

*Methods of referencing standards in legislation
with an emphasis on European legislation*

Enterprise Guides



European Commission

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Foreword

The European legislator makes broad use of standards to support Community legislation. Taking into account the current reflections about governance and better regulation which recommend an increased use of co-regulatory and self-regulatory practices, it may be expected that the use of standards to support legislation will increase as well.

The methods applied while making reference to standards in legislation vary significantly. The following document gives an overview of the different methods showing concrete examples with their advantages and disadvantages. It is geared at all legislators at European, Member State and country candidate level and aims to provide recommendations for 'best practice' to be applied if, while drafting legislation, the option of using standards is chosen.

Introduction

Standards are technical documents, prepared by all interested parties (companies, consumers, workers, public authorities) on the basis of a number of principles (e.g. consensus, openness and transparency). Unlike regulations, they are not adopted by an authorised public authority but within private, independent and - in the case of European standards - officially recognised standards organisations.¹ Standards are a priori not binding and their application is voluntary.

Standards can also play an important role in legislation, in particular in technical regulation. If a legislator includes standards in a legal act or makes reference to them in one way or another standards can obtain legal quality. The standards thus become a part of the requirements of a specific legislative act or of the system.

The advantages to legislators of making use of standards in legislation are manifold. Instead of being obliged to find solutions for difficult technical questions themselves, legislators can rely on the technical expertise of the standards developers and at the same time save public money. Moreover, thanks to the consensus-based, open and transparent procedure of setting standards and the subsequent broad acceptance of standards, the legislator can expect a broad acceptance of his legislation as well. Finally, standards reflect the latest 'state of the art' i.e. the latest technical developments. However, in order to follow the latest technical developments, standards must be regularly revised.² Accordingly, a legislator making use of standards to support legislation should take that into account and choose a legislative option allowing him to avoid having to adapt the whole legal act every time a standard is revised.

At European level, the Community, in its legislation, makes broad use of the option of referencing standards. This is confirmed by a recent study³ in which all Community acts in which reference is made to standards are listed. Standards to which reference is made are international standards, European standards and, to a lesser extent, national standards. The methods used vary significantly, depending on the political will of the legislator. The European legislator makes direct and indirect reference to standards.

¹ Directive 98/34/EC of the European Parliament and the Council laying down a procedure for the provision of information in the fields of standards and technical regulations (OJ L 204 of 21.7.1998) recognises CEN, CENELEC and ETSI as the official European Standards Organisations.

² The statutes of the European standards organisations foresee a regular revision at least every five years.

³ Falke, Internationale Normen zum Abbau von Handelshemmnissen, July 2001.

Direct references can be dated or undated. The legislator can allow the use of standards to remain voluntary or make them mandatory.

The different possibilities for making use of standards in legislation may be combined, thus establishing a large variety of ways of referencing standards in legislation.

Based on an analysis of the different combinations applied by the European legislator, this note intends to present examples of the different types of references used by the European legislator and the procedures chosen by him to adapt legislation to technical developments in standards. It further aims to examine their advantages and disadvantages in the light of legal certainty, and the procedural implications of the legislator's obligation to adapt legislation if a referenced standard is revised.

I . Direct references to standards

Direct references can be established by the primary European legislator (the European Parliament and the Council), but the task to carry out necessary adjustments can be delegated to the administrative authority (Commission, sometimes supported by a Committee). In this case, a specific standard is directly quoted within a legal text. There are two types of direct references: the dated direct reference and the undated direct reference. By way of a direct reference, in many cases, a standard is made mandatory. Thus, depending on the level of the referenced standard (national, European, international), barriers to trade may be created. Moreover, direct references require regular adaptations of the legislative act in order to remain in line with technical development. Finally, a detailed ex-ante control by the legislator is necessary as to the technical content of the standard.

A) The dated reference

A reference to a standard is dated if the legislative act quotes the standard by its number and by its date.

General advantages of the dated reference

The major advantage of a direct, dated reference is its legal certainty. The legislator is the 'master of the procedure' in autonomously choosing exactly the technical

solution he wants to be applied. On the other side, the addressee of the legal act knows exactly which technical solution he has to apply in order to comply with the legislation. In addition, he can recognise the imposed technical solution in the legal act itself.

General disadvantages of the dated reference

Nevertheless, the disadvantages of such a method prevail. As mentioned above, every time a standard is adjusted to the latest state of the art or even entirely replaced, legislation using that standard will also have to follow if it wants to respond to the latest state of the art. This will require complicated and time-consuming legislative procedures especially if the right of adaptation of the legal act is not delegated by the primary European legislator (the European Parliament and the Council).

Examples of dated references

The abovementioned procedural disadvantages of dated references are most often avoided in European legislation. While examining the abovementioned study with regard to dated standards used in European legislation, one can recognise that specific procedures are introduced which simplify the adaptation of the legal act to revised standards.

1) Such a procedure can consist in delegating the adaptation of the legislative act to the Commission supported by a committee ('comitology').

For example Art. 2(2) of Council Directive 79/196/EEC of 6 February 1979 on the approximation of the laws of the Member States concerning electrical equipment for use in potential explosive atmospheres employing certain types of protection⁴ (complementing Directive 76/117/EEC) holds that 'harmonised standards in the meaning of Article 4(4) of the (basic) Directive 76/117/EEC shall mean standards listed in annex I hereto'. These standards are quoted as 'EN 50 014/ Electrical Equipment for Use in Potentially Exclusive Atmospheres/1/ March 1977'.

Article 5 of the same Directive then states that 'the contents of the harmonised standards referred to in annex I may be amended by following the procedure laid down in

⁴OJ No. L 43 of 1979, p. 20 ff, to be abrogated.

Article 7 of the (basic) Directive 76/117/EEC', establishing a management committee following the comitology rules.

Accordingly, in the case of an adaptation, it is not necessary to trigger the whole legislative process (Commission proposal, discussion in and adoption by the Council/Parliament) but instead, to consult a management committee and to find a final solution as foreseen by the comitology procedure. A further advantage is that, in the case of dated references which might in this situation be used more often, the legitimated authority remains the 'master of the procedure'. Constitutional problems can be avoided. Legal certainty for the addressee is ensured as well. Nevertheless, Article 7 of the abovementioned directive is badly formulated: it is not the legislating authority itself which decides on 'the amendments to the contents of harmonised standards' but the respective standard organisation. The legislating authority decides whether to adapt the annex to the Directive to the amended standard.

Nevertheless, a committee still needs to be consulted. The legal act does not automatically follow the development of the 'state of the art'.

2) The right for adaptation can also be delegated to the Commission alone.

For instance, Commission Regulation (EC) No 2316/1999 of 22 October 'laying down detailed rules for the application of Council Regulation (EC) No 1251/1999 establishing a support system for producers of certain arable crops',⁵ by which the Commission was entitled to regulate the details, quotes in its Article 4 EN ISO 9167-1: 1995 and EN ISO 5508: 1999 as the applicable testing methods.

This type is similar to the delegation to a committee and maintains the advantages of a dated reference, at the same time removing complicated and time-consuming adaptation proceedings. Nevertheless, a permanent adaptation of the legal act remains necessary as well.

3) An example of a means to avoid such an obligation is provided by Directive 94/2/EC of the Commission of 21 January 1994⁶ implementing Council Directive 92/75/EEC with regard to energy labelling of household electric refrigerators, freezers and their combinations. Therein, Art. 1(2) establishes that 'the information required by this Directive shall be measured in accordance with EN 153 of May

⁵ OJ L 280 of 30 October 1999.

⁶ OJ in 1994 L 45, p. 1 ff.

1990 or with harmonised standards the references of which have been published in the OJ'. This alternative combines the clear dated reference with the option to use other methods, thus removing the obligation of regular adaptations. Nevertheless, the wording of the above Article may easily lead to confusion with the user since he might not know which standard to use if EN 153 of May 1990 is replaced but still quoted in the Directive.

B) Undated references

In the case of an undated reference, the European legislator only quotes the number of a specific standard, not the date.

General advantages of the undated reference

Compared to the dated reference, this method is certainly more flexible. In the case of a revision of a referenced standard, the legal act itself does not need to be adapted. The reference still corresponds to the state of the art.

General disadvantages of the undated reference

The undated reference comprises many negative aspects. The text allows the use of subsequent revised versions of the same standard. The question arises as to what will happen if the standards are entirely replaced or if the quoted pre-standard has in the meantime become a standard. In such a case, an adaptation of the legal text with all its procedural impact might be necessary as well. Moreover, with undated references, the legislator loses its position as the 'master of the procedure' and shifts his authority for reference to standards organisations that are not legitimised for this. Constitutional questions may arise.

Examples of undated references

1) Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedure and the rules for the affixing and use of the EC conformity marking, which are intended to be used in the technical harmonisation Directives⁷ says under point A(m) that 'notified bodies which can prove their conformity with harmonised standards (EN 45000 series) are presumed to conform to the requirements of Directives'.

⁷ OJ L 220 of 30 August 1993.

This practical example demonstrates the flexibility of the undated reference type. If the EN 45000 series is updated, no adjustment of the Decision should be necessary. Doubts remain however, if the EN 45000 series are not only updated but completely replaced as is currently the case with EN ISO/ IEC 17025. For reasons of clarity and certainty, an adjustment of the Decision seems preferable.

2) In many cases, the wording 'or later modified version', 'or revised version' or 'in the valid version' are added to the number of the undated standard. Thus Art. 1 of the Commission Decision of 16 January 2001 establishing two reference methods of measurement for PCBs pursuant to Article 10(a) of Council Directive 996/59/EC on the disposal of polychlorinated biphenyls and polychlorinated terphenyls⁸ stipulates that 'European standards EN 12766-1 and prEN 12766-2 and subsequently upgraded versions shall be applied as the reference method for the determination of PCB in petroleum products and used oils'.

Here again, the question remains what should happen if the standards are completely replaced or, in the case of the quoted prEN, have become a formal standard.

II. Indirect references to standards

Unlike direct references, indirect references to standards are generally made where the legislator intends to allow or promote their voluntary use. Barriers to trade are avoided. Moreover, indirect references may allow the technical development to be followed more easily. In this case, a revision of the relevant standard does not require a corresponding adaptation of the basic legal act.

A) New Approach

Within the New Approach legislation aiming at harmonising technical regulation in the Single Market, standards play an important role. Within the New Approach, the European legislator clearly defines his political objectives by defining detailed essential requirements (mostly on health and safety) which a manufacturer must meet in order to comply with the legislation. No reference to specific

⁸OJ 2001 No. L 203, p. 31.

standards is made in the legislation itself, the New Approach is operational without standards.

However, pursuant to the aforementioned Directive 98/34/EC, the Commission can request the European standards organisations to elaborate harmonised European standards necessary to comply with the essential requirements defined in the respective legislation. Standards thus complement legislation as they provide technical specifications of the essential requirements set up by the European legislator. Any manufacturer who wants to market his products within the Single Market must meet the essential requirements. One way of doing this is to comply with harmonised European standards, the references of which are published in the OJ. In this case, the New Approach Directives confer presumption of conformity of a product with the legislation.

Thus, the New Approach leaves the technical work complementing and specifying legislation to bodies without legislative authority. Unlike in the case of direct referencing, an ex- ante control of the technical work by the legislator does not take place. The European legislator has faith in the accountability of the European standards system. This system does and must, according to consideration n° 24 of Directive 98/34 ensure that 'European standardisation system is organised by and for the parties concerned, on the basis of coherence, transparency, openness, consensus, independence of special interests, efficiency and decision making based on national representation'. Nevertheless, there is the opportunity of an ex- post control. By introducing the possibility of formal objections against a harmonised European standard, the New Approach has also established a system allowing both the Commission and the Member States to control the conformity of a harmonised European standard with the legal requirements defined by legislation.

General advantages of the New Approach

The way in which standards are used in the framework of the New Approach avoids most of the disadvantages demonstrated with the other solutions mentioned above. Thus:

- The legislator can request the European Standards Organisations to carry out technical work which is necessary to support technical regulation. The European standards system is accountable. An ex- ante control of the result of the standardisation work is not necessary. Nevertheless, the European legislator maintains control

of the final results as he needs to publish the references of these standards in the OJ in order for the standards to have legal effect (presumption of conformity). Constitutional doubts that a non-legitimised actor is carrying out legislation cannot emerge;

- If there is a revision of the standard, no revision of the legislative act itself is necessary, the references of the revised standards just need to be published. The New Approach legislation always corresponds to the 'State of the Art';
- The addressee of the legislation has certainty about the requirements he has to meet since the references of relevant standards are published in the OJ.

General disadvantages

Despite the above mentioned advantages it must be admitted that the legislator has less influence on the final outcome than in the case where he can himself choose a standard. An ex-post procedure of safeguard cannot provide the same quality of control as an ex-ante legislative procedure. Therefore, it must be ensured that the system of European standardisation remains as accountable as it presently is⁹.

A New Approach example

The essential rules are more or less the same in all New Approach Directives. The recent Directive 1999/5/EC of the European Parliament and of the Council of 9 May 1999 on radio equipment and telecommunication equipment and mutual recognition of their conformity is a good example among many.¹⁰

Article 2(h) of this Directive defines a 'harmonised standard as a technical specification adopted by a recognised standards body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34 for the purpose of establishing a European requirement, compliance with which is not compulsory.'

Article 5 of the same Directive stipulates that 'where apparatus meets the relevant harmonised standards or parts of it whose reference numbers have been published in the

⁹ This was only recently confirmed by the Council in its resolution of 28 October 1999 on the role of standardisation in Europe (OJ 141 of 19 May 2000).

¹⁰ OJ L 091 of 7 April 1999.

Official Journal of the European Communities, Member State shall presume compliance with the essential requirements referred to'

Article 9§3 of the Directive establishes a procedure of formal objections against shortcomings of harmonised standards not complying with the essential requirements of the Directive.

B) 'State of the art'

A further method of making use of standards to support legislation but not to quote them directly is the so-called reference to the 'state of the art' or 'acknowledged rules of technology' within legislation. State of the art in this case means that if a manufacturer meets the latest standards which, however, are in no way specified, the law presumes that this manufacturer complies with the relevant provisions. The state of the art model is somewhat similar to the New Approach. Community legislation does not have such a type of reference whereas Member States' legislation does¹¹. The mere reference to the state of the art is problematic. The only advantage to this solution is that it is not necessary to adjust legislation in case of a revision of the relevant standard. The disadvantages prevail. The legislator leaves complementary legislative work to non-legitimised organisations without having any possibility of control. A manufacturer has no certainty which standard exactly corresponds to the state of the art.

Summary

The analysis has demonstrated that Community legislation mainly makes use of two methods of using standards to support legislation: the direct reference either dated or undated and the indirect reference in the New Approach. The examples mentioned above have shown that the direct references contain disadvantages per se (barriers to trade, need to adjust legislation) which the primary European legislator tries to reduce partly by delegating the task of adjustment to the administrative authorities. Nevertheless, there remain different types of delegations. Moreover, there is no coherent application of the method of direct references. Sometimes, direct referencing is confusing (dated and undated reference) and raises constitutional problems (undated reference).

¹¹ Schepel, Falke; 'Legal Aspects of standardisation in the Member States of the EC and EFTA, Vol. 1, pp. 187, 188.

In the New Approach method, the European legislator combines the advantages of direct referencing (legal certainty) with those of indirect referencing (avoiding barriers to trade, no adjustment of legislation necessary). In addition, the New Approach Directives have a coherent construction and are based on the same principles. Making use of the accountable European standardisation system renders an ex-ante control of the technical results unnecessary. The risk of confusing the addressee of legislation can be more easily avoided.