

# CEN-CENELEC GUIDE 30

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**European Guide on  
Standards and  
Regulation**

***Better regulation through  
standards – guidance for  
policy makers***

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## Executive summary

This guide, aimed primarily at public authority policy makers and elected representatives, offers an introduction to the complementary nature of market-based standards and public policy and legislation within the European Union and Member States.

Standards have the potential to provide more assistance than at present to public authorities in their regulatory policy actions. This guide describes how standards may support legislation and policy with market-based solutions in order to achieve regulatory goals effectively.

Legislation is mandatory, set by public authorities and is accompanied by sanctions for non-compliance. Standards are market-based tools developed for and by interested parties; their usage is voluntary and they are employed when the market needs them. Standards can also support regulatory interventions and about 20% of European Standards are used in this way to support EU policies and legislation.

Better and smart regulation seeks to ensure that policies and legislation place the minimum burden of compliance on market players whilst achieving regulatory objectives. Standards can be used by public authorities as a tool for better regulation. They bring a number of benefits, including the simplification of legislation, broad market acceptance and enabling innovative solutions without the need to change the regulatory framework, thus reducing the cost of making regulation and contributing to the opening of international markets.

Standards can support legislation and policy through self-regulatory and co-regulatory approaches. A self-regulatory approach commonly involves a group of businesses agreeing to meet certain voluntary standards. The relevant public authority accepts that this action will meet its policy objectives.

A co-regulatory approach involves a partnership between public authorities and economic operators, with each side developing part of the solution to deliver the public policy objective. Public authorities set the regulatory framework through legislation and standardization organizations create or put forward standards explicitly to support that legislation. The European 'New Approach'/New Legislative Framework is the clearest example of a co-regulatory approach with over 4000 European Standards providing one means to comply with European Union harmonization legislation. Co-regulatory approaches are also used by Member States across the EU, enabling national public authorities to simplify legislation and benefit from the broad market acceptance and international links that standards bring.

The guide also includes in its final chapter information on how standardization stakeholders and the European public authorities interact in practice when standards support legislation.

## Introduction

This guide offers an introduction to the use of standards as a policy tool for better and smart regulation within the European Union. It is aimed primarily at policy makers and elected representatives at both the European and national levels, and will also be useful to standards-developing communities within Europe (particularly CEN, CENELEC, their members and standards experts).

In Europe, Regulation 1025/2012 sets the legal framework for European standardization<sup>1</sup>. Three European Standardization Organizations – CEN, CENELEC and ETSI<sup>2</sup> – and their national members, are recognized under this Regulation and they produce European Standards to meet the needs of the single market including support to legislation and policies.

CEN and CENELEC, as independent, not for profit organizations, have a catalogue of around 19000 European Standards, from which some 20% are ‘harmonized standards’ that give presumption of conformity to EU legislation (see Chapter 3 co-regulation).

Already an important tool for better regulation in the European Union and in its Member States, the use of standards to support legislation and policy has the potential to further the efficient and effective delivery of policy goals, simplify legislation, ensure stakeholder acceptability, promote innovative approaches and reduce barriers to trade.

Standards are documents for voluntary use developed on the basis of stakeholder consensus and facilitated by specific standardization organizations. Regulation, for the purposes of this guide, is considered in a broad sense, covering both legislation and public authority regulatory policy.

As a practical introduction to using voluntary standards to support policy and legislation, this guide sets out to:

- Describe the role of voluntary standards vis-à-vis public authorities’ policy and legislation
- Clarify the benefits of using voluntary standards to support policy and legislation and the ways in which this can be achieved
- Give current examples of how standards complement legislation and policy
- Explain the processes of standards development for the purpose of supporting policy and legislation.

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<sup>1</sup> [http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/general-framework/index\\_en.htm#h2-1](http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/general-framework/index_en.htm#h2-1)

<sup>2</sup> CENELEC is responsible for electrotechnical standardization, ETSI for standardization in the telecommunications field and CEN for all other technical areas.

## Chapter 1: standards and regulation: different and complementary

Standards cannot override the provisions of legislation; in all cases the mandatory requirements set by public authorities take precedence over voluntary standards.

### ***What is regulation?***

Regulation is the way in which public authorities seek to control behaviours. Policy makers have a number of ways to respond to the challenges they face and different types of instruments are available to them. These include legislation as well as other policy tools, such as market-based instruments that directly involve the participation of stakeholders (self- and co-regulatory approaches). Legislation states what individuals and businesses must do, or must not do, and is usually backed by enforcement and sanctions.

In Europe, legislation is created and enacted by the co-legislators of Council of the European Union and the European Parliament (for the ordinary legislative procedure). These institutions follow rules of procedure that are laid down in European law. The application of legislation is mandatory; it is accompanied by enforcement mechanisms and the possibility of sanctions where provisions have been breached.

Depending on the type of European legislation, national implementation by the Member States of the European Union may be required. This is the case for European directives, which must be implemented in the Member States, most commonly by national legislation.

In this guide, the meaning of 'regulation' is not restricted to the specific European Union legislative act of the same name.

### ***What are standards?***

Standards are, in essence, an agreed way of achieving a set objective. They may take a number of forms, including specifications for products, systems and services, methods of testing, terminology and definitions, information requirements, interfaces and processes<sup>3</sup>. Standards are performance-based wherever possible.

Standards are developed primarily to meet the good practice needs of industry and the other interested parties and encourage the take-up of that good practice in the broader economy. Standards can support public authorities' policy and compliance with legislation; about 20% of European Standards perform this function.

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<sup>3</sup> The term 'standard' is defined in EN 45020:2006 *Standardization and related activities – General vocabulary* (ISO/IEC Guide 2:2004) as a: "document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context."

Standards are voluntary in the sense that there is no obligation to comply with them or to implement them, except in the rare cases where legislation requires it. Participation in standards development is also voluntary.

Standards help to:

- Facilitate international trade, particularly by reducing technical barriers
- Support the opening of markets, for example for emerging technologies
- Ensure the quality and safety of products and services
- Enhance protection and confidence for consumers and society in general
- Achieve compatibility between products and/or components
- Facilitate innovation through providing a stable and interoperable technological base
- Enable better business performance by enhancing processes and setting guiding principles
- Determine contractual and public procurement requirements
- Reduce costs, eliminate waste and improve efficiency
- Minimize liability risks
- Protect the environment, and
- Support legislation and government policy.

This guide relates specifically to standards produced by CEN and CENELEC and their members, the National Standards Bodies and National Electrotechnical Committees, noting that a considerable proportion of those standards come from the international standards organizations ISO<sup>4</sup> and IEC<sup>5</sup> through long-standing cooperation agreements.

In the 'formal' standardization system<sup>6</sup>, standardization organizations ensure that their standards development processes meet the requirements of the Technical Barriers to Trade Agreement (TBT Agreement) of the World Trade Organization (WTO)<sup>7</sup>. CEN and CENELEC provide the framework for technical experts from all interested parties (industry including SMEs, public authorities, consumers, trade unions, academic and research bodies, testing, certification and accreditation organizations, environmental stakeholders, etc) to develop standards. A standard is agreed on the basis of the consensus<sup>8</sup> of those interested parties who have participated in its development; it is subject to an open consultation of its proposed provisions and is then periodically reviewed to ensure that its content remains up to date.

European Standards must be implemented as national standards by each of the thirty-three members of CEN and CENELEC and conflicting national standards must be withdrawn. This gives a single standard for the whole of the European Union, and beyond. The standardization organizations hold the copyright in standards. They are responsible for making them publicly available and the revenues from sales of standards are used to finance the standardization system.

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<sup>4</sup> International Organization for Standardization, <http://www.iso.org>

<sup>5</sup> International Electrotechnical Commission, <http://www.iec.ch>

<sup>6</sup> The 'formal' standardization system is that of ISO, IEC and ITU at international level, CEN, CENELEC and ETSI at European (regional) level and the National Standards Bodies, National Electrotechnical Committees and ETSI National Standards Organizations at national level.

<sup>7</sup> [http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm); these requirements are contained in Annex 3 to the Agreement and are added to by the decision of the TBT Committee on principles for the development of international standards, namely: transparency, openness, impartiality, consensus, effectiveness, relevance, coherence and consideration of the concerns of developing countries.

<sup>8</sup> Consensus is defined in ISO/IEC Guide 2:2004 as "general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments."

### ***The differences between standards and legislation***

The WTO TBT Agreement clearly delineates standards from legislation (referred to in the Agreement as ‘technical regulations’) in its Annex 1 definitions: standards are voluntary in application whereas legislation is mandatory. This essential difference is also recognized by the European Union. For example, the first recital of EU Regulation 1025/2012 states: ‘The primary objective of standardisation is the definition of voluntary technical or quality specifications’.

The key characteristics of standards as distinct from legislation are presented in Table 1.

**Table 1: Characteristics of standards and legislation**

Legislation	Standards
<b>Mandatory</b>	Voluntary
<b>Created by legislator</b>	Developed by private standardization organizations
<b>Consultation according to public authorities’ policies</b>	Full open and transparent public consultation
<b>Decided by legislator</b>	Based on consensus of interested parties
<b>Revised when legislator decides</b>	Considered for revision every 5 years maximum
<b>Sets requirements determined by legislator</b>	Give state of the art solutions
<b>For the New Approach/New Legislative Framework:</b>	
<b>Sets high level essential requirements</b>	Give technical means of meeting essential requirements

## Chapter 2: Better and smarter

While the primary purpose of the use of standards is different from that of legislation and policy, standards can serve a very useful function to support public authorities' initiatives. This is enshrined in the WTO TBT Agreement, which states that legislation should wherever possible be based on international standards developed by ISO and IEC.

Similarly, the UN ECE (United Nations Economic Commission for Europe) 'reference to standards' method asserts that international standards should be used to support legislation in such a way that standards remain voluntary.

The European New Approach/New Legislative Framework, on which much of the European single market is built, is an example of how standards and legislation work well together (more detail can be found in Chapter 3).

### ***Understanding the link between standards and legislation***

Both the European Commission document 'Methods of referencing standards in legislation with an emphasis on European legislation'<sup>9</sup> and the ISO-IEC guide 'Using and referencing ISO and IEC standards for technical regulations'<sup>10</sup> investigate the different ways of using standards to support legislation.

These include making in legislation an indirect reference to a standard, as in the European New Approach/New Legislative Framework (see Chapter 3, section 2. Co-regulation), or directly incorporating the standard into a legislative text.

The method of indirect reference enables the legislator to rely on the flexibility of the voluntary standardization framework. Standards will be updated when required, responding to market needs and without necessitating changes to legislation. This brings the benefit of maintaining the separation between voluntary standards and mandatory legislation. For this reason, indirect referencing of standards is recommended by CEN and CENELEC.

### ***Better regulation/smart regulation***

In the last twenty-five years, public authorities in Europe have moved towards a doctrine of 'better regulation'. Better regulation is generally considered to mean the processes of delivering policy in the most efficient and effective way, seeking to minimize the administrative burden placed by regulation on enterprises and making enforcement easier.

The European Commission has developed its better regulation policy into one of 'smart regulation'. This concept seeks to ensure that regulation:

- Places the minimum possible administrative burden on business, especially SMEs
- Is fit for the purpose identified
- Has been through a rigorous impact assessment
- Has been subject to a screening for simplification
- Is evaluated periodically and amended/withdrawn as required.

<sup>9</sup> [http://ec.europa.eu/enterprise/policies/european-standards/files/library/enterprise-guides/doc/guide\\_standards\\_en.pdf](http://ec.europa.eu/enterprise/policies/european-standards/files/library/enterprise-guides/doc/guide_standards_en.pdf)

<sup>10</sup> [http://www.iso.org/iso/standards\\_for\\_technical\\_regulations.pdf](http://www.iso.org/iso/standards_for_technical_regulations.pdf)

Standards can be used as tools to deliver smart/better regulation as part of self- or co-regulatory approaches (more detail in Chapter 3). This is recognized in policy documents from public authorities that set out their regulatory policies. For example, the European Commission's impact assessment guidelines (SEC(2009) 92) state that the set of policy options considered when seeking the best means to meet a policy objective should include self- and co-regulation and the use of European or international standards.

Similar policies have been developed by the European Member States. In the UK, for example, the Department of Business, Innovation and Skills' Better Regulation Framework Manual (2013) sets the following principle: 'The Government will regulate to achieve its policy objectives only...having demonstrated that satisfactory outcomes cannot be achieved by alternative, self-regulatory, or non-regulatory approaches'. In France, the Conseil d'État has carried out a 2013 study on 'soft law' ('Le droit souple') that has recognized the use of soft law approaches to achieve policy objectives when the instruments can demonstrate the necessary legitimacy, utility and effectiveness.

### ***What are the benefits of using standards as a tool for smart/better regulation?***

CEN and CENELEC standards bring a range of benefits to policy makers as a support to legislation and policy:

- European Standards are implemented identically and simultaneously in the whole of Europe on the basis of pan-European consensus, which mean that standards have a broad market acceptance. This ensures that legislation and policy supported by standards have a high level of stakeholder acceptability, minimize burdens on industry and can reduce the cost of compliance
- Standards can enable simplification of legislation, with government intervention restricted to the high level policy objectives and standards providing technical solutions
- The cost of standards development is borne by the market players, and public authorities no longer need to set out all technical details in legislation and policy
- Standards are regularly updated and can therefore meet the needs of emerging technologies and promote innovative approaches, without the need to change the regulatory framework
- The broad geographic acceptability of standards (European/international) enables market access and promotes the competitiveness of European industry around the world<sup>11</sup>
- Using standards to support legislation and policy brings a simple means for public authorities to meet WTO TBT obligations.

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<sup>11</sup> It is important to note that it is key that the standards in Europe remain as close to international standards as possible in order to take best advantage of this market access opportunity.

## Chapter 3: How standards can work for you

As one of the instruments available to public authorities, standards may support legislation or otherwise help deliver policy outcomes. The approach to standards taken by public authorities, national or European, may be either that of self-regulation or co-regulation, depending on the specific policy objectives and context. Both approaches are considered here..

### **Self-regulation**

The European Union's Interinstitutional Agreement on better law-making of 2003 defines self-regulation as "the possibility for economic operators, the social partners, non-governmental organizations or associations to adopt amongst themselves and for themselves common guidelines at European level<sup>12</sup>".

Self-regulation is a tool used in circumstances where a public authority seeks to implement policy without creating legislation.

A self-regulatory approach commonly involves a group of businesses agreeing to meet certain voluntary standards to regulate their behaviour. The group is responsible for ensuring that it meets the requirements of the standards. The relevant public authority accepts that this action will meet its policy objectives, as the voluntary agreement to use the standard is an alternative to taking legislative action (often described as an 'alternative to regulation').

The public authority can trigger the development of a new standard, for example when the European Commission issues a standardization request<sup>13</sup> ('mandate'), and it may fund its development. Alternatively, the public authority may rely on an existing standard or work with industry to develop a code of practice.

Public authorities can encourage the take-up by industry of this approach by indicating that legislation could be considered if the self-regulatory approach is not successful.

A number of case studies on standards supporting public authorities' policy through self-regulatory approaches are given in Annex I.

### **Co-regulation**

The EU's Interinstitutional Agreement on better law-making defines co-regulation as "the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisations, or associations)<sup>14</sup>".

Co-regulation involves a closer relationship than a self-regulatory approach between industry and other stakeholders on one hand and public authorities on the other. It involves public authorities setting the regulatory framework through legislation and standards organizations creating or putting forward standards explicitly to support that legislation.

<sup>12</sup> [http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003Q1231\(01\)](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003Q1231(01))

<sup>13</sup> To note: European Commission mandates are not exclusive to self-regulatory approaches and indeed are more common with a co-regulatory approach.

<sup>14</sup> [http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003Q1231\(01\)](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003Q1231(01))

Co-regulation does not mean that standards are used as part of legislation, or that standards bodies are creating legislation; rather it is a partnership between public authorities and industry, with each side developing part of the solution to deliver the public policy objective.

The co-regulatory approach can take many forms, and in some instances it is quite similar to a self-regulatory approach. Nevertheless, there will always be legislative action by a public authority when a co-regulatory model is used.

The co-regulatory approach has been used most notably with the European 'New Approach' to technical harmonization where over 4,000 European Standards are used to support regulation.

The 'New Approach', and now the New Legislative Framework, is a co-regulatory model introduced in the European Union in 1985 that is used to harmonize technical product legislation in Europe (most commonly Directives, but with new European policy there are an increasing number of Regulations). It has been the cornerstone of the creation and successful functioning of the European single market for goods.

Definitive guidance on the New Approach/New Legislative Framework is given in the European Commission's document 'The 'Blue Guide' on the implementation of EU product rules 2014'<sup>15</sup>. In brief, this approach involves the European Union legislator setting top level requirements ('essential requirements') that need to be met by enterprises that wish to place products on the market. The precise means of meeting these requirements is left to those making products available on the market. The European Standardization Organizations have developed, under Commission 'mandate', standards that give the technical expression to these essential requirements. After being notified to the European Commission and publication of the references of standards in the Official Journal of the European Union, compliance with these standards then gives a presumption of conformity with applicable requirements of the legislation.

This means that compliance with the standards remains voluntary, although the use of the harmonized standard to gain a presumption of conformity may be the easiest, quickest and cheapest means to meet the legal requirements.

Other co-regulatory approaches may use standards in different ways, possibly making a reference directly in the legislation to the standard. This issue is covered in the section 'Importance of the distinction between standards and legislation', above.

A number of case studies on co-regulatory approaches are given in Annex II.

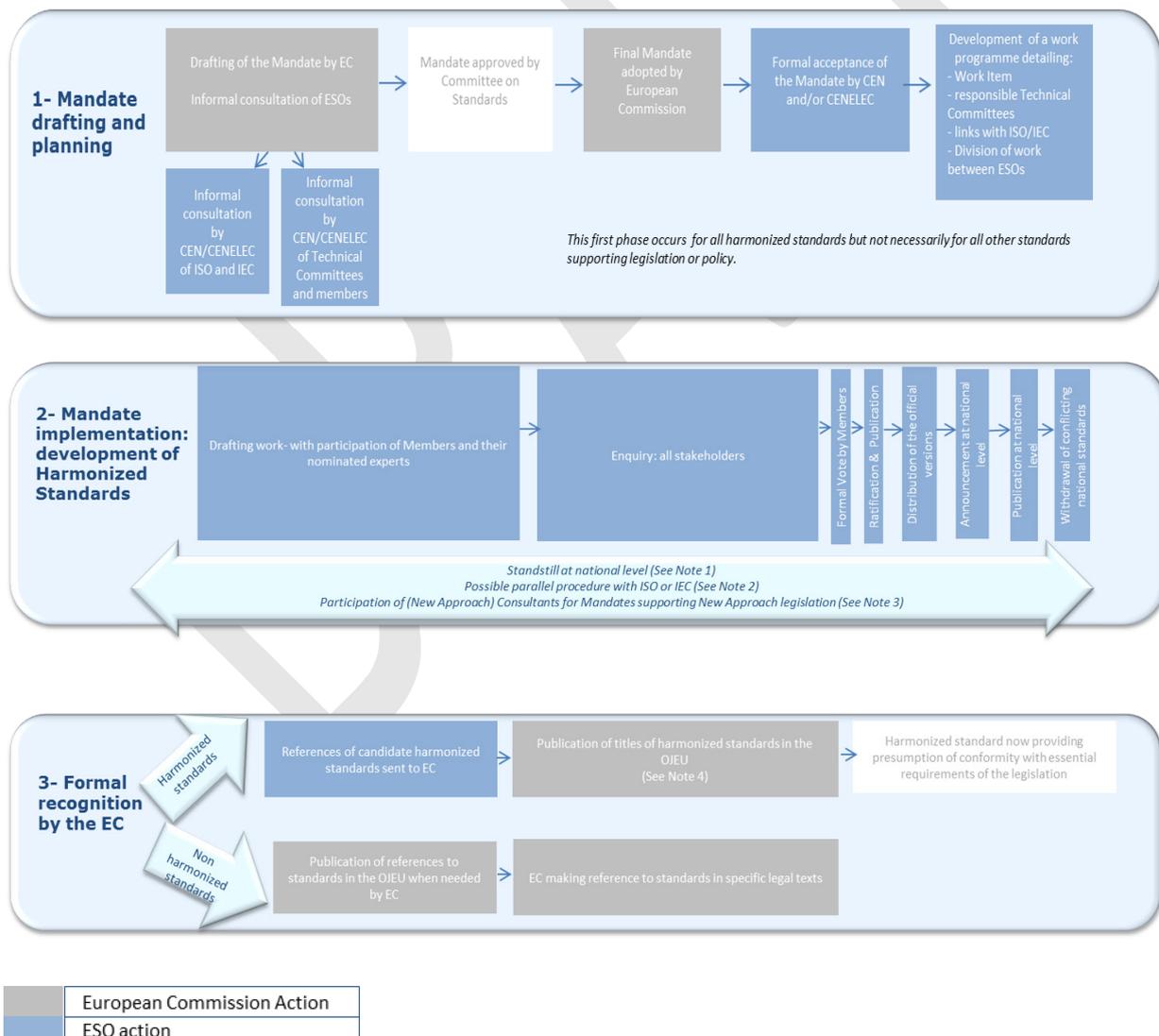
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<sup>15</sup> Found at: [http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index\\_en.htm](http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm)

## Chapter 4: The standards-making process supporting regulation

European Standards from CEN and CENELEC follow well-established development processes that are continually updated to meet the needs of the market players. European Standards that might be used to support legislation and policy follow the same development processes; there is no distinction within CEN and CENELEC.

Having said that, when standards are to be used to support legislation and policy there are specificities to their development, for example with regard to the standardization request (commonly referred to as a ‘mandate’). The following three process maps reflect these processes and show how the European Commission (EC) is responsible for drafting the standardization request and consulting with the European Standardization Organizations (ESOs), how CEN and CENELEC develop standards in response to the request and how the Commission then proceeds to recognize the standards through publication in the Official Journal of the European Union (OJEU).



**Note 1:** Standstill :as soon as work is started at European level, there is an agreement between National Members not to develop or publish a new or revised national standard on the same subject that could endanger the progress of the work at European level. This standstill is compulsory for harmonized standards (Art. 3.6 of Regulation 1025/2012)

**Note 2:** Different processes can apply for projects voted under parallel procedure with ISO or IEC.

**Note 3:** New Approach Consultants, when involved in the process, are guiding the standard development in order to ensure that the harmonized standard are developed in line with the terms of a Mandate. Before Formal Vote, a formal assessment is sought from the New Approach Consultant.

**Note 4:** EC decides on which standards are superseded by the new harmonized standard, and when.

## Closing: Contacts and references

### *Annex I Case studies on self-regulation*

#### **EN 301549:2014 Accessibility requirements suitable for public procurement of ICT products and services in Europe**

This standard was developed on the basis of European Commission standardization mandate M/376 'standardisation mandate to CEN, CENELEC and ETSI in support of European accessibility requirements for public procurement for products and services in the ICT domain'. The European Commission issued the mandate to the ESOs to support EU policies for (e-)accessibility, without European legislation in this area.

The EN is intended in particular for use by public authorities and other public sector bodies during procurement to ensure that websites, software and digital devices are more accessible. It is reinforced by a suite of three other Technical Reports that give guidance and support to the application of the standard.

#### **BS 42020:2013 Biodiversity – Code of practice for planning and development,**

This British Standard enables industry to meet planning and development requirements set by government in response to the European Biodiversity Strategy and United Nations biodiversity (Aichi) targets. It provides recommendations and guidance to ensure that actions and decisions taken at each stage of the planning process are informed by sufficient and appropriate ecological information. This assists the better integration of biodiversity into all stages of the planning, design and development process.

#### **PAS 91:2013 Construction Prequalification Questionnaires**

This PAS (a national, sponsored, fast-track standards product) from BSI, the UK National Standards Body, enables companies more easily to take part in the prequalification stage for tenders for public construction contracts. It provides a common language and uniform structure for prequalification that simplifies the process for industry and gives greater confidence to procurers that they are carrying out the prequalification process correctly.

The development of PAS 91 was triggered by UK Department of Business, Innovation and Skills. It responds to public policy in terms of supporting business competitiveness through minimizing costs of compliance and encouraging the participation of SMEs in public procurement.

#### **NEN 4400 Temporary work businesses and (sub)contractors**

In the Netherlands, employment agencies agreed on a national standard for their operational behavior, NEN 4400. Companies that hire employees using employment agencies certified to this standard are deemed to meet employment and taxation rules.

## ***Annex II Case studies on co-regulation***

There are about 25 European Union legislative acts that follow the New Approach/New Legislative Framework. These include directives on the safety of machinery and toys, low voltage electrical equipment, gas appliances, lifts and recreational craft, measuring and non-automatic weighing instruments.

For example, European Directive 2004/108/EC on electromagnetic compatibility requires that all products to which the legislation applies meet the essential requirements in Annex 1 of the Directive. When equipment meets the requirements of harmonized European Standards, the references of which have been published in the Official Journal of the European Union, it is presumed to meet the essential requirements of the Directive as covered by that standard. The references of over 150 harmonized standards have been published in the Official Journal under this Directive.

There are also a number of directives that use standards as a means of compliance even though they do not strictly speaking follow the New Approach. One example is the General Product Safety Directive, 2001/95/EC (a replacement regulation is currently in the legislative process), where compliance with harmonized standards can provide a presumption of conformity.

A further example is the EU Water Framework Directive (Directive 2000/60/EC), which establishes a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater. It includes in Annex V methods for sampling and analysis based on specific reference to existing standards or '*Relevant CEN/ISO standards when developed*' or '*Any relevant CEN/ISO standards*'. The development of some of these standards followed European Commission mandates to CEN.

There are also co-regulatory examples from European Member States. The French decrees on solid fuel barbecues and on playground equipment state that compliance with relevant standards (with references published in the French Official Journal) will meet the requirements of the legislation. In both of these cases, the use of standards remains voluntary.

In the Czech Republic, compliance with certain standards (references published by the Czech standards body, UNMZ) brings a recognition that the requirements in specific Government Orders have been met, for example on non-harmonized construction products.

In Italy, the National Standards Body, UNI, has an agreement with government whereby it publishes standards in the field of the safety of installations in building. Meeting the requirements of these standards demonstrates compliance with Decree 37/2008