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Chapter 6

Procedure for formal objections against harmonised standards

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Formal objection to a harmonised standard Guidelines for the administrative procedure

1. Formal objections – general aspects

1.1. Definition

The New Approach directives contain a clause according to which a harmonised standard can be challenged through a formal objection. The Decision No 768/2008/EC on a common framework for the marketing of products¹ provides in Annex I, Chapter R3, Article R9 for a “standard” text of such a clause:

Formal objection against harmonised standards

- 1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in ... [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, hereinafter the "Committee", giving its arguments. The Committee shall deliver its opinion without delay.*
- 2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.*
- 3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.*

The institute of a formal objection makes it possible for Member States or the Commission to object in cases in which a harmonised standard does not entirely satisfy the requirements in Community harmonisation legislation. However, a harmonised standard does not necessarily need to meet all essential requirements included in the directive concerned. A harmonised standard can only be challenged if it is considered to have a shortcoming as regards an essential requirement it claims to cover. The relationship between the content of a harmonised standard

¹ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218/82, 13.08.2008, p. 82

and the essential requirements covered is indicated preferably in the harmonised standard itself (e.g. as annex thereof).

1.2. Legal consequences

The introduction of a formal objection gives rise to the obligation of the Commission to decide on the formal objection, taking into account the opinion of the Standing Committee². The Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.

While of itself the acceptance of a formal objection has no legal consequences for the existence of the said harmonised standard, it does for the legal effects related to the application of this harmonised standard. These legal effects consist of the presumption of conformity to essential requirements of products manufactured on the basis of this harmonised standard and the choice of the conformity assessment procedures.

It must be stressed that it is part of the New Approach concept that standardisation remains a voluntary process based on consensus achieved in the framework of independent bodies. In principle, the public authorities accept the results of this process, provided that certain conditions are fulfilled, such as compliance with the mandate (the mechanism by which the Commission requests the European standardisation bodies³ to carry out some standardisation work in support of European policies and legislation) and respect for the principles embodied in the general guidelines agreed upon by the Commission and the European standardisation bodies.

What is more, additional procedures have been introduced, such as the possibility of checking by independent consultants within the context of standardisation. Similarly, to monitor the correct execution of the mandate, the public authorities may be encouraged to participate in the standardisation process through their national standards bodies, and in the case of ETSI in a different appropriate format) with a view to avoid raising a formal objection later on in the process.

The formal objection procedure does not constitute a procedure of appeal available to the Member States or the Commission, when the latter note that their observations were not taken into account during the standardisation process. As part of the New Approach concept, however, the public authorities maintain their responsibility concerning the safeguarding of the interests which the essential requirements are aimed at protecting. The procedure described in this document covers, therefore, the formal objection to a harmonised standard on account of the fact that it presents shortcomings in relation to the essential requirements of a directive, of a kind to harm the interests, which the essential requirements are designed to protect. To prevent later formal objections, the opinions on safety matters forwarded by national authorities participating in the standardisation work should be considered seriously.

² The Standing Committee set up by Article 5 of Directive 98/34/EC (OJ L 204, 21.7.1998, p. 37–48), also known as the '98/34 Committee' or the 'Committee on Standards and Technical Regulations'

³ see Annex I of the Directive 98/34/EC (OJ L 204, 21.7.1998, p. 37–48)

Confirming the existence of such a shortcoming is no longer the act of a single Member State, but is based on the opinion of the Standing Committee composed of all the Member States. The consequences of this opinion have to apply at Community level according to the procedures laid down. In the light of the opinion delivered by the Standing Committee and also on the basis of all available information, the Commission will decide on the measures to be taken. This decision will be communicated to the Member States and the Commission will inform the parties concerned in an appropriate publication.

A formal objection falls outside the framework of standardisation and is not subject to the provisions or procedures established by the standardisation bodies. It cannot be invoked with respect to a document that has not yet received the status of a harmonised standard.

1.3. Relationship to the safeguard clause

The question arises of the relationship between the formal objection procedure and the procedure for a safeguard clause against a product, on the grounds of a shortcoming in a harmonised standard. A formal objection does not necessarily have to be preceded by an introduction of a safeguard clause, however such a situation is not excluded. In this context reference must be made to the texts of the New Approach directives.

The Commission shall bring the matter before the Standing Committee and shall initiate the procedure for a formal objection to the harmonised standard in the following two cases:

- when the Commission considers that, on the grounds of a shortcoming in the harmonised standard, the safeguard measure against a product is justified,
- when the Commission notes that such a measure is not justified, but that the Member State in question intends to maintain its position.

It is obvious that in these two cases the formal objection is considered to have been introduced by the Member State in question. Thus the introduction of a safeguard clause against a product, on the grounds of a shortcoming in a harmonised standard, does not require the separate introduction of a formal objection to this harmonised standard, but nor does it exclude it.

2. Formal objections – procedural steps

2.1. Introduction of a formal objection

a. Introduction by a Member State

As this is a formal procedure, which may entail legal consequences for economic operators, it is necessary for Member States that they introduce a formal objection by a formal step. In order to ensure a maximum of transparency at the level of procedures, it is suggested that this formal objection be introduced to the Secretariat-General of the Commission, through the intermediary of their Permanent Representation to the European Union.

At the same time the Member State shall also send a copy to the Commission service responsible for managing the directive concerned and to the European standardisation bodies concerned. In order to prevent unnecessary formal objections, the Member State shall consult the European standardisation bodies concerned before introducing a formal objection,

A Member State may forward any documents concerning a formal objection to a harmonised standard in one of the official languages of the EU. The Commission services will ensure that these documents are made available in at least one of the working languages used by the Standing Committee.

However nothing impedes a Member State from bringing a formal objection before the Standing Committee, in conformity with the internal rules of this Standing Committee. Withdrawal of a formal objection must be notified using the same channels as those used for introducing a formal objection.

b. Introduction by the Commission

A formal objection by the Commission shall be brought before the Standing Committee in at least one of the three (EN/DE/FR) working languages used by the Standing Committee, and, if provided for, the sectoral committee, giving reasons for doing so.

2.2. Earliest date possible for introducing a formal objection

2.2.1. Before introducing a formal objection to a harmonised standard, it is advisable to check whether the following two conditions have been fulfilled:

- (a) the standard, qualified as a harmonised standard, has been **ratified** by CEN or CENELEC, or adopted by ETSI. In fact the text of a standard is only definitive when it is ratified⁴ or adopted.
- (b) a **request** has been made to the Commission by a European standardisation body **to publish the references** of this harmonised standard in the Official Journal of the European Union (OJ), in the C series. Indeed, it is always possible that the European standardisation body concerned is of the opinion, after its final examination, that the harmonised standard in question does not correspond to the terms of the mandate and/or meet the essential requirements of the directive concerned and, as a result, it will not ask for the publication of its references.

2.2.2. The question has been raised as to whether, on the basis of existing directives, the references of a harmonised standard must have been published in the Official Journal before a formal objection can be introduced. The reason for this question is given by the

⁴ Even if some Member States are not able to be familiar with the text of a standard before it has been forwarded to the national standardisation bodies, with the request to include the standard in their national collection, there is nothing to stop those who are aware of the ratified/adopted, harmonised standard from already formulating a formal objection.

fact that the standard article used in the New Approach directives establishes a formal objection procedure which may lead to the “withdrawal” of the reference of a harmonised standard; however it is unclear as to whether this procedure also applies to harmonised standards which have not yet been published in the Official Journal, since the legal text only refers to a withdrawal but not to the non-publication.

In agreement with the Member States, a practice has evolved whereby, for reason of economy of procedure and in the absence of other procedural provisions, a formal objection can indeed be introduced before the harmonised standard has been published. However, the two conditions indicated in 2.2.1 must be met, i.e. the harmonised standard must have been ratified/adopted and the publication of its references as a harmonised standard must have been requested. Of course, the same procedural guarantees must be respected as those, which are applicable, when the harmonised standard's references have already been published in the Official Journal. It has to be noted that the possibility of introducing a formal objection before publication may not be considered as a new legal framework but as the consequence of an interpretation of the existing legal rules.

To provide for legal certainty with respect to the question whether a formal objection can be introduced before the references of a harmonised standard have been published in the Official Journal, the Decision No 768/2008/EC on a common framework for the marketing of products explicitly provides in Article Annex I, Chapter R3, Article R9, para. 2 that the Commission shall have the possibility to decide „ ... not to publish ... the references to the harmonised standard concerned in the Official Journal of the European Union ...“.

2.3. Information to be forwarded when introducing a formal objection

In order for the Commission services and the other Member States to be able to examine properly a formal objection to a harmonised standard, the file on such an objection must contain at least the following:

- a reference to the directive concerned and an explicit reference to the safeguard clause of this directive;
- the references of the harmonised standard (number, year and title);
- precise details as to the part of the harmonised standard which is contested and as to the related essential requirements;
- an indication of the type(s) of products concerned, where necessary;
- detailed arguments justifying why the harmonised standard is being contested in relation to the directive’s provisions;

Other information, such as statistics on accidents and suggested measures to be taken, may be useful.

A Member State may, if necessary, suggest a time limit by which the opinion of the Standing Committee should be delivered, having regard for the respective consultation procedures of this Standing Committee and of the sectoral committee/group of expert concerned.

In the case of a formal objection coming from the Commission's services, a similar file must be constituted.

2.4. Dealing with formal objection files

The texts of the directives require that the Standing Committee and *a fortiori* the Commission take urgent action. This urgency is justified, either because complying with the harmonised standard may create situations leading to risks connected with the failure to respect essential requirements, or to avoid legal uncertainty which would affect economic operators, notified bodies and the authorities responsible for market surveillance.

2.5. The Standing Committee

As laid down in the New Approach directives, it is up to the Standing Committee of Directive 98/34/EC to give an opinion on any formal objection to a harmonised standard. The Standing Committee shall deliver an opinion without delay.

The Commission services handling contacts with the Standing Committee Secretariat on standardisation issues will forward the file and useful information to this Standing Committee.

As soon as a formal objection has been received, the respective sectoral service of the Commission will forward the file for evaluation to the committee/group of experts for the directive concerned. A formal objection will therefore automatically be dealt with first by this sectoral committee or group of experts before the opinion of the Standing Committee is sought. This will help save time by precluding situations such as this Standing Committee simply sending back the file to the sectoral group concerned at its first meeting on the subject.

The service responsible for the Secretariat of the Standing Committee for standardisation questions will submit the proposal of measures to be taken to the Standing Committee for its opinion. This proposal will be drawn up by the responsible sectoral service of the Commission on the basis of all available information, such as the assessment of the committee/group of experts for the directive concerned and the opinions of other Commission services involved.

2.6. Sectoral committee/group of experts

The sectoral service responsible for the directive in question will examine the file coming from a Member State in order to verify the justification for a formal objection. It will make direct contact with the ministries concerned and will consult all the interested parties. This service will ask the European standardisation body concerned to communicate any opinion that the consultant might have expressed, and what follow-up measures were taken.

This sectoral service will be responsible for consulting the committee/group of experts of the directive concerned. A clear assessment of the formal objection, that has been introduced, will

have to be obtained from this latter sectoral group. Its assessment will be communicated to the Standing Committee as soon as possible.

2.7. Decisions and publications

2.7.1. Decisions

Every formal objection introduced with regard to a harmonised standard will be the subject of a decision (acceptance or rejection) on the part of the Commission once the consultation procedures have been completed.

A decision will also be taken if the formal objection has become irrelevant meanwhile. An example would be if the harmonised standard had already been reviewed and was now regarded as satisfactory.

2.7.2. Addressees of a decision

The Commission decision will be addressed to the Member States.

2.7.3. Publication

Any Commission decision regarding the acceptance of a formal objection to a harmonised standard will be published in the Official Journal. It is only in this way that all the parties concerned will be able to be aware of the legal situation that follows, depending on the case, from non-publication or restrictive publication in the OJ of references to the harmonised standard in question. Should the decision be taken to withdraw a publication that has already appeared or to decide not to publish the references of the harmonised standard, the publication of this decision in the Official Journal will be the only way of informing all the interested parties.

Commission decisions which reject formal objections to harmonised standards will not be published in the Official Journal.

2.7.4. Partial decisions

It must be acknowledged that a formal objection and the related Commission decision do not always concern the whole of the harmonised standard but only some of its parts or clauses.

2.7.4.1. Case where the references of a harmonised standard have not yet been published in the OJ

In order for those parts of the harmonised standard that are not contested to be used as soon as possible, the Commission will carry out a so-called “partial publication”. This will comprise a Commission Decision specifying the precise part of the harmonised standard that will not give presumption of conformity, and indicating the reasons why.

2.7.4.2 Case where the references of the harmonised standard have already been published in the OJ

In order to allow the manufacturers to continue to confer presumption of conformity for the uncontested parts of the harmonised standard, the Commission will carry out a "partial withdrawal". This will comprise a Commission decision specifying the part of the harmonised standard, that will no longer give presumption of conformity, and indicating the reasons why. A partial withdrawal of the publication of the references is in practice a partial publication completely replacing a previous publication.

2.7.5 Publication options for references and decisions

The annexed table shows the various possibilities as regards both, the publication of the harmonised standard's references in the OJ and the publication of the decision concerned.

3. Formal objections – other aspects

3.1. Request to review the harmonised standard

Whenever the Commission has agreed with a formal objection to a harmonised standard, it will forward a precise mandate to the European standardisation body concerned to review the harmonised standard in question. This mandate will be the subject of an opinion delivered by the Standing Committee, if possible at the same time as its opinion on the formal objection concerned. The mandate may take the form of a simple letter or be a precise and detailed request according to the nature of the case and the standardisation work already in progress to remedy the problem that has been caused. The Commission will adopt the necessary measures to ensure the close follow-up of this mandate. The Standing Committee will be kept informed on a regular basis of progress with the respective standardisation work.

A mandate of this kind could, moreover, also be conferred when a formal objection has been rejected, but the Commission and the Standing Committee are of the opinion that it is nevertheless necessary to (partially) review the harmonised standard.

3.2. Suspension of a formal objection

In the past, some Member States have proposed suspending a formal objection procedure that had already been introduced in certain cases because the standardisation revision work was making good progress.

A suspension of a formal objection creates a situation of legal vagueness. A formal objection refers to a serious situation for either safety or health, and sometimes both, and hence requires urgent action. The deadlines for action and the processing of the file are no longer under the control of the public authorities but depend on the progress of standardisation work and its results, which are not guaranteed in advance. Although it has to be recognised that close cooperation between the public authorities and the European standardisation body is useful and even necessary, such situations of legal vagueness should be avoided.

Thus there are only two possible scenarios:

- the Member State maintains its formal objection and the Commission services are obliged as a result to pursue the procedures described in this document in order to halt a situation of legal uncertainty;
- the Member State withdraws its formal objection in the light of a precise mandate to the European standardisation body concerned to solve the problems raised by its formal objection.

3.3. Other communication than formal objections from the public authorities regarding a problem with a harmonised standard

The formal objection procedure does not undermine the rights of Member States to communicate to the Commission, or directly to the Standing Committee, any problem related to the application of the essential requirements in a harmonised standard, even before it has been ratified/adopted. In some cases the problem could be serious enough for a formal objection to be introduced at a later stage. Such communications could therefore avoid a formal objection at a later stage. These communications do not have the legal consequences of a formal objection. If the harmonised standard has not been ratified yet, the Member States are invited to approach their national standards bodies – members of the European standardisation bodies - as a first step if any problem related to the application of the essential requirements in a harmonised standard arises.

3.4. The continuous checking of the standardisation process

The procedure for a formal objection and notification of the intention to introduce such an objection, do not preclude the Standing Committee from examining, in the framework of its work, the progress of standardisation activities, including the conformity of draft standards with the requirements of the directives and the mandates, and from informing the standards bodies of its conclusions. This type of dialogue may be useful because potential problems may be solved before the standard is ratified. The possibility for such an examination, which may occur at any moment during the process of the development of the standard, has no formal character. Communication of a position does not have legal consequences.

3.5. Informing the Standing Committee

The Standing Committee shall be informed by the Commission regularly and systematically of the way the procedure described above is progressing and its results for each formal objection file. For this purpose, a reference document was established by the Commission which is presented in each meeting of the Standing Committee.

The Standing Committee shall also be informed by the Commission of every communication expressing an intention to introduce a formal objection.

Annex: Table indicating different cases of „Decisions and Publications“

Annex: Table indicating the different cases of „Decisions and Publications“

Case			Commission decision		Publication of the decision in the OJ
No	Conclusion following consultations		Have the harmonised standard's references already been published?		
	Formal objection	Is the harmonised standard deficient?	Yes	No	
1	The objection to the harmonised standard is accepted	Totally	Yes	Complete withdrawal from publication of the harmonised standard's references	Yes
2			No	The harmonised standard's references will not be published	
3		Partially	Yes	Partial withdrawal from publication of the harmonised standard's references	
4			No	Partial publication of the harmonised standard's references	
5	The objection to the harmonised standard is rejected	-	Yes	Publication of the harmonised standard's references is not withdrawn	No
6		-	No	Publication of the harmonised standard's references	

NB: 1. Partial publication means the publication of the harmonised standard's references with an indication as to the parts which do not confer presumption of conformity
 2. A partial withdrawal consists, in a single action, of the complete withdrawal of the previous publication and of a new partial publication