

CEN AND INNOVATION

POSITION PAPER



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“Innovation is the process of turning ideas into manufacturable and marketable form”

(Watts Humphreys)

1. Principles of innovation and standardization

To develop Europe into the most innovative economy in the world by 2010, is one of the aims outlined in the Lisbon Agenda of the European Council in the year 2000. Furthermore, it is essential for industry in Europe to be competitive in the global market. One of the prerequisites for Europe to remain among the worldwide industrial leaders is to boost and facilitate innovation. What exactly does this signify? Innovation is based not only on the capability of European industry to develop new products, processes and procedures, but also its ability to do things in simplified and more efficient ways. In addition to the industrial sector, standardization also covers other societal interests such as the environment, consumers, Small and Medium Sized Enterprises etc.

Inventions versus innovation

To understand the role of standardization in this field one has to differentiate between inventions and innovation. Innovation can be defined as the “process of turning ideas into manufacturable and marketable form” (Humphreys) or as the “commercialization of all new combinations based upon the application of new materials and components, the introduction of new processes, the opening of new markets, and/or the introduction of new organizational forms” (Joseph Schumpeter). Hence, innovation is one step further from a mere invention, for example an object, process, or technique, which displays an element of novelty but is not commercialized.

Standards help inventions to become innovations. Without standards, inventions could not have found the same level of market success. The role of standards in finding a consensus among European civil society (industry, consumers, interest groups etc.) on the best product or procedure, ensures that industry invention is translated into standards innovation. CEN develops European Standards in response to market requests from industry. It therefore plays an important role as a business facilitator, offering a common platform for Europe and beyond. Standardization also favours a broad diffusion of knowledge by bridging the gap between laboratories and the market so that inventions can be discussed between different interested parties.

In economic terms, the changes resulting from innovation must increase value: customer value, or producer value. Standards are a tool for achieving these results through their contribution to the removal of trade barriers and, hence, access to open markets and the reduction of costs. Innovations are intended to bring benefits to industry and consumers alike, and the succession of many innovations grows the whole economy. Since CEN covers a wide range of sectors, its accumulated European Standards and other deliverables contribute to the growth of the whole economy. Different studies conducted at national level (e.g. by BSI and DIN) have shown the link between standards and economic growth.

Standards simplify innovation

The term innovation may refer either to radical or incremental changes to products, processes or services. The often unspoken goal of innovation is to solve a problem.

Standards have made a significant contribution to the solution of many production and process problems. Quality standards, such as EN ISO 9001 or EN ISO 14000, have globally contributed to the sometimes radical, sometimes gradual, improvement of quality procedures in many companies. The same can be said of many other European Standards.

In the organizational context, innovation may be linked to performance and growth through improvements in efficiency, productivity, quality, competitive positioning, market share, etc. All organizations can innovate, including for example hospitals, universities, and local governments. Since CEN covers a wide range of activities with its sector-oriented approach, it is part of the innovation cycle. However, standards by nature may come towards the end of the cycle. Since standards are market driven, the innovative spirit needs to come from the market. CEN then provides the platform to translate these ideas and proposals into concrete orientation documents.

Standards and patents

An important aspect in the process of invention/innovation relates to intellectual property rights and patents. Knowledge of existing standardization in the area concerned as upstream as possible in the process can widen the platform, increase the impact or facilitate the step from invention and patent to innovative products and processes.

Standards and research

Standards not only enhance innovation itself, however, but accompany the whole process of research and development. They do this with a full range of different documents such as quality standards, testing method standards, standards that support internal communication and reduce production costs, standards to ensure interoperability and the usability of products and services. Globally it can be said that inventions without standards have no chance of becoming innovations.

During the Competitiveness Council of 4 December 2006, the Council acknowledged the importance of the contribution of standardization to innovation:

“Standards can be decisive for the commercial success, in helping to aggregate demand for innovation activity. The current European standardization system has to adapt to the needs of fast-moving markets, especially in services and high-technology products. Increasingly, multiple standards emerge which, when not interoperable, fragment the Single Market. The Union should also be more active in influencing global standardization systems.”

2. Innovative standardization

The aim of this paper is to illustrate CEN's role in the innovation cycle by means of examples taken from the different CEN sectors. However, it does not contain an exhaustive list of all projects conducted in CEN to boost innovation. It merely intends to give some examples in each sector. CEN is keen actively to support innovation in all its sectors and is doing so in many ways. In response to market demands, the standardization process has already been accelerated and simplified. Electronic working tools have been introduced to speed up processes and reduce bureaucracy, facilitating the involvement of all interested parties.

More than 10 years ago, CEN started a project called 'Paperless CEN'. At the time it was difficult to imagine the high level of electronic working that CEN has achieved today: the whole standards development and monitoring process is now supported electronically.

The work of the CEN Technical Committees has undergone a major evolution with the introduction of an electronic collaborative platform (Livelink). All participants in CEN Technical Committees and Governance Bodies can now access their working documents at any time, from anywhere in the world. Electronic templates are available to TC Secretaries to guide the drafting of standards and all standards documents are exchanged electronically between the parties involved. The documents are available in a few seconds and only to authorized users. 'Snail mail' is no longer a part of the standardization process!

Although not yet systematic, teleconferences and electronic meeting platforms are also being progressively integrated in CEN's way of working.

The CEN Work Programme is available on-line (PROJEX-ONLINE) to the players directly involved in the standardization process, providing high transparency on all CEN's projects and standards' details, planning, interactions and legislative aspects as well as monitoring tools. For a wider audience, the CEN Work Programme is available on the CEN website.

The standards acceptance process is also managed electronically via the e-Balloting systems. National votes are registered on-line and balloting results are available immediately at closure.

The high investments made by CEN in modern technologies have contributed considerably to speeding up the delivery of standards and meeting CEN's 3-year timeframe objective for the development of European Standards.

In addition to electronic working tools, CEN has adopted the so-called 'new deliverables' – Technical Specifications, produced quickly in a Technical Committee, and CEN Workshop Agreements (CWAs), produced in more informal groups of interested parties without geographical or other participation restrictions.

Work in CEN is undertaken by experts from all parts of European civil society. Industry, governments, consumers, environmentalists and other interest groups send their representatives who contribute to the development of draft documents. This unique consensus procedure enables CEN to pick up on current innovative developments very early, in whatever field. Standardization translates valued criteria such as quality, interoperability or efficiency into real attributes of products and services. Standards help ideas to become reality by transforming them into manufacturable and marketable products and even services. Very often good ideas never see the light of day because they cannot overcome the hurdles for entering the market. Standards can help these ideas to become reality. Our deliverables in Europe play a vital role in this respect, bringing *European* ideas onto the global market and thereby strengthening the European economy.

2.1 Environment

Climate change and energy shortage are very high on the political agenda in current world affairs. Standardization is responding to these pressing challenges with a number of environmental standards that support not only the Kyoto protocol, but also sustainable development in diverse areas such as transport, construction and energy.

a. Biofuels

When driving through Europe, cars continue to run without problems because petrol is abundantly available in the right specification because car fuel is standardized. On a large number of fuel pumps, a small label indicates with which standard the fuel complies, for example:

- EN 228:2004, Automotive fuels – Unleaded petrol - Requirements and test methods
- EN 589:2004, Automotive fuels - LPG - Requirements and test methods
- EN 590:2004, Automotive fuels - Diesel - Requirements and test methods

The first editions of these standards were published in 1993 and have since been revised on several occasions. These standards have become trendsetters for several non-European countries and complement the European Directive on petrol and diesel fuels (2003/17/EC).

These standards relate to the fuel specifications for fossil fuels but, for several years now, there has been a tendency to look for alternative fuels, and, more particularly, biofuels. As a general rule, the production costs of bio-based fuels are higher than the classical fossil fuels, but the recent price increases of fossil fuels have renewed attraction to alternative automotive fuels. In addition, other important considerations are increasing attention:

- The decision to set a target for the use of biofuels for all diesel and petrol for transport purposes of 2 % by the end of 2005 and to 5.75 % by the end of 2010 (Directive 2003/30/EC)
- The Kyoto Agreement
- The security of energy supply

In order to stimulate the use of biofuels, the authorities are examining the current taxation systems on automotive fuels. CEN is also contributing to the achievement of these objectives, in particular, through its development of standards for alternative automotive fuels. CEN/TC 19 'Gaseous and liquid fuels, lubricants and related products of petroleum, synthetic and biological origin', a Technical Committee where stakeholders like car manufacturers, petroleum companies and biofuel producers can sit around the table, has elaborated European Standards for Biodiesel, notably:

- EN 14214:2003, Automotive fuels - Fatty Acid Methyl Esters (FAME) for diesel engines - Requirements and test methods
- EN 14213:2003, Heating Fuels - Fatty Acid Methyl Esters (FAME) - Requirements and test methods

The new Biodiesel standard has expanded the biodiesel market, which saw a 65 % production rise in 2004-2005, facilitated trade and brought down production costs due to economies of scale. Meanwhile, work has started on the development of

specifications for bioethanol. The draft standard prEN 15376 lays down the ethanol characteristics as a blending component for petrol (i.e EN 228:2004). Today the use of E85, a fuel composed of approximately 85 % ethanol, is still a niche market but one that is growing progressively. In some EU countries - e.g. Spain and Sweden - adapted cars can use this type of fuel. But also here, CEN has been active and CEN Workshop Agreement 15293:2005 lays down the technical specifications for this fuel. Another niche market is that of emulsion fuels. This diesel fuel is typically used by specific heavy duty fleets, for example urban buses, and helps to reduce air pollution in big cities.

The lack of a European specification for emulsion fuels was an incentive in the development of CWA 15145:2004, Automotive fuels - Water in diesel fuel emulsions for use in internal combustion engines - Requirements and test methods. All these standardization activities, excluding those connected with emulsion fuels, have been mandated by the European Commission and are supporting the Commission's policy. Looking ahead to the future, BT/WG 149 'Liquid and gaseous alternative fuels' has drafted a report, identifying which additional European Standards for alternative fuels should be developed, in order to stimulate their use throughout Europe.

b. Energy management

A new Sector Forum has been created to facilitate the exchange of information and identify further standardization needs in the field of energy management.

Energy is essential for the functioning of our society. All economic activity requires energy resources, whether to manufacture goods, provide transportation or to run computers and other machines. We also depend on energy for heating our homes in winter and cooling them in summer.

Nonetheless, energy is also a source of pollution. 80% of the energy the EU consumes is from fossil fuels – oil, natural gas and coal. The burning of fossil fuels for energy is a major source of air pollution, contributing to global warming and climate change. In addition, the dependence on imported oil and gas increases the vulnerability of the EU to instability in energy supply or higher prices resulting from international crises.

Making better and more rational use of energy and managing it more effectively have therefore become essential for the sustainable development of our modern society.

Standardization can contribute to this objective by promoting best practice and providing authorities and private organizations with the tools to design sound policies, optimize installations and systems and improve energy efficiency.

CEN has already carried out work in areas such as the measurement of energy consumption of domestic appliances, energy efficiency of buildings and fuels and biofuels. In addition, a working group on Energy Management was created in 2002 with the intention of identifying any possible gaps, and new areas of standardization in the field of energy management corresponding to market and regulatory needs.

In its final report, published in 2005, the joint working group identified a series of high priorities for standardization on energy management and recommended the creation of an advisory body with the aim of initiating investigation on any further

standardization needs and developing a common view on the general strategy for improvement of energy efficiency standardization.

Following the recommendation of CEN, several existing technical bodies have started work or intend to start work on the priorities identified. In addition, a new Sector Forum on Energy Management has been recently created.

CEN Workshop 27 – Lifetimes in Energy Efficiency calculations – has just completed a new Workshop Agreement in only six months. The completed document is currently being processed for publication.

c. Energy performance of buildings

Essentially five CEN Technical Committees (CEN/TCs 89 'Thermal performance of buildings and building components', TC 156 'Ventilation for buildings', TC 169 'Light and lighting', TC 228 'Heating systems in buildings' and TC 247 'Building Automation, Controls and Building Management') are involved in elaborating and adopting standards for a methodology for calculating the integrated energy performance of buildings and estimating the environmental impact. This is therefore helping Member States to implement Directive 2002/91/EC on the Energy Performance of Buildings.

The Technical Committees are considering the complete energy flow of a building, going from primary energy use and its environmental impact, including CO₂ emissions, to its final destination, such as lighting. All energy aspects of buildings are covered, for example: air conditioning, boilers, heating, solar heating, heat pumps, CHP (cooling, heating and power), district heating, ventilation, etc. The final standards will give the possibility for energy certification.

To coordinate the horizontal work given under Mandate 343 and, more specifically, the interoperation between the resulting standards, a CEN Task Force, CEN BT/TF 173, has been created. In addition to its coordination role, this Task Force will establish an umbrella document (CEN/TR) outlining the way the different standards are working together (such as inputs, outputs, interactions, definitions ...). The Task Force will also provide a detailed overview of relations between standards and procedures in the form of an XML based database structure:

- to produce overviews at different levels;
- to provide hyperlinks to navigate from one procedure to the next, following the input-output relations;
- to give an overview in printed text of graphs.

Today, the CEN programme in response to the mandate has resulted in a total of 39 CEN work items (WIs) and two voluntary additional WIs have been added. 25% of the WIs reached the CEN Management Centre for CEN Formal Vote preparation, the rest are expected in the coming months.

The publication of the standards is expected in 2007 and an additional European Standard is being considered to complete the documentation and understanding around those standards (the likely title is 'Common definitions, symbols and subscripts for the main commonly used quantities in the EPBD related EN and EN ISO').

The years 2008 and 2009 will bring feedback (questions, comments, suggestions) from Member States and CEN Members following national implementation and EU projects are also expected to provide relevant results. After this, it is envisaged that a major revision of this programme will take place in 2010.

d. Life cycle assessment of buildings

Following Mandate 350 on 'Development of horizontal standardized methods for the assessment of the integrated environmental performance of buildings', a new CEN/TC 350 was established with the title 'Sustainability of construction works' and the scope 'Responsibility for the development of voluntary horizontal standardized methods for the assessment of the sustainability aspects of new and existing construction works and for standards for the environmental product declaration of construction products' The standards will be generally applicable (horizontal) and relevant for the assessment of the integrated performance of buildings over their life cycles. The standards will describe a harmonized methodology for the assessment of the environmental performance of buildings and life cycle cost performance of buildings, as well as the quantifiable performance aspects of the health and comfort of buildings.

The resulting standards will provide the means for the quantification of the impacts of the construction industry and for understanding the results of its decisions. The standards will provide essential elements in a strategy leading to, for example, the mitigation and possible avoidance of climate change through understanding the effects of decisions taken in the construction industry.

At another level, a major benefit of these standards will be derived from the EU-harmonized methodology itself. This is because it is necessary to assess simultaneously life cycle cost performance and health and comfort, in the comparison of the environmental performance of buildings in accordance with principles of sustainability (embodied in the integrated performance of buildings).

The idea behind the concept of the integrated performance of buildings includes consideration of the building as a whole with required performance and functions to fulfill. During its life cycle, from the raw materials in building products, through different processes, ending in the final disposal of building components, a building has environmental and economic impacts as well as impacts on the health and comfort of users.

The basic principles underlying the standards fully support EU environmental policies, such as the Integrated Product Policy (IPP) COM(2003) 302, the Sixth Community Environment Action Programme (6EAP) and several thematic strategies derived from the 6EAP.

The programme of work will provide a standardized voluntary approach for the delivery of environmental information on construction products, and to assess the environmental performance of buildings, and more generally the integrated performance of buildings in the framework document.

The objective is to cover all kinds of building products and all kinds of buildings, new and existing buildings, and possibly other construction works, if appropriate. The programme of work will ensure that existing standards are taken into account,

particularly the existing ISO standards from ISO/TC 59/SC 17 'Sustainability in building construction', ISO/TC 59/SC 14 'Design life' and ISO/TC 207 'Environmental management':

- the development of a set of standards for environmental product declarations (EPD) for building products, including the implementation of the ISO/TC 59/SC 17 standard ISO 21930 as EN ISO, and the development of an European Product Category Rule.

The work programme consists of the following work items:

- Sustainability of construction works – Framework for assessment of buildings;
- Sustainability of construction works – Assessment of environmental performance of buildings – Calculation methods;
- Sustainability of construction works – Use of environmental product declarations;
- Implementation of ISO 21930 Building construction – Sustainability in building construction – Environmental declaration of building products as EN ISO;
- Sustainability of construction works – Environmental product declarations – Product category rules;
- Sustainability of construction works – Environmental product declarations – Communication formats;
- Sustainability of construction works – Environmental product declarations – Methodology and data for generic data;
- Integrated performance of buildings – Description of the building life cycle.

e. Hydrogen and fuel cells

A Working Group on Fuel Cells has prepared *prEN 50465 'Gaseous hydrogen – Hydrogen generators using fuel processing technologies'*.

Furthermore in 2004, the three standardization organizations CEN, CENELEC and ETSI have been mandated (Mandate 349) to prepare a feasibility study in the area of hydrogen and fuel cells.

f. Ecotechnologies

The 6th Framework Programme – Global Change and Ecosystems Section – launched several calls for the development of testing networks on environmental technology verification (ETV) to support the implementation of the Environmental Technology Action Plan - ETAP. Three projects, focused on ETV, have started within the last year. AIRTV (www.airtv.eu) on the verification of air emission abatement technologies is the most recent one, starting in November 2006. CMC is a partner in this project, but also in a similar project, PROMOTE (on soil and groundwater protection, led by DECHEMA, Germany). These two research projects AIRTV and PROMOTE will facilitate innovation in Environmental Technologies, with the support of CEN Workshop Agreements, at least during the first stage.

As a result CEN has announced new Workshop 32, Environmental Technology Verification for Soil/Groundwater Remediation and Monitoring Systems (ETV-SGS).

g. Biotechnologies

Another new area of activity pioneered in the CEN Workshop environment will be laboratory biosafety and biosecurity. A new Workshop in this domain, with extensive participation from Europe, the US and Asia, will, as a first step, develop and promote documents concerning management of biological risks - a new field for standardization. It has developed following initial discussions with key stakeholders including representatives of the European and American Biological Safety Associations (EBSA and ABSA respectively), the Asia Pacific Biological Safety Association, the World Health Organization (WHO) and Det Norske Veritas (DNV), with associated discussion regarding the certification process, what might be regarded as best practice and where the biosafety/biosecurity community are at present in terms of standardization, certification and their development needs.

The objective of this CEN Workshop is to develop and promote the adoption of recognized standards for management of biological risks.

2.2 Services

Since Europe is losing more and more of its traditional industries to new emerging economies, alternative sectors have to be developed. CEN is supporting European industry and the single market by successfully developing harmonized European-wide specifications for growing services.

a. Facility Management

After identifying the need for European Standards in the field of facility management services, the Dutch industry approached the Dutch Standardization Institute (NEN) and initiated two European projects through CEN, creating a Technical Committee. Prior to work beginning on the two European Standards, only four European countries had national standards for facility management.

The CEN Members therefore agreed to develop two European Standards, covering the classification of facility costs and definitions of facility-related terms in order to help improve the transparency of the market. The total market for facility management services in Europe is about 450 billion Euros per year. However, the regional and economic differences between the private and the public sector have, until recently, slowed down the harmonization of the European facility management market.

Johnson Controls, UPC, Shell, IBM, AstraZeneca, and EuroFM, the European Facility Management Network, were all involved in the European standardization work. This high level of interest and participation in the development of these two European Standards showed both the need and the importance of such work at European level. The standards on facility management will help smaller and larger organizations to cooperate and exchange knowledge and business on a European basis. Quotations based on the standards, will improve the possibilities for comparing different organizations and thus support decisions to outsource certain activities.

EN 15221 'Facility Management – Terms and Definitions'
EN 15222 'Facility Management – Agreements'

b. Real Estate

Anticipating increases in both people's mobility and in European real estate transactions, the European Confederation of Real Estate Agents (CEI) approached the Austrian Standards Institute (ON) and launched the development of a European Standard on the quality of services provided by real estate agents. The CEN Members agreed to develop a standard which will cover various aspects, including terminology for transactions, requirements for the qualifications of personnel, the provision of information and services, insurance requirements and codes of ethics.

In some countries, the profession of real estate agents is regulated by law, in some there is no qualification structure at all, while in others there are certification systems operated by branch associations. Harmonizing the service requirements of real estate professionals through a European Standard could thus help to ensure confidence in the reliability of market transactions. A very high number of participants at the first European meeting on real estate services proved both the need and interest in such a project at European level. Private real estate agents from most European countries were represented, among them experts from Austria, Finland and Slovakia.

A European Standard will help break down barriers in trade both for real estate agents themselves and for their customers. It will also improve the effectiveness and efficiency of property transaction costs between real estate agencies in different countries, boost the confidence of customers and improve the quality of the profession. Work on the standard started in 2005.

c. Print media analysis

Media Analysis provides advertisers with insights regarding which media consumers find most useful when purchasing or selecting products, whether advertisements are reaching the right audience and whether they are generating the best response. In 2003 the expenditure for print media advertising in the three largest European markets - France, Germany and the UK – amounted to approximately 23 billion Euro.

The cross-national dimension of media planning is increasing and this increase is leading to a growing need for fully comparable data on media consumption all over Europe. In view of this, DIN (German Institute for Standardization) made a proposal to carry out work on standardization in the field of print media analysis. This standardization proposal aims at meeting the need for cross-border comparability of media consumption data by establishing common terminology, service quality requirements and common methods and techniques for the collection and processing of data in all European countries.

It is expected that standardization will contribute to the development of a European market for print media advertising. Following the acceptance of the proposal by the CEN Technical Board (Resolution BT 11/2006), Task Force 'Print media analysis services' was created to carry out standardization work in this field.

2.3 Transport

Transport in the 21st century must fulfil two requirements: it has to be effective and sustainable. CEN supports work in these two directions: European Standards help to create fast and interoperable trans-European networks, whilst also looking after the long-term impact of energy use in transport.

a. Electronic fee collection

Together with ETSI, our partner European Standards Organization, CEN has provided a standards work programme in the field of electronic fee collection for road vehicles (passenger and freight). This is in connection with the development of a European Electronic Toll Service (EETS), which has been foreseen by Directive 2004/52/EC on the interoperability of road toll systems across Europe. The proposed standards will help to reduce traffic congestion and ensure that road users pay a fair fee; they will avoid the continuation of self-contained incompatible systems in different European countries. We are awaiting the Commission's response to this work programme.

b. RTTT

CEN/TC 278 'Road Transport and Traffic Telematics' was established in 1991. Its scope was then defined as follows:

Standardization in the field of telematics to be applied to road traffic and transport, including those elements that need technical harmonization for intermodal operation in the case of other means of transport.

In addition to the electronic fee collection issue mentioned above, the Technical Committee elaborates standards across a far wider field, including:

- access control
- freight and fleet management
- telematics in public transport
- traffic and traveller information
- road data
- traffic data
- dedicated short-range communication
- human-machine interfaces
- automatic vehicle and equipment identification (see above)
- architecture and terminology
- recovery of stolen vehicles

A number of standards developed within this Technical Committee are helping to increase the safety of people on the roads.

Human-Machine Interaction

The number and quality of in-car electronic systems / functionality is permanently increasing. This is true for driver 'infotainment' (e.g. Navigation) and driver assistance systems. Such systems may provide an increase in traffic safety but may also imply certain risks while driving. This is influenced by good or sub-optimal Human Machine Interface or Human Machine Interaction solutions (HMI).

The approach taken can be described as problem-oriented risk/benefit approach to implementation. This approach focuses on assessment methods rather than simplistic 'pass/fail' criteria, which are outside the scope of the Working Group.

Real-time traffic and travel information (RTTI) can contribute greatly to safety. In order to facilitate access to the public sector data, and to enable the private and public sectors to cooperate in the service provision, the European Commission published in 2001 a Recommendation on the deployment of Traffic and Travel services in Europe. The Real-time Traffic and Travel Information (RTTI) Working Group provides further tools and normative documents for facilitating the take-up of measures for accessing the public sector data, enabling the establishment of public-private partnerships, and the provision of reliable, high-quality RTTI services in Europe.

Road Maps

The Road Maps Working Group promotes the development of Industry Road Maps, and, based on them, elaborates in collaboration with experts from the Member States corresponding Public Sector Road Maps, which predict product development and deployment, and indicate the investments required for improvements in the road networks and in the information infrastructure.

The main objective of the Working Group is to allow development of regularly reviewed road maps with technical steps and socio-economic implications for the introduction of Intelligent Integrated Road Safety Systems, as well as to develop public sector road maps indicating the required improvements and related potential of public and private investments in the road and information infrastructures.

eCall

By accelerating the response time to accidents by about 50%, eCall will reduce the severity of injuries caused by road accidents, thus contributing to the objective of reducing road deaths in the EU.

This improvement would meet the objective of reducing road casualties and fatalities that has been fixed in the Commission's European Road Safety Action Programme and agreed by the Council¹.

There is a high potential for safer road traffic in the future, supported by intelligent integrated vehicle systems and appropriate infrastructure improvements. The whole market deployment is affected by different high complex aspects like technological, social, business, financial, legal and consumer aspects. A balance between the automotive industry, the consumer demand, standardization and road authorities is needed.

¹ Communication on Information and Communications Technologies for Safe and Intelligent Vehicles, COM(2003)0542, 15.9.2003.

c. High speed trains - aerodynamics

Within railway engineering the discipline of aerodynamics is not such a classical one as running safety or braking. Thus, for a long time there have been no European regulations or even standards on railway aerodynamics.

Against the background of the growth of European high speed railways and the need for Technical Specifications for Interoperability (TSI), this situation has changed. Railway aerodynamics, with its prominent aspects of train-induced aerodynamic loads and cross wind safety, has become a standard issue not only for high speed rail.

CEN has supported this process through the EN 14067 series which is dealt with and drafted by Working Group 6, 'Aerodynamics' of CEN/TC 256 'Railway applications'. Currently, the EN 14067 series contains six parts, namely:

Part 1: Symbols and units

Part 2: Aerodynamics on open track

Part 3: Aerodynamics in tunnels

Part 4: Requirements and test procedures for aerodynamics on open track

Part 5: Requirements and test procedures for aerodynamics in tunnels

Part 6: Requirements and test procedures for cross wind assessment

In 2003, the first three parts were issued and published as EN 14067-1: 2003, EN 14067-2: 2003 and EN 14067-3: 2003. In 2005, part 4 – which contains detailed test procedures for open track aerodynamics related to the requirements of TSI HS RST (Rolling Stock) – was published as EN 14067-4: 2005. This year, part 5 – which contains the corresponding test procedures for tunnel aerodynamics – successfully passed through the formal vote process and was published as EN 14067-5: 2006. Working Group 6 has just finished the first draft of prEN 14067-6 which will now enter the CEN enquiry process. This draft standard contains detailed test procedures which, in this case, are also related to the cross wind requirements put up by the new TSI HS RST.

All in all, the current EN 14067 series already contains all test procedures needed to support the aerodynamic requirements contained in the new TSI HS RST and the new TSI HS INS (Infrastructure). Moreover, current Working Group 6 projects on cross wind will lead to a standard which will deal with issues addressed but not yet tackled by TSI HS RST and TSI HS INS.

CEN is currently talking to Railway manufacturers about a complementary workshop.

d. Space

CEN will respond in 2007 to an EC/EFTA mandate to establish a programme for space related standards to:

- ensure an adequate safety level for space hardware and services,
- foster European Union projects such as the Galileo satellite navigation system, the Global Monitoring for Environment and Security (GMES) and projects in the satellite telecommunications field,
- stimulate the emergence of European end-user terminals,

- mitigate space related threats such as debris and
- support the international competitiveness of the European space industry.

The mandate is an element of the European Space Programme. The European Space Programme will pave the way for integrating a variety of space systems from the EU, the European Space Agency and individual Member States into a European space infrastructure, which will support the implementation of a wide range of EU policies. The functioning of all systems within this integrative approach and the full utilization of its potential can only be guaranteed by the preparation of the necessary standards.

e. Air traffic management

The Regulation (EC) N° 549/2004 of the European Parliament and of the Council laying down the framework for the creation of the Single European Sky (SES)¹ was adopted by the European Parliament on 29 January 2004 and by the Council on 2 February 2004.

The European Standardization Organizations, CEN, CENELEC and ETSI have received a mandate related to the achievement of the objectives of the interoperability Regulation through the adoption of the priority 1 set of Community specifications (CS) for the interoperability of the European Air Traffic Management network (EATMN).

CEN was asked to produce European Standards that satisfy the essential requirements and/or implementing rules of the interoperability Regulation for systems in four areas:

- Software Assurance Levels (SWAL)
- Airport - Collaborative Decision Making (A-CDM)
- Advanced Surface Movement Guidance and Control Systems A-SMGCS
- Interoperability of Flight Data Processing (Air Traffic Control - Air Traffic Control)

2.4 Healthcare

Healthcare standardization in the past has mainly focused on products (see examples below). In 2007, CEN will embark on a new strategy for healthcare services that deals with both classical services as well as the booming area of alternative medicine.

a. Tissue engineering

Sometimes also called reparative/regenerative medicine, tissue engineering is an emerging interdisciplinary area of research and technology development (involving cells, genetic material, small molecules, polymer therapeutics, proteins, and biomaterials) that has the potential to revolutionize medical science and considerably improve the quality of life for millions of people.

Tissue engineering is a relatively new scientific field that has immense potential to advance clinical treatment (wound treatment, organ failure, cancer patients, fire

victims etc.); in the area of wound repair the technology has already generated new products that are now addressing previously unmet clinical needs. Some products are already in use clinically, and their number will certainly increase rapidly in the future. Today, tissue engineering can already be used to restore, maintain, or enhance tissues and organs and thus often reduces the recovery time for patients. The potential impact of this technology, however, is far broader. In the future, such engineered tissues could reduce the need for organ replacement, and will help to accelerate the development of new drugs that may cure patients.

Standards in the field of tissue engineering for medical purposes should address issues such as risk management, quality management systems, biological and microbiological safety, as well as terminology. Standards for tissue engineering are therefore being proposed (in some cases, the development of a first set of standards has already started), and becoming of significant value in the development of tissue engineered products.

In CEN, TC 316 'Medical devices' utilizing tissues is responsible for this very promising area. At the moment, there are several proposals for new work in this field in ISO. The CEN Advisory Board for Health Standards (ABHS) has created a task force to monitor activities at the international level.

b. Connectors

The increasing complexity of medical interventions, and the associated medical devices, has led to a requirement for users to connect a number of external tubes to various types of diagnostic and therapeutic devices. Standards in this area help to ensure the patients' safety and facilitate the healthcare personnel's work. CEN/TC 205 'Non-active medical devices' and TC 215 'Respiratory and anaesthetic equipment' follow the work on this issue.

2.5 ICT and information society standards

This area is characterized by its fragmentation, and European needs are not adequately taken into account. However CEN is doing what it can both within the context of the Commission's 2006 ICT Standardization Work Programme and more widely. The work programme complements the Action Plan for European Standardization of 2005 by dealing in more detail with ICT matters. The objective is to consolidate the achievements of the previous eEurope Standardization Action Plan and to further promote the use of standards in support of EU policies and legislation as set out in the above mentioned Communication COM(2004) 674.

The 2006 ICT Work Programme therefore, reflects not only domains where the need for standardization work is already recognized, but it also extends its coverage to new legal and policy domains which have recently emerged and thus have not yet been addressed. Priority will be given to standardization actions aiming at ensuring interoperability, facilitating ICT uptake in key areas (e.g. e-business, e-health, etc.), and ensuring accessibility. The 2006 ICT Standardization Work Programme has been developed further to a wide consultation between the Commission services and the ESOs, and due to its nature has to be considered as a 'living' document which can be modified if necessary.

A number of key areas are of particular current importance.

a. eBusiness

Electronic Business, the process of doing business electronically (or eBusiness for short), is more than 'Electronic Commerce'. While e-Commerce describes the world of business-to-consumer commercial transactions, the term 'eBusiness' usually refers to a broader scope of electronically-enabled activities, including business-to-business, business-to-consumer and business-to-public sector.

In order to be able to reap the full benefits of eBusiness, a degree of harmonization of business processes is required: companies are increasingly using information and communication technologies to link these processes. Not only internally, but also (and this is where the real 'eBusiness' comes in) with their suppliers, customers and for cooperation with business partners. This means that these parties must be able to read, and interpret correctly, each others' data. Today, many systems cannot do this without special manual intervention or compatibility programmes. To overcome this efficiently requires seamless automatic cooperation, amongst others based on compatible standards for computer systems. This cooperation process is called interoperability; it is basically the single most important hurdle for business trying to use the internet for transactions.

Good interaction with all partners

Interaction between organizations is dependent on a number of factors. For example, size, type of business and type of documents. But, many individual trading communities, or even geographical areas, use different solutions and are continuing to develop new ones. In order for these different trading communities to transact with each other, interaction is needed. Things become even more difficult if trade is taking place across national boundaries, or where interaction is required between small and big partners. Small businesses represent almost half of the European Union's GDP, but an even higher transaction volume, since the value of their transactions is usually small. So there must be good interaction with all partners across the supply chain to achieve beneficial results.

Another complicating factor is that competitors have to agree with each other. Only when an infrastructure that allows for seamless interoperability has been agreed upon as a basic facility, may competition take off. The CEN/ISSS eBusiness Interoperability Forum aims to increase European awareness of the need for interoperability in eBusiness. In view of this aim, this roadmap can be considered a proposal to eBusiness stakeholders to work together to continuously expand and enable seamless, secure and easy cross-border eBusiness.

CEN is also working – through a Workshop - as the 'European Entry Point' to the UN/CEFACT eBusiness standards process, thereby ensuring that detailed European technical needs are addressed in global standards. eInvoicing is another area of current activity – our Workshop in that domain complements Commission activities in connection with the establishment of the Single European Payments Area.

b. eInclusion

An innovative approach is required to ensure that information society products and services are universally available across society. There is activity in a number of areas, but principally, CEN, with its partner European Standards Organizations, has been asked under EU/EFTA mandate, to work in support of European accessibility requirements for public procurement for products and services in the ICT domain. It is hoped this work will start in 2007.

eInclusion standards work may also include standardization activities aiming at providing access to information (including structured documents, graphic information and web accessibility), mobility orientation and navigation (e.g. e-maps, feedback on routes of buses, trams, metros, targeted at people with disabilities, e.g. visually impaired people, improved alarm and emergency services for disabled and elderly people, and accessibility of public internet points).

c. eGovernment

Government-to-citizen (and Government-to-business) transactions will become more and more electronic. The standards work is in its infancy, although care must be taken not to re-invent incompatible standards compared with, for example, those used for eBusiness.

CEN has begun work to develop a framework for the eGovernment standardization effort, designed to set out the ways in which this should be accomplished in Europe. A number of innovative specific standards issues are also highly relevant:

- Virtual administrative dossiers for business;
- Standardization of elements of company identification (starting from ISO models);
- Mutual recognition of electronic signatures;
- Harmonization of user interface to various eProcurement platforms such as multilingual interfaces, glossary of terms and steps in the procurement process;
- Information concerning Government purchase orders and invoices;
- Long term archiving of eDocuments (technically/organizational/legally).

d. eHealth

A Focus Group in this domain made recommendations in 2005 on eHealth interoperability and the Commission has followed this up with a standards mandate – the first requirement is for the European Standards Organizations to draw up a work programme.

However, some other innovative work has already started. In spring 2007, we shall be starting a Workshop devoted to the provision of a common data set for a European Electronic Health Insurance Card (eEHIC), and another on coding of information in relation to tissues and cells, and to their traceability, to help facilitate transplants. In a third development, CEN/TC 251 is beginning work on standardization of electronic messaging for pharmaceutical products.

e. eLearning and eSkills

CEN has a long-standing Workshop on Learning Technologies which assures the further development of European Standards for e-learning, by promoting relevant industry and stakeholder participation, and by ensuring that the European requirements are properly addressed by global initiatives such as IMS, IEEE LTSC and ISO/IEC JTC1/SC36 'Information technology for Learning, Education and Training'. Areas of interest include e-portfolio, life-long competency framework, curriculum exchange formats and vocabularies, assessment and accessibility. The work of this Workshop has extended now into a new Technical Committee, CEN/TC 335.

To further strengthen the process of convergence of ICT Skills Frameworks within the European Union, a number of actions are proposed, taking place in CEN/ISSS Workshop eSkills:

- Provide information about e-skills frameworks, highlighting criteria that help to compare and to contrast various approaches and help companies and ICT professionals to select or adapt a framework that best fits their purpose and needs;
- Encourage existing frameworks to progress towards convergence during stages of review and updating;
- Clarify the options for the top-level structure of a European e-Competence² Framework, drawing on the views of stakeholders and support approaches to methods and tools that could prove helpful in the development of a European e-Competence Framework;
- Work towards a European e-Competence reference framework and the provision of information as to how each national framework/profile or proficiency model is related to it.

f. RFID – Radio Frequency Identity

RFID is currently the subject of a major standards effort globally, but without effective overviews and coordination, and raising serious issues concerning data privacy and security. CEN/TC 225 'AIDC technologies' has recently created an ad hoc Group on RFID which forms a European platform on these issues. The task of the Group is to review the work being developed by ISO/IEC JTC1 SC31 WG4/SG5 to determine if any particular European perspective needs to be taken. These standards are:

- ISO/IEC 24729-1 Information technology * Radio frequency identification for item management * Implementation guidelines * Part 1: RFID-enabled labels.
- ISO/IEC 24729-2 Information technology * Radio frequency identification for item management * Implementation guidelines * Part 2: Recyclability of RF tags.
- ISO/IEC 24729-3 Information technology * Radio frequency identification for item management * Implementation guidelines * Part 3: RFID interrogator/ antenna installation.

² Taking into account the emergence in recent years of competence in many Member States, the term competence framework in preference to skills framework should be used as a more comprehensive and holistic concept.

The basic objective is to ensure that the various parts of ISO/IEC 24729 are applicable and operable in Europe. There is no intention to produce separate European Standards, unless absolutely necessary, e.g. to comply with requirements of European Directives that are not addressed in ISO/IEC 24729.

Following the publication of the 2007 Commission ICT work programme, and other discussions within the European Commission, Directorate-General Information Society and Media, CEN/TC 225 is preparing further proposals.

2.6 Food safety

Food scandals and hygiene insufficiencies have put food safety high on the political agenda. New production methods as well as higher consumer expectations require actions. CEN is supporting these actions with a growing number of test methods.

a. Detection of Genetically Modified Organisms for foodstuff

Recent food scandals and consumer insecurity have put GMO tracing in foodstuff high on the public agenda. However, in the past it was very difficult to trace GMOs. Between 2004 and 2006 CEN developed five methods of analysis for enabling the detection of GMOs in derived foods, novel foods if they contain protein or DNA resulting from genetic modification. Labelling of GMOs is mandatory.

b. Food contaminants

Mandates on food hygiene, animal feedingstuffs and mycotoxins

The European Commission has issued three mandates on hygiene, animal feedingstuffs and mycotoxins in the context of the EC Regulation 882/2004 of 29 April 2004 on official feed and food controls. Article 11 of the Regulation allows the use of analytical test methods adopted as European Standards by CEN to achieve these controls:

- **Mandate 381 Food Hygiene**

The mandate includes a programme of standardization concerning: the elaboration of validated new test methods (or revision) for the microbiology of foodstuffs (e.g. histamine, detection of food-borne viruses, listeria monocytogenes, E Coli ...). CEN/TC 275 *Food analysis – Horizontal methods* will be in charge of the realization of the new mandate.

- **Mandate 382 Animal feedingstuffs**

Some new analytical methods will be developed for animal feedingstuffs (e.g. additives in animal feedstuffs such as monensin, narasin, salinomycin, probiotics and undesirable substances such as zearalenone and deoxynivalenol). It will be implemented by CEN/TC 327 '*Animal feedingstuffs- Methods of sampling and analysis*'.

- **Mandate 383 Mycotoxins**

The mandate includes the development of some new tests for mycotoxins in food and food for infants and young children. CEN/TC 275 *Food analysis - Horizontal methods* will follow-up its completion.

2.7 Technology

a. Nanotechnology

Nanotechnology offers possible solutions to many current problems, by means of smaller, lighter, faster and better performance of materials, components and systems. This opens up new opportunities for wealth creation and employment. Applications of nanotechnologies will have an impact on all aspects of life and will enable dramatic advances to be realized in all areas of communication, health, manufacturing, materials, and knowledge-based technologies. Industrial and consumer applications and uses of nanotechnologies are expected to grow dramatically during the coming years, with the world market predicted to be in excess of one trillion dollars by 2015. Sustaining the growth necessary to achieve such a figure from current, relatively modest levels, will require considerable investment in technological and manufacturing/business related infrastructure, especially standards.

Currently, standardization in the field of Nanotechnology is focused on:

- Terminology, classification and nomenclature;
- Measurement and characterization;
- Health, safety and environmental issues;
- Nanotechnology products and processes.

b. Safety of machinery

A practical standard to evaluate control systems for safety

Best of Two Worlds

Since 1996 the categories of EN 954-1 [1] have been widely used to describe the safety level of machinery control systems with safety functions. More than 900 product standards, e.g. for machining centres, presses and printing machines, require a category, and a decision as to whether the control system should be realized with additional online testing or even a second independent channel, depending on the expected risk at the machine. This will ensure the protection of the operator even when parts of the hardware or software fail. The categories describe the structure of the safety-related control system using the reliability of the components used, the effectiveness of tests and the fault tolerance.

Other relevant standards for functional safety are IEC 61508 [2] and its sector-standard IEC 62061 [3] for the machine industry, both defining an SIL. Both are applicable for E/E/PES, even though the probabilistic approach is of generic character. Therefore during the revision of ISO 13849-1 (EN 954-1) the opportunity was taken to integrate software-requirements and probabilistic aspects, therefore continuing to evaluate all technologies within one standard.

The following keywords fit to EN ISO 13849:

- Covers all technologies (mechanical, hydraulic, pneumatic and E/E/PES)
- Scope: All machinery
- Focus on technical design,
- Only little requirements concerning organization
- Harmonized according to the European machinery directive (February 2007)
- Application standard (type B1)
- Two parts of approximately 80 and 60 pages with much informative information
- Practicable, simplified methods, based on typical architectures (categories)
- EN since 1997, revision published 1 November 2006

As a result of this ambitious goal to have one standard fitting for nearly all technologies, using a modern approach balanced with the old categories, the standard document has become noticeably thicker. However it is written in a very practicable fashion which can be proved through working examples [4].

References

- [1] EN 954-1:1996, Safety of machinery - Safety-related parts of control systems, also available as ISO 13849-1:1999, International Organization for Standardization, Switzerland
- [2] IEC 61508, Functional safety of electrical/electronic/programmable electronic safety-related systems, International Electrotechnical Commission, Switzerland
- [3] IEC 62061, Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems, International Electrotechnical Commission, Switzerland
- [4] Schaefer, M., Hauke, M., EN 954-1: Design of safety-related parts of control systems, 3rd International Conference Safety of Industrial Automated Systems, 13-15 October 2003, Nancy, proceedings, pp. 4-31 to 4-36, published by: Institut National de Recherche et de Sécurité - INRS, Vandoeuvre/France

c. Border Security

The enhancement of the European border security level will require a better interoperability of the technologies deployed at borders. The STABORSEC supporting activity will identify the technical standards that will support such improvement.

This work will be based on the results produced by the border security group of the European Security Research Advisory Board, and by other European research projects. STABORSEC will identify the standards and their full assessments, including conformity and evaluation mechanisms, to guarantee an effective interoperability in the domain of border security.

STABORSEC will produce a detailed prioritized inventory of the standardization efforts to be deployed to cover appropriate interoperability needs. This output will be public, will guide the upcoming European standardization activities, and will contribute to the enhancement of border security levels.

CEN – at this assessment stage – is already involved in the activities mainly through the cooperation of the CEN Technical Board Working Group 161.

2.8 Packaging

Standards are currently on the way for putting brail marking on packaging (particularly medicine) and users' notes. This is responding to a need expressed in 'old approach' legislation. Standards are also being developed to facilitate the use of packaging for people with impaired hand function; it is well known that some members of the family are not able to open some packaging, for example jars of produce, but this need must be balanced by the requirement that some packaging is not 'openable' by children.

2.9 Personal Protective Equipment (PPE)

CEN has established a Workshop on Humanitarian Mine Action (HMA). In the content of this workshop, specifications were developed concerning the test and evaluation (T&E) of Personal Protective Equipment. The objective of this CEN Workshop is to establish tests and evaluation specifications for Personal Protective equipment in Humanitarian Mine Action.

2.10 European Public Procurement

CEN, together with several other National Standardization Bodies, is participating in the *Steppin* approach to stimulate innovative business solutions by incorporating open standards in European public procurement. *Steppin* is the acronym for **ST**andards in **E**uropean **P**ublic **P**rocurement lead to **IN**novation and was chosen to be stimulating to stakeholders in the area of Public Procurement: they should 'step in'.

Steppin is a Consortium of 14 partners from 7 Member States. The partners are a combination of experts in standardization, innovation and procurement, networked with experienced users of the public and private procurement process. This way the project combines theory and practice in such a way that the final-results (e.g. handbook for public procurement) are practical and future-proof.

The main objective of the project is to get full benefits for Europe from innovative business solutions that are being stimulated by taking open/public standards into account in public procurement in all Member States. Thus the questions for the project are: 1) how should standards play the required role and with what procedures, and 2) how to implement and stimulate the use of new procedures and methods by public and private sector organizations.

The *Steppin* approach for the first question (how to do it) is to gather all relevant information and opinions from all over Europe and then to extract from this a 'best theory'. Then in a number of Euro-regional workshops with users and experts this theory will be validated. A baseline survey will be performed on the basis of tenders in the TED database and, at the same time, best practice will be gathered.

The second question (ensure it is going to be done) is approached by extensive interaction with the public and private sectors. *Steppin* will organize 15 workshops all

over Europe in 2007 to discuss 'best practice & best theory' with users, experts, sector representatives and management from the public sector. The discussion will lead to a handbook that describes roles, responsibilities and methodology and provides practical guides for how to make your own best practice in open standards for innovation. Furthermore, the workshops will lead to voluntary commitment to this new approach, as the stakeholders have developed the approach themselves. Finally, the *Steppin* approach is leading to networks of stakeholders, which are vital for the further spread of this concept and way of thinking.

At the end of 2007, *Steppin* will undertake a concise survey to identify the differences already made during the project by comparison with the baseline. The handbook and the results of the surveys will be presented at a congress in November 2007 for stakeholders and also specifically for decision makers in the public sector, in order to enable formal support for the new concept for public procurement. The project will be finished with policy recommendations for the Commission and will be executed in full coordination with Commission Services and with other relevant projects of the 6th FP.

In more technical terms, a new CEN Workshop entitled "Interoperability in the implementation of electronic public procurement in Europe" will specify a basic framework for technical interoperability in pan-European electronic transactions, based on implementation of the consortium standard known as OASIS Universal Business Language 2.0. The results will be input as global eBusiness standards into UN/CEFACT,

3. Conclusion

CEN – as a multi-sectorial organization – is playing a major role in facilitating innovation in Europe in a multitude of sectors. This is not a static process. Projects are further developed every day and new ones added to the CEN Work Programme. Updated and further information on all of the above areas of work and more CEN activities is available on the CEN website: www.cen.eu.