



# CEN-CENELEC GUIDE 30

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**European Guide on Standards and  
Regulation - Better regulation  
through the use of voluntary  
standards - Guidance for policy  
makers**

**Edition 1, 2015-06**

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## **Executive summary**

This guide offers an introduction to the use of market-based standards in the implementation of legislation and public policy ('regulation') within the European Union, EFTA, their member states and other countries following European single market rules.

In the context of the European single market, European Standards, as defined in Regulation (EU) No. 1025/2012, are tools that enable trade and promote the competitiveness of business and industry. They are developed for and by interested parties through formal processes managed by the European Standardization Organizations.

In addition to the benefits that standards bring to the market, their use can also support the implementation of legislation and public policy, in particular better/smart regulation.

Standards are voluntary tools of the market whereas legislation is the prerogative of the public authorities and is mandatory in application. The responsiveness of standards to the needs of the market is therefore the critical factor in their effectiveness as a support for better regulation: public authorities recognize that the broad acceptance and use of standards can meet their policy objectives.

The use of standards in implementing legislation and public policy can bring a wide range of benefits to policy makers, including:

- broad market acceptance;
- simplification of legislation or policy;
- support to emerging technologies and the promotion of innovative approaches, without the need to change the regulatory framework;
- a close link to international standards, enabling international market access and thus promoting the global competitiveness of the European industry.

This can be achieved either through co-regulation, where legislation recognizes the role of standards (e.g. European New Approach to technical harmonization), or through self-regulation, where the market delivers a solution to public policy needs.

This CEN-CENELEC guide is a non-binding reference document. Any questions about the subject matter should be addressed to CEN and CENELEC directly.

## Introduction

This guide offers an introduction to the use of market-based standards as a policy tool for better and smart regulation within the European Union and the wider membership of CEN and CENELEC. It is aimed primarily at public authority<sup>1</sup> policy makers<sup>2</sup> and elected representatives<sup>3</sup> at both the European and national levels. It is expected also to be useful for standards-developing communities within Europe (particularly CEN, CENELEC, their members and stakeholders).

In Europe, Regulation (EU) No. 1025/2012 sets the legal framework for European standardization<sup>4</sup>. Three European Standardization Organizations<sup>5</sup> – CEN, CENELEC and ETSI<sup>6</sup> – and the national standardization bodies<sup>7</sup> are recognized under this Regulation. They produce European Standards<sup>8</sup> to meet the needs of the market players, bringing benefits to the single market and supporting the competitiveness of European industry and business. In addition, standards can be used to support the implementation of legislation and policy<sup>9</sup>.

CEN and CENELEC, as independent, non-profit organizations, have a catalogue of around 19 000 European Standards, from which some 20 % are defined by the European Union as 'harmonized standards'<sup>10</sup>. The use of most of these harmonized standards gives a presumption of conformity with EU legislative requirements (see 3.3, Co-regulation).

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

Standards are documents for voluntary use developed on the basis of stakeholder consensus and facilitated by standardization organizations. Regulation<sup>11</sup>, 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 the implementation of legislation and policy, this guide sets out to:

- describe the role of voluntary standards vis-à-vis public authorities' legislation and policy;
- clarify the benefits of using voluntary standards to support the implementation of legislation and policy and the ways in which this can be achieved;

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<sup>1</sup> See glossary, Annex A, for more information.

<sup>2</sup> See glossary, Annex A, for more information.

<sup>3</sup> See glossary, Annex A, for more information.

<sup>4</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>5</sup> Term defined in Regulation 1025/2012.

<sup>6</sup> CENELEC is responsible for electrotechnical standardization, ETSI for standardization in the telecommunications field and CEN for all other technical areas.

<sup>7</sup> Term defined in Regulation 1025/2012.

<sup>8</sup> Term defined in Regulation 1025/2012. A considerable proportion of these European Standards are identical to or based on international standards and can thus bring access to international markets.

<sup>9</sup> See glossary, Annex A, for more information.

<sup>10</sup> Term defined in Regulation 1025/2012

<sup>11</sup> See glossary, Annex A, for more information.

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- give current examples of how standards complement legislation and policy;
- explain the processes of standards development where standards support compliance with legislation and policy in addition to their market function.

## 1 Standards and regulation: different and complementary

### 1.1 General

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

### 1.2 What is regulation?

Regulation is the way in which public authorities seek to guide or control behaviours. Public authorities have a number of ways to meet their policy objectives and different types of regulatory instruments are available to them. These include legislation and other tools that can support the implementation of policy, such as market-based instruments that directly involve the participation of stakeholders (self- and co-regulatory approaches).

In this guide, the term 'regulation' means both legislation and other policy actions. It is not restricted to the specific European Union legislative act of the same name.

Legislation states what individuals and businesses must do, or must not do, and is usually backed by enforcement and the possibility of sanctions.

In the European Union, legislation is proposed by the European Commission and enacted by the co-legislators of the Council of the European Union and the European Parliament (for the ordinary legislative procedure). Compliance with legislation is mandatory; it is accompanied by enforcement mechanisms and possible sanctions where requirements have been breached.

Depending on the type of European legislation, national legislative action by the Member States may be required. For example, European directives shall be implemented by the Member States, most commonly by national legislation; European regulations are directly applicable without further implementing legislation.

### 1.3 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>12</sup>. Standards are performance-based wherever possible.

Standards are developed primarily to meet the good practice needs of industry, businesses and other interested parties<sup>13</sup> and to encourage its take-up in the broader economy. The use of standards by market players can in addition support the implementation of public authorities' policy and legislation and help stakeholders to comply with legislation; about 20 % of European Standards perform this supplementary function.

This guide relates specifically to standards adopted by CEN and CENELEC (European Standards) and their members, the National Standards Bodies and National Committees respectively, noting that a considerable proportion of those standards come from the

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<sup>12</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."

<sup>13</sup> Industry including SMEs, public authorities, consumers, trade unions, academic and research bodies, testing, certification and accreditation organizations, environmental stakeholders, etc.

international standards organizations ISO<sup>14</sup> and IEC<sup>15</sup> through long-standing cooperation agreements.

CEN, CENELEC and their members 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>16</sup>. CEN and CENELEC provide the framework for technical experts to develop standards<sup>17</sup>. A standard is agreed on the basis of the consensus<sup>18</sup> of those interested parties who have participated in its development; it is subject to a public and open consultation of its proposed provisions and is then periodically reviewed to ensure that its content remains up to date.

European Standards shall be implemented as national standards<sup>19</sup> by each of the thirty-three members of CEN and CENELEC and conflicting national standards shall be withdrawn. This gives a single standard for accessing the markets of the whole of the European Union, and beyond, which is the main value of standards for business. The European Standardization Organizations hold the copyright in European Standards. Members of CEN and CENELEC are responsible for making European Standards publicly available and the revenues from copyright and sales of standards are used to finance the European standardization system.

Standards are voluntary in the sense that there is no obligation to comply with them, implement them or participate in their development; they are tools for market players that can 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 and the development of technology 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

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<sup>14</sup> International Organization for Standardization, [www.iso.org](http://www.iso.org)

<sup>15</sup> International Electrotechnical Commission, [www.iec.ch](http://www.iec.ch)

<sup>16</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 supplemented 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>17</sup> See glossary, Annex A, for more information.

<sup>18</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.”

<sup>19</sup> Term defined in Regulation 1025/2012



- support the implementation of legislation and government policy.

#### 1.4 The differences between standards and legislation

The WTO TBT Agreement clearly distinguishes standards from ‘technical regulations’ (a type of legislation<sup>20</sup>) in its Annex 1 definitions: standards are voluntary in application whereas technical regulations are mandatory. This essential difference is also recognized by the European Union. For example, the first recital of Regulation 1025/2012 states: ‘The primary objective of standardization is the definition of voluntary technical or quality specifications’.

In rare cases legislation makes the use of standards mandatory.

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 interested parties through private standardization organizations’ processes
<b>Consultation depending on 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 at least every 5 years
<b>Sets requirements determined by legislator</b>	Provide state of the art solutions
<b>For the New Approach/New Legislative Framework:</b>	
<b>Sets high level essential requirements</b>	Offer technical means of meeting essential requirements of legislation

#### 1.5 Harmonization with national regulations

In some instances, national legislation may not necessarily be compatible with the provisions of a European Standard under development. CEN and CENELEC technical committees generally manage successfully to accommodate such national legislation. If this is not possible, however, a European Standard may include information about the incompatibility with national legislation by means of an informative annex; this is called an A-deviation.

<sup>20</sup> A technical regulation is a specific type of legislation: it is defined as a “Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory” (TBT Agreement, Annex 1).

## **2 Better and smarter**

### **2.1 General**

While the primary purpose of the use of standards is different from that of legislation and policy, the use of standards can serve a very useful function to support the implementation of public authorities' initiatives. This is enshrined in the WTO TBT Agreement, which states that WTO members should use international standards as the basis for their technical regulations wherever possible. Regulation 1025/2012 recognizes, for the European single market, that international standards are developed by the international standardization organizations ISO, IEC and ITU<sup>21</sup>.

Similarly, the UN ECE (United Nations Economic Commission for Europe) 'reference to standards' method asserts that public authorities should make use wherever possible of international standards when creating legislation, and 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 3.3, Co-regulation).

### **2.2 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>22</sup> and the ISO-IEC guide 'Using and referencing ISO and IEC standards to support public policy'<sup>23</sup> investigate the different ways of using standards to support the implementation of legislation.

These include making in legislation an indirect reference to a standard, as in the European New Approach/New Legislative Framework (see 3.3, Co-regulation), or directly incorporating a standard, or parts of a 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 in an innovation-friendly manner. For this reason, indirect referencing of standards is strongly recommended by CEN and CENELEC.

It should be noted that the incorporation of provisions of a standard into legislative text by public authorities has the potential to infringe the copyright of CEN and CENELEC. More detail can be found in the relevant CEN-CENELEC guides, such as Guide 8 - CEN-CENELEC Guidelines for Implementation of the Common IPR Policy on Patent and Guide 10 - Policy on dissemination, sales and copyright of CEN-CENELEC Publications.

### **2.3 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 on enterprises and making enforcement easier.

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<sup>21</sup> International Telecommunication Union, [www.itu.int/](http://www.itu.int/)

<sup>22</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>23</sup> <http://www.iso.org/iso/PUB100358.pdf>. Also, see the accompanying website: [www.iso.org/policy](http://www.iso.org/policy)

The European Commission has developed its better regulation policy into one of 'smart regulation'<sup>24</sup>. 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.

Standards can be used as tools to support smart/better regulation as part of self- or co-regulatory approaches (more detail in Clause 3). This is recognized in public authorities' regulatory policy documents. 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 EU 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* carried out a study on 'soft law' ('Le droit souple') in 2013 that recognized the use of soft law approaches to achieve policy objectives when the instruments can demonstrate the necessary legitimacy, utility and effectiveness.

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

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

- European Standards are developed on the basis of pan-European consensus and implemented identically and simultaneously throughout Europe, which means that standards have a broad market acceptance. This ensures that legislation and policy supported by the use of standards have a high level of stakeholder acceptability, can 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 solutions that can be used to meet those objectives.
- The cost of standards development is borne by the market players, and public authorities no longer need to set out all details in legislation.
- 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.

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<sup>24</sup> [http://ec.europa.eu/smart-regulation/index\\_en.htm](http://ec.europa.eu/smart-regulation/index_en.htm)

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- The broad geographic acceptability of standards (European/international) enables market access and their use can promote the competitiveness of the European industry around the world<sup>25</sup>.
- Requesting standards to support the implementation of legislation and policy brings a simple means for public authorities to meet WTO TBT obligations.

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<sup>25</sup> It is of paramount importance that standards in Europe remain as close to international standards as possible in order to take the best possible advantage of this market access opportunity.

### 3 How standards can work for policy makers

#### 3.1 General

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

#### 3.2 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>26</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 stakeholders, most commonly 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 may accept that this action will meet its policy objectives, as the voluntary agreement to use the standard is acknowledged as a valid alternative to taking legislative action (often described as an 'alternative to regulation'). See examples from the Netherlands on temporary work and from the UK on biodiversity.

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

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

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

*This British Standard enables organizations 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.*

Public authorities can encourage the development of a new standard, for example when the European Commission issues a standardization request<sup>27</sup> (formerly known as a 'mandate') – see the example on accessibility standards. Alternatively, public authorities may rely on an existing standard or work with industry and other interested parties to develop a code of

<sup>26</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>27</sup> Standardization requests are issued under Article 10 of Regulation 1025/2012. To note: European Commission standardization requests are not exclusive to self-regulatory approaches and indeed are more common with a co-regulatory approach. Standardization requests have to be relevant to the needs of the market and are to be accepted by one or more European Standardization Organizations before standards development work commences.

practice. In some cases, public authorities may fund the development of standards/codes that will be used to support policy implementation.

***EN 301549:2015 Accessibility requirements suitable for public procurement of ICT products and services in Europe***

*This standard was developed on the basis of the European Commission's 'standardization mandate to CEN, CENELEC and ETSI in support of European accessibility requirements for public procurement for products and services in the ICT domain' (M/376). 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.*

Public authorities can encourage the take-up of this approach by promoting its use as an alternative to regulatory intervention. See the UK example of prequalification questionnaires for public procurement in construction.

***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.*

### **3.3 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 recognized in the field (such as economic operators, the social partners, non-governmental organisations, or associations)<sup>28</sup>".

Co-regulation involves a closer relationship than a self-regulatory approach between industry and other stakeholders on the one hand and public authorities on the other. It involves public authorities setting the regulatory framework through legislation and standards organizations bringing together the stakeholders who create or put forward standards that, in addition to performing their market function, can explicitly support that legislation.

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 stakeholders, with each side developing part of the solution to achieve the public policy objective.

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<sup>28</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))

The co-regulatory approach has been used most notably with the European 'New Approach' to technical harmonization; over 4 000 European Standards are used to support the implementation of 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. See the example of the Electromagnetic Compatibility Directive.

*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.*

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 European Union Regulations). It has been the cornerstone of the creation and successful functioning of the European single market for goods.

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>29</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, following a Commission standardization request, standards that give the technical expression to these essential requirements; these are known as 'harmonized standards'. After being notified to the European Commission and the subsequent publication of the references of the harmonized standards in the Official Journal of the European Union, compliance with the 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 harmonized standards to gain presumption of conformity may be the easiest, quickest and cheapest means to meet the legal requirements.

The co-regulatory approach can take many forms, and in some instances it is quite similar to a self-regulatory approach. Nevertheless, a co-regulatory model always involves legislative action by a public authority. See the examples of the General Product Safety Directive and the Water Framework Directive.

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<sup>29</sup> Found at: <http://ec.europa.eu/DocsRoom/documents/4942/attachments/1/translations/en/renditions/native>

*There are 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 with the general safety requirement of the legislation as expressed through the requirements of a specific Commission Decision.*

*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 many co-regulatory examples from European Union Member States, where legislation refers to the use of standards, which still remain voluntary. This is the case with 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.

#### *Co-regulation in the EU Member States*

*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, many business activities are regulated by their professional associations (e.g. lawyers and doctors). For those that do not have such associations (e.g. photographers or professions operating in the field of translation and interpretation), Law 4/2013 "promotes the voluntary self-regulation and the qualification of the people carrying out these activities, by being in compliance with UNI technical standards, including the national adoptions of ISO and EN standards". This means that the law recognizes that the requirements, expertise, operations and communications to final users, which are identified in UNI technical standards, represent the general principles and criteria in this form of co-regulation.*

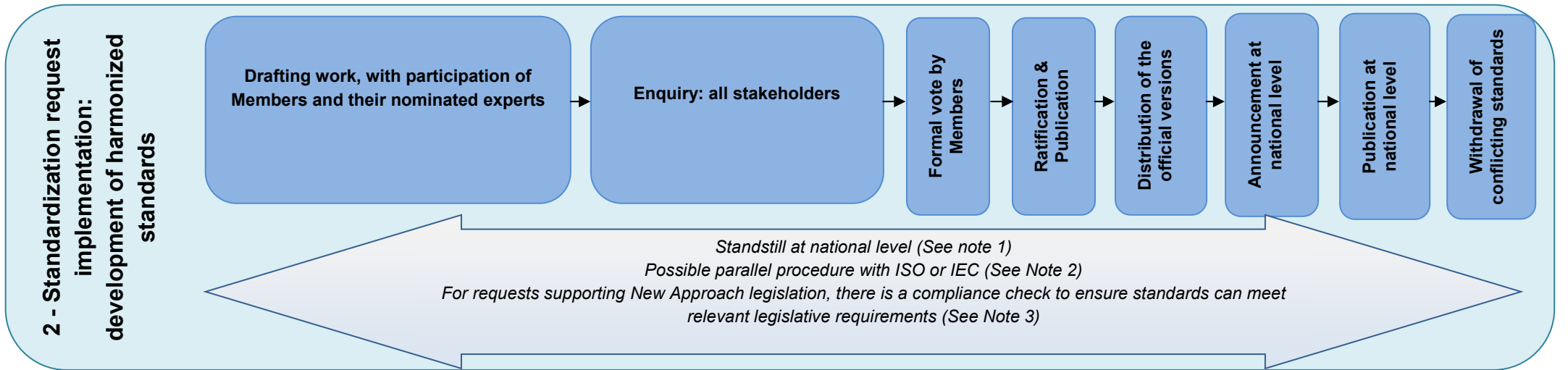
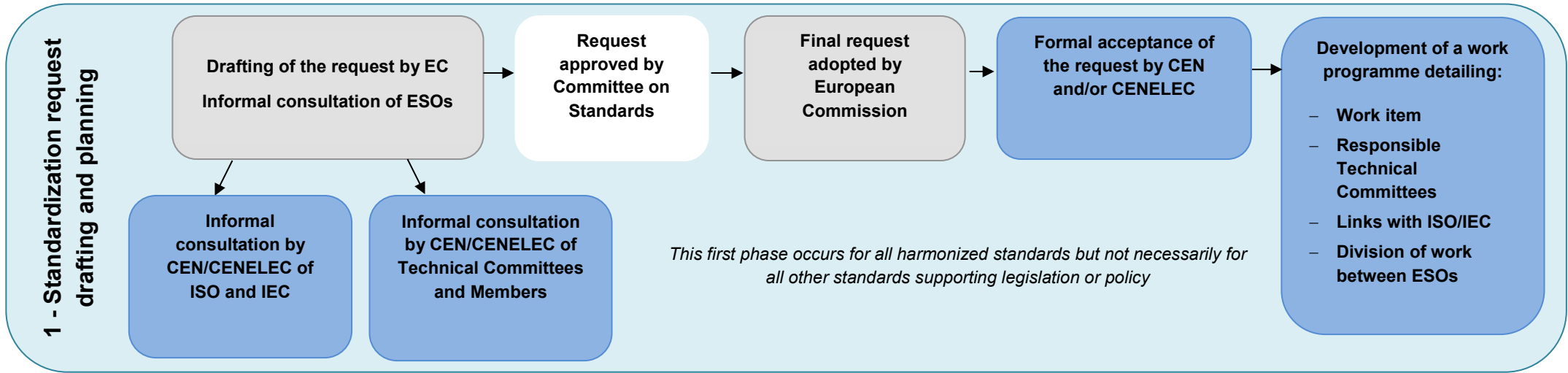


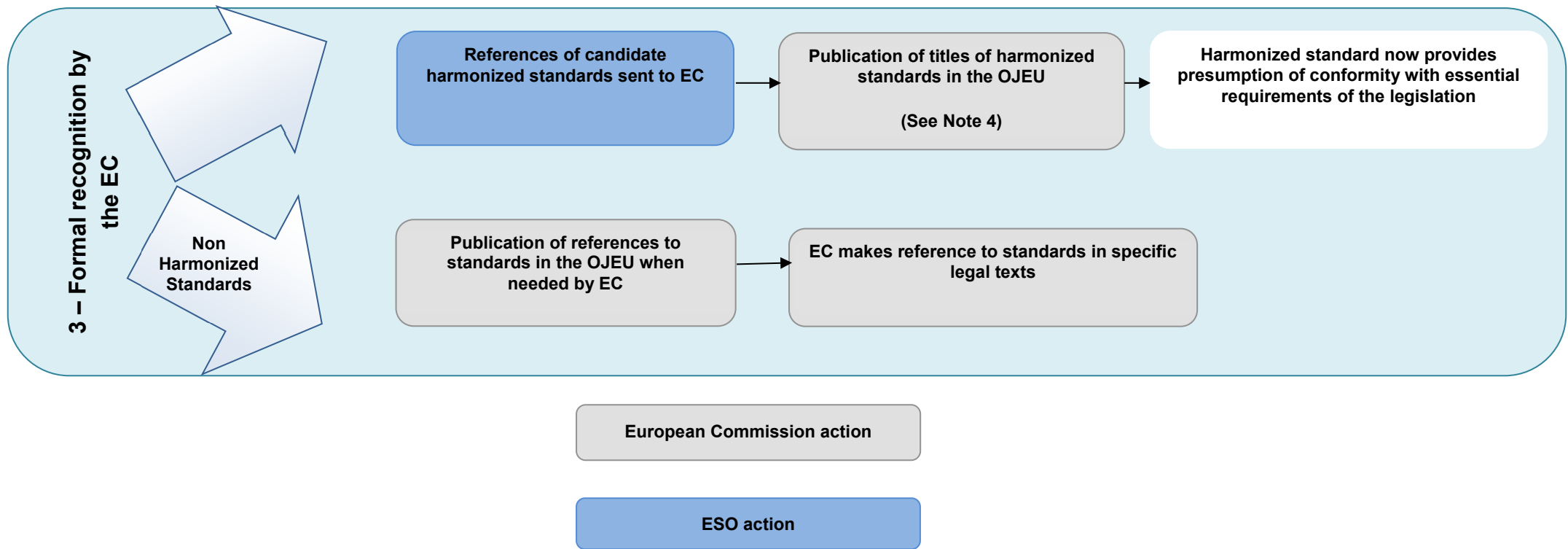
#### **4 The standards-making process and additional elements when supporting regulation**

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 the implementation of legislation and policy follow the same development processes; there is no distinction within CEN and CENELEC.

However, when standards are to be used for the implementation of legislation and policy there are additional elements in their development, for example the standardization request ('mandate') that comes from the European Commission. The following three process maps reflect these processes and show that:

- The European Commission ('EC' in the process maps below) drafts the standardization request and consults with the European Standardization Organizations ('ESOs') and other stakeholders,
- CEN and CENELEC develop standards in response to the request,
- The Commission then proceeds to recognize the standards through publication in the Official Journal of the European Union ('OJEU'), following a compliance check.





**Note 1:** Standstill = as soon as work is started at European level, there is an agreement between CEN and CENELEC 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:** As one means of delivering the compliance check of standards with legislative requirements, “New Approach Consultants” may guide standards development in order to ensure that harmonized standards are developed in line with the terms of a request. Before formal vote, a formal assessment is sought from the New Approach Consultant.

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

**Figure 1 — Process maps for the development of Commission requested standards**

## Annex A

### Glossary of terminology

Elected representatives	Means parliamentarians, whether MEPs or national representatives.
Policy makers	Means civil servants and civil service bodies involved in developing and delivering policy, in a broad sense.
Public authority	Means governmental bodies, such as the European Commission and national Member State governments, and agencies at both European and national levels.
Regulation	For the purposes of this guide, 'regulation' means all measures available to public authorities to deliver their policy objectives, i.e. both legislation and other regulatory policy actions. It is not restricted to the specific European Union legislative act of the same name. Throughout the guide the text refers to legislation or to policy actions where relevant.
Standards supporting legislation and policy	As market-based tools, European Standards support industrial competitiveness and the single market. Public authorities recognize that the market can bring standards solutions to its public policy challenges, such as helping to meet legislative or policy objectives. They may refer to certain standards in legislation or policies, for example by conferring a presumption of conformity with legislative requirements when the provisions of standards are met (New Approach/New Legislative Framework). Standards provide this effective support to legislation and policy when they are taken up and used in the market; the voluntary character and market relevance of standards is critical. It is therefore the use of standards in the market that can support the effective implementation of legislation and policy.

<p>The CEN and CENELEC framework for European standardization</p>	<p>The European standardization framework provided by CEN and CENELEC is based on the principle of having a single European Standard implemented identically throughout the member countries of CEN and CENELEC. Conflicting national standards are withdrawn and no new work can start on issues covered by European Standards. This framework has a governance system based on the participation of the national members. Standards development follows the national delegation principle, whereby national consensus positions are developed in each interested member country and are brought to the European committee where the European Standard is agreed.</p>
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## Annex B

### List of abbreviations

CEN	European Committee for Standardization, <a href="http://www.cen.eu">www.cen.eu</a>
CENELEC	European Committee for Electrotechnical Standardization, <a href="http://www.cenelec.eu">www.cenelec.eu</a>
EC	European Commission, <a href="http://ec.europa.eu">ec.europa.eu</a>
ETSI	European Telecommunications Standards Institute, <a href="http://www.etsi.eu">www.etsi.eu</a>
IEC	International Electrotechnical Commission, <a href="http://www.iec.ch">www.iec.ch</a>
ISO	International Organization for Standardization, <a href="http://www.iso.org">www.iso.org</a>
ITU	International Telecommunication Union, <a href="http://www.itu.int">www.itu.int</a>
OJEU	Official Journal of the European Union, <a href="http://europa.eu">europa.eu</a>
UN ECE	United Nations Economic Committee for Europe, <a href="http://www.unece.org">www.unece.org</a>
WTO TBT Agreement	World Trade Organization Technical Barriers to Trade Agreement, <a href="https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm">https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm</a>