secondary law is directly linked to the primary law and is derived from it. The EC bodies however can accept the secondary law only in those areas, in which they are authorized for it by the primary law. The secondary EC law is composed of legal acts adopted by common EU institutions.

The individual constituent agreements allow the EC bodies to issue legal standards, so called legal acts of the *acquis communautaire*: regulations, directives, decisions, recommendations, and standpoints [14]. Nature of these most important legal acts is explained in the following portion of text. The bodies authorized for adopting these acts are the Council of the European Union or the Council of the European Union together with the European Parliament, in some cases also the European Commission. Their executors are usually the member states under the supervision of the European Commission and a series of specialized committees composed of the EU apparatus representatives.

The above sources of law together with the concepts and strategies, so called Green or White books of the European Commission, expository studies and other documents (non-binding, so called soft regulations) form a so-called comprehensive „*acquis communautaire*“, i.e. „all that has been achieved in the legal area within the Community“. This French term does not have an equivalent in most other languages.

Legal acts of the communitarian law form a set of tools that enable the EC institutions to act on the national legal orders in different extent. The most radical form is the replacement of a national legal regulation with a EC standard. This is followed by the EC standards, via which the EC institutions influence the legal orders of the member parties only indirectly. In a concrete case, there is also a possibility to adopt measures against an addressee defined or definable by name. And finally, there are also such legal

acts that do not contain any binding rules for member countries or for the EC citizens [11].

Characteristics of the most important acts of the communitarian law

Regulation has an immediate effect and directly binds all the subjects of the EU member countries without performing any transposition into EU member national legal regulations. It asserts an absolutely identical law in the entire EC regardless of the state borders. The member countries are thus denied the possibility to apply provisions of the given regulation incompletely or to choose only some of these provisions. Apart from that, the states are not allowed to avoid the binding force of the regulation with reference to the form and legal practice in the domestic law [20].

From the point of view of the national legislation, this is a legal regulation superior to other normative legal acts. This means that the legal or physical entity can appeal to these standards directly before the national courts of the member countries of the European Union. It is of a normative and generally binding nature. In practice, the basic regulations are generally issued by the Government, which is originally authorized for issuing these acts. The Council often authorizes the European Commission for issuing implementation regulation in the form of power delegation [21].

Decision has a nature of an individual legal act. For the reason of its direct and immediate effect, it represents a legal act similar to EC regulation in terms of applicability. Decision has individual validity, in which it differs from the regulation. The addressees of the decisions must be individually identified and the decision is binding only for them. The addressees of the decision are directly bound by them. Any implementing act is not necessary for application of the decision. Via such decision, the EC institution can require an EU citizen of a member state to act or to refrain from acting, or to award rights or impose duties on it. The decision is binding in all its parts (exactly as the regulation) [11].

Directive is not binding for the member countries as a whole, but only in terms of the result, which is to be achieved. The selection of forms and means is left on the internal bodies of each individual EU member state. This is how the member states can take into account their national specific aspects in achieving the EC law objectives. The procedure is that the directive does not automatically replace the national legal regulation, but the member states are obliged to amend their national law according to the EC provisions. This results in a two-level legislative process:

At the first level (EC law level) the directive obligatorily stipulates the result, which the given addressee, i.e. multiple member states or all the member states must achieve within a stipulated period of time. The EC institutions can predefine such result by means of a detailed provision, so the member states have no room left for their factual modifications. Such procedure is used mainly in the area of technical standards or for environmental protection.

At the second level (national law level) the result defined by the EC law is factually achieved within the national law of the member countries. Although the member countries are basically free to choose the form and means for execution of directives, this stage is followed by assessment, whether the given amendment was implemented in the national legislation in accordance with the EC law, according to its criteria. The principle is that the implementation of the directive must constitute such situation that clearly enough and concretely expresses the rights and duties contained in

the directive, thus the EU citizen is given a possibility to exercise the given directive before the court. This usually requires adopting a binding national legal act or abrogation or amendment of an existing legal or administrative regulation. Transposition of the directive into the national law of the member states must be completed within a specified time. The period for transposition is often two years.

Directive is a tool for ensuring unity of the EC law on one side and respecting the diversity of national specific aspects on the other. The utmost goal of the directive is not – as opposed to regulation – the unification of law, but its harmonisation. **The directive represents one of the basic tools for realizing internal EU market and technical harmonisation.**

Recommendation and Opinion

Recommendation and opinion represent legally non-binding acts of the EC. They assume voluntary performance and are not enforceable by law. Both these acts represent rather a suggestion or instruction. Actual meaning of recommendations and opinions consists in political and moral area [11], [22].

3 OLD AND NEW APPROACH TO TECHNICAL HARMONISATION

National technical regulations were being replaced with the European ones in the EEC countries by means of directives since 1957. This approach labelled as the old approach to technical harmonisation turned out to be a failure mainly because of the fact that the achievement of agreement in a technical regulation requires longer time than in the case of technical specification. Development in technology is fast and therefore the life cycle of the technical specifications is significantly shorter than that of the technical regulations. This resulted in slow introduction of new technical knowledge into practice and necessity of frequent update of directives.

The directives of the old approach contained apart from basic provisions all the technical specifications in the form of annexes. This approach excluded involvement of all the individual requirements for the individual product categories. The technical specifications are getting obsolete with the progress and detailed binding regulations must then be frequently updated in order to prevent their becoming a brake of innovations of products and production methods. This approach was very lengthy, clumsy and detailed. The groups of products generally representing a higher degree of risk still preserve a system of binding regulations with detailed technical specifications. These directives usually called sector directives are valid for example for motor vehicles, food products, chemical substances or pharmaceuticals.

In 1985, the EEC defined its priority consisting in achievement of a unified internal market. This meant a new, accelerated and more effective harmonization procedure for solution of technical barriers of the trade. In order to satisfy this requirement the Council of Ministers adopted in 1985 a so-called New approach to technical harmonization and standards (Council resolution of 7th May 1985 no. 85/C/136/01). The new approach retracted from the previous system based on technical details. The EC legal acts (in technical harmonization mainly directives) focus on defining basic requirements, the description of possible recognized technical solutions for compliance with the basic requirements is contained in the harmonized standards. These standards are created on the basis of EC mandates) by the European bodies for

normalization: CEN (The European Committee for Normalization), CENELEC (European Committee for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institut) [5].

The policy of New approach to technical harmonization and standards means that apart from harmonized standards each EU member state must introduce national legislation complying with the basic parameters of the directive. The directives do not specify how the requirements must be established, but clearly and precisely specify the required results. The standards are voluntary. The manufacturers do not have to obey the harmonized standards in order to comply with directive. The manufacturers are free to choose any technical solution, which complies with the basic directive requirements. However, when they conform to the harmonized standard, so-called presupposition of compliance with the directive applies. The manufacturers and bodies for evaluation of compliance can choose other suitable technical solutions, for example use of other - mainly national - standards. In such cases, it is not possible to anticipate compliance and the manufacturers themselves, there where it is necessary it must provide a licence of compliance with the basic directive requirements. This may require application of more stringent procedures of compliance assessment. The manufacturers must specify compliance with a directive by means of a CE compliance mark.

There are three methods of proving the compliance with directive:

1. By complying with the harmonized standards, i.e. those that were elaborated by the European normalization bodies (CEN, CENELEC a ETSI) for supporting the basic requirements of the relevant directive;
2. If the product does not comply with the harmonized standard, then it is possible to evaluate the compliance directly with the directive;
3. If the harmonized standards do not exist, the compliance of the product can be assessed by a third party (notified entity); the manufacturer or its authorized representative (for example importer) will append the CE mark in order to document the compliance. [20]

The CE mark is of concern mainly for the supervising bodies rather than for an end user; it is supposed to show that the products can be freely placed in the internal market. If the compliance testing involved a notified body, the CE mark is followed by a number of the notified entity. The CE mark is not mark of quality and safety and does not replace these marks.

4 CURRENT PRINCIPLES OF TECHNICAL STANDARDIZATION IN THE EUROPEAN UNION

The development of technical standardization has changed considerably since the end of the ninetieths and is characteristic by passing to “global technical standards” which are supported by majority of the developed countries in the world. The current global market is characteristic by mutual penetration of various industrial sectors. In principle, no sector today is completely independent on products, production procedures, services and the like created in other sector. New aspect in the area of technical standardization is also the rapidly continuing convergence of technologies. Typical example is the use of information and communication technologies in building global information and communication infrastructures. The utilized technologies should be

rapidly normalized in this quickly developing sector. There should not be any organizational or procedural barriers, which would halt or delay this process. The above technologies are characteristic by their fast life cycle, and the life cycle of the normative documents must be adapted to it.

Technical standardization serves, directly or implicitly, for ensuring communication of partners in the area of industry by means of rules based on mutual agreement. This also ensures their wide acceptance. The standards can therefore be perceived as documented agreements containing technical specifications or other determining criteria ensuring that the materials, products, procedures and services suit the given purpose. They are qualified recommendations and their utilization is voluntary.

Current technical standardization in the EU is characteristic by close link to the international standardization system. The standardization process based on international consensus ensures that the final standards for products or services represent collective knowledge and experience of all the concerned parties – industry, governments, research institutes, testing laboratories and consumers' organizations. The utility of the international standards is currently recognized across sectors without exceptions. This does not include only enforcement of creation and use of technical standards on the largest possible scale, but mainly the replacement of national technical regulations with international standards where possible. Non-existence of the unified normative documents in different countries is the cause of technical barriers in the international trading. In order to be able to remove these barriers it was necessary to agree on globally recognized standardization documents, which led to establishment of the international standardization structure of standardizing organizations. Current international standardization system is ensured by three most important standardization organizations:

- **ISO** (*International Organization for Standardization*);
- **IEC** (*International Electrotechnical Commission*);
- **ITU** (*International Telecommunication Union*).

The existing standardization system is in principle defined by **Directive of the European Parliament and Council 98/34/ES on procedure in providing information in the area of standards and technical regulations** and amended with rules for services of information company by adopting the **Directive of the European Parliament and Council 98/48/ES** [5]. The directive forms a basic frame of the European standardization, which is based on common European standardization system consisting of three European standardization bodies and national standardization bodies of the EU countries. Common goal is to create a system of the European harmonized standards [9], [20]. For achievement of this goal the European Union uses a **notification process** introduced by this directive. The directive imposes an obligation on the member country to ensure that each proposal of national regulation or national standard is before adopting notified to other EU and EC members that have the right to raise comments, if they assume that the proposal violates the principles of free movement of goods and services and introduces trade barriers. Both standards and regulations are subject to notification. If a conflict occurs, such regulation cannot be accepted. Any state that would do it is facing a sanction. This applies also in case when it does not notify of a regulation proposal at all.

In case of standards the intents to create or change a standards are notified of if the acceptance of the European of International standard is not identical. The information is reported to the EC and standardization bodies of the EU. In the Czech Republic the notification of standards falls within the responsibility of the Czech Standardization Institute (ČNI).

The regulations are notified if it is not a complete EU regulation transposition. In practice it means that it is necessary to notify of all the regulations containing technical specifications above the scope of standardization. Therefore, also the national regulations introducing the European directives and other harmonized regulations, if other requirement or requirements for products or services, which are not contained in the regulations, are added to national regulation. The information is reported to the EC and national contact places in the individual member countries. The contact place in the Czech Republic is the Czech Office for Standards, metrology and testing (ÚNMZ).

The directives 98/34/ES and 98/48/ES introduced definitions of concepts and rules ensuring the technical harmonization in the EU. Only those parts are selected and quoted for the purposes of publishing that are substantial for understanding of the process of current harmonization of technical regulations and standards. The directives include other areas that are not mentioned here. [5]

Definitions and explanations of other concepts from the normalization area are presented by internal directives CEN/CENELEC [1] and ISO/IEC [25].

Technical regulation (definition according to directive) [5]

*„Technical regulation“ means **technical specifications and other requirements or rules for services** including relevant administrative regulations, whose observance is binding de jure or de facto during introduction to the market, service provision, entrepreneurial activity of service provider or during use in the member state or in its major part, as well as the legal and administrative regulations of member countries prohibiting the production, import, sale or use of a certain product or prohibiting provision or use of certain service or entrepreneurship of service provider [5].*

The binding nature of technical specification, other requirement or rule for services may be given in two ways:

1. **de jure**, when the compliance with technical specification or other requirement or rule for services is defined as a binding legal regulation (law, ordinance, government decree, etc.);
2. **de facto**, there, where the technical specification is not defined by a formal and binding regulation by the relevant state, but where the state invites for its observance; in consequence of similar effects, which they may have on trade, these measures are considered equivalents of binding regulations.

Example:

The technical specification may be included either directly in the text of law, ordinance or government decree (“de jure” regulations), or in other document which the law or other legal regulation refers to and makes it binding (“de facto” regulations).

Demonstrative enumeration of **de facto technical regulations** is divided in the directive into three categories:

De facto technical regulations include the following:

- *Legal and administrative regulations of a member country referring to technical specifications or other requirements or rules for services or professional rules or the rules of best practices, which themselves contain reference to technical specifications or other requirements or rules for services, where the harmonization with them is a precondition of compliance with the obligations imposed by the above legal or administrative regulations;*
- *Voluntary agreements, in which the public authority body is the contracting party and which in the public interest define compliance with technical specifications or other requirements or rules for services, except for specifications for competitive tendering in assigning public contracts;*
- *Technical specifications or other requirements or rules for services associated with fiscal or financial measures influencing the consumption of products or services by inviting to compliance with these technical specifications or other requirements; this does not apply to technical specifications or other requirements or rules for services relating to national social welfare systems [5].*

Technical specification (definition according to directive)

„Technical specification“ means specification included in the document which defines the required product characteristics, like quality standards, property indicators, safety or dimensions including the requirements for product like trade name, terminology, symbols, testing and testing methods, packaging, product marking or labelling with data and procedures in evaluation of conformity [5].

Technical specification specifies the required product characteristics. Enumeration specified in the definition in the directive is demonstrative.

Standard (definition according to directive)

„Standard“ is a technical specification approved by a recognized standardization body for repeated or permanent use, whose observance is not binding and which is classified within one of these categories:

- *International standard: Standard accepted by international standardization body, accessible for wide public;*
- *European standard: Standard accepted by the European standardization body, accessible for wide public;*
- *National standard: Standard accepted by national standardization body, accessible for wide public.*

European standardization body (definition according to directive)

„European standardization body“ is a body specified in the Annex no. 1 of the 98/34/EC directive;

The following standardization bodies are considered European according to the directive:

| | |
|----------------|---|
| CEN | European Committee for Standardization |
| CENELEC | European Committee for Electrotechnical Standardization |
| ETSI | European Telecommunications Standards Institute |

National standardization body (definition according to directive)

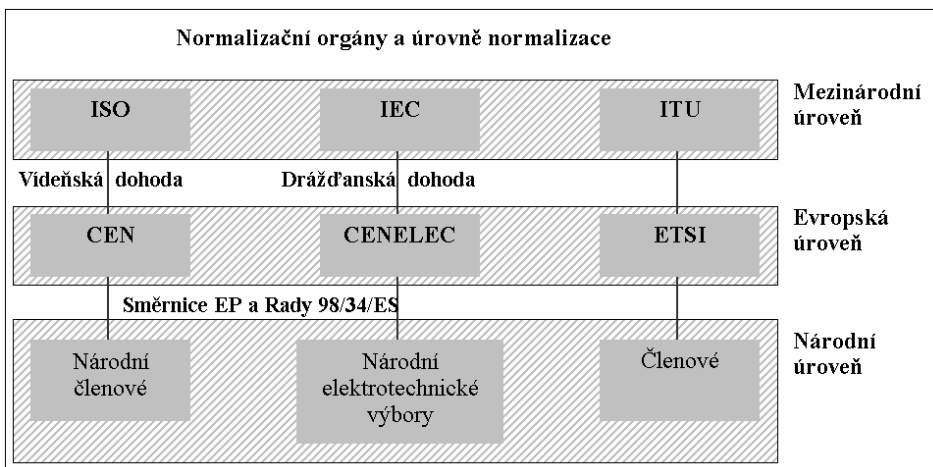
„*National standardization body*“ is a body specified in the Annex no. II of the 98/34/ES directive; [5]

5 STRUCTURE OF TECHNICAL STANDARDIZATION SYSTEM IN THE EU

The structure of current system of technical standardization in the EU is schematically shown in figure 1. The system is composed of two levels – European and national – and is directly interconnected with international standardization level. The function and mutual cooperation of the individual standardization bodies within the European Union is defined by the 98/34/EC directive.

In all cases, where it is possible the CEN works in parallel with ISO (exactly as ENELEC and IEC) and tries to accept international standards (IS) and transpose them into the European standards (EN). Cooperation with these organizations is regulated by agreements that were signed in 1991. These include Vienna Agreement between CEN and ISO (reviewed in 2001) and Lugano Agreement between CENELEC and IEC (reviewed by Dresden Agreement of 1996). The number of such accepted international standards in CEN ranges around 32%. 70% of standards in CENELEC is almost identical with the IEC standards and over 8 % of standards is based on IEC standards [20].

While 15 years ago approximately 80% of all standards were elaborated on national level, 90% of all standards are nowadays elaborated on the European or International level. Concrete example of successful application of international and European standards may be the Global system for mobile communication (GSM). Other important examples stimulating the development and application of standards are Galileo and in the area of geoinformation science mainly INSPIRE.



Caption: Normalizační orgány a úrovně normalizace – Standardization bodies and standardization levels; ISO - International Organization for Standardization, IEC - International Electrotechnical Commission; ITU - International Telecommunication Union; Viedeňská dohoda – Vienna Agreement; Drážďanská dohoda – Dresden Agreement; CEN - European Committee for Standardization; CENELEC - European Committee for Electrotechnical Standardization; ETSI - European Telecommunications Standards Institute; Směrnice EP a Rady 98/34/ES – 98/34/EC Directive of the European Parliament and Council; Národní členové – National members; Národní elektrotechnické výbory – National Electrotechnical Committees; Mezinárodní úroveň – International level; Evropská úroveň – European level; Členové – Members; Národní úroveň – National level

Figure 1 Structure of technical standardization system

National standards in Europe will probably always exist, but it is possible to expect that their number will drop below 5-10% of used standards and that they will be replaced by the European and international standards. [4].

The European standardization bodies control the creation of the European standards. National members subsequently issue these standards as a part of their national sets of standards, and the member countries are obliged to adopt all the European standards within 6 months from their date of issue, cancel all the conflicting national standards and when the activities associated with the new European standards are initiated all the works on the national level regarding the same subject must standstill, if they did not reach the stage of public amendment proceedings.

Therefore it is not possible to buy an EN European Standard, but only an assumed national standard, for example ČSN EN (Czech), BS EN (British), DIN EN (German) or NF EN (French). It is possible that a national standardization body accepts directly an international standard that was not yet transposed into EN. This procedure is permitted by the 98/34/EC Directive. Such standard is then identified as for example ČSN ISO, ČSN IEC, ČSN ETS.

European and international standards are introduced in the national standardization system by adopting:

- translation, i.e. issue of national standard (for example ČSN), containing national title page, national preface, complete translation of the standard original and national annex, if it is necessary (in case of ČNI approximately 60 % of total

volume of the adopted standards). Via translation mainly the European harmonized standards are adopted and standards of wide use;

- original, i.e. issuance of national standard containing national title page, national preface, reprint of the English or English and French version of the adopted standard and national annex, if it is necessary;
- accepting for direct use by announcement in a Bulletin (so called Endorsement), i.e. issue of cover with the name in the national language and identification of the adopted standards, into which the English original of the adopted standard is inserted. In case of the Czech Republic it means that the use of the European standard has been announced in the Bulletin of the Czech Office for Standards, Metrology and Testing and if the customer requires the standard, it will receive the text of the English original inserted in the cover with the name of the standard and its identification in the Czech language.

European standards are approved in three official languages: English, French, German.

6 CONCLUSION

The European technical standardization is derived from the European legislation rules given by the New approach, where the standardization is generally shifting from the national to the European level. While 15 years ago approximately 80% of all standards were elaborated on national level, 90% of all standards are nowadays elaborated on the European or International level [20]. Concrete example of successful application of international and European standards may be the Global system for mobile communication (GSM), which serves to more than one billion people in more than 200 countries. Another example could be and should be the Galileo system or the European geoinformation infrastructure INSPIRE.

Technical standardization is an integral part of the EC policy and can significantly contribute to the fulfilment of the points of the “Lisbon strategy” whose main goal is the growth of competitive strength of businesses, elimination of barriers, better regulation and increase of employment in the EU. The Commission therefore undertook to intensify the use of technical standardization as a support of the European legislation and policy. It strives for creation of a strong European system of standardization, including adequate infrastructure, which is able to ensure that the international standards that were elaborated and made by the European standards for support of the EC policies, were harmonized with these policies. Diversified system based on many mutually competing national standardization bodies cannot fulfil such task. Therefore, the European standardization must continue to be based on cooperation of all the concerned subjects, starting with the EC, European standardization bodies, national standardization bodies, national bodies, enterprises up to the non-government organizations, professional groups and individuals, which are interested in the standardization.

The main international commitments of the European Union in the area of standardization are expressed in the WTO (*World Trade Organization*) agreement on technical barriers of trade. This agreement requires the technical regulations and international standards to be elaborated and applied in a non-discriminating way, without

creating useless barriers to trading. It recommends that international standards be used for elaborating technical regulations, if possible [6].

Another from the series of documents that proved the indisputable role of standardization as a part of policies for performing a „creation of better legal regulations“ are the documents of the European Parliament and Council [24], [3] of 1999 and [2] of 2002. The growing importance of standardization in support of the EU policies was also officially declared in the communication of the Commission to the European Parliament and Council „*The role of European standardisation in the framework of European policies and legislation*“ (10/2004) [26]. This document was a result of an analysis performed by the Commission that referred to evaluation of current situation in the area of standardization and its goal was to define key areas, in which it is possible and necessary to further improve the European system for standardization. The conducted studies proved that the development of standardization creates additional value and increases competitive strength. For example the study issued by the Austrian standardization body ON (Der Nutzen der Normung für Unternehmen und Volkswirtschaft) states that the benefit of standardization in Austria was 1.74 billion €, whereas the costs amounted to 43 million €. The benefit was therefore 40 times higher than the costs [26]. The German institute for standardization (DIN) published that the standardization in Europe adds approximately 1% to the gross national product value. Another aspect pointed out is that the added value created by standardization is of at least the same importance as the value created by patents [7], [15]. The European commission therefore incorporated the utilization of standards into various documents associated with its policies.

The standardization follows the “bottom-up” approach. It is a matter of self-regulation influenced by industrial and social parties concerned. It seems however that many of these, mainly the small and medium enterprises, are not aware of the advantages of the standards. It is therefore necessary that the standardization activities in the area of new technologies be better understood, that the awareness and their knowledge be on higher level, that the interest of the concerned parties in the technical standardization increase.

The European standardization is a key to successful introduction of new technologies; it stimulates innovation and offers great possibilities for improvement of everyday life. Expansion of standardization activities into new and untraditional areas requires perfect function of the entire European standardization system. This system must be based on the principle of voluntariness, partnership and cooperation of all the concerned parties starting with the EU bodies through standardization bodies of the member states up to the institutions and subjects of the private sector, professional associations and individuals from professional public.

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SUMMARY

Technical harmonization represents an important tool of the EU for a promotion of the strategy for the unified internal market. A new quality can be recognized in relation with a New approach to harmonizing of technical rules and technical standards. A fundamental change in the system of European technical standardization was brought forward by a Directive of the European Parliament and Council no. 98/34, procedure for the provision of information in the field of technical standards and regulations.

This Directive, together with other directives, leads to the successive convergence of the standards both on the European and global level. In the EU member states, 15 years ago approximately 80 % of all the standards were elaborated from the national level, but the situation changed dramatically and nowadays 90 % of all the standards are elaborated from the European or international level. These new standards gradually substitute the old ones. The European standardization process is the key to successive application of the new technologies; it stimulates innovation process and finally, it offers great opportunities for improvement of everyday life. The expansion of standardization activities into the new and non-traditional branches requires appropriate function of the whole European standardization system. It has to be based on the voluntariness, partnership and coordination of all the concerned bodies including the EU bodies, national standardization bodies as well as institutions and private bodies, associations and individual experts.

RESUMÉ

Technická harmonizace představuje důležitý nástroj Evropské Unie pro propagaci strategie pro jednotný vnitřní trh. Novou kvalitu lze rozeznat ve vztahu k Novému přístupu k harmonizaci technických pravidel a technických norem. Zásadní změna v systému Evropské technické standardizace byla prosazena směrnicí Evropského parlamentu a Rady č. 98/34 postup při poskytování informací v oblasti technických norem a předpisů.

Tato směrnice spolu s dalšími vede k následné konvergenci standardů jak na Evropské tak světové úrovni. V členských státech Evropské Unie před 15 lety bylo přibližně 80% všech norem vypracováváno na národní úrovni, ale situace se dramaticky změnila a dnes je 90% všech norem vypracováváno na Evropské nebo mezinárodní úrovni. Tyto normy postupně nahrazují normy staré. Evropský normalizační proces je klíčem k následné aplikaci nových technologií; Stimuluje proces inovace a v neposlední řadě nabízí ohromné možnosti zlepšení každodenního života. Expanze normalizačních činností do nových a netradičních oblastí vyžaduje dobré fungování celého evropského normalizačního systému. Ten musí být založen na principu dobrovolnosti, partnerství a spolupráci všech zainteresovaných stran počínaje orgány EU, přes normalizační orgány členských států až k institucím a subjektům privátní sféry, profesním sdružením a jednotlivcům z řad odborné veřejnosti.

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