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Chapter 6

Procedure for Formal Objections against standards

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Formal objection to a standard

Guidelines for the administrative procedure

1. Preliminary remarks

The New Approach directives contain provisions for cases where a harmonised standard is considered to have one or more shortcomings as regards the essential requirements of the directives concerned. When such cases occur, the Member States and the Commission may introduce a formal objection to the standard in question.

The "standard" text of the article in the New Approach directives, sometimes called as the "safeguard clause", usually runs as follows:

"When a Member State or the Commission believes that the harmonised standards referred to in Article ... do not entirely satisfy the essential requirements referred to in Article ..., the Commission or the Member State concerned shall bring the matter before the Committee set up by Directive 98/34/EC - hereinafter referred to as the "Committee" - giving its arguments. The Committee shall deliver its opinion without delay.

In the light of the Committee's opinion, the Commission shall notify the Member States whether the standards concerned must be withdrawn or not from the publications referred to in Article"

The present document has been drawn up taking into account current legislation and in the light of experience acquired in handling such formal objections to standards.

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

Given the possible legal effects of a formal objection, it is necessary to ensure equal treatment of such files. It is therefore important to define the elements of good administrative practice in this field..

The procedure described below takes over the few elements already fixed for the administrative procedure set out for the application of the safeguard clause in respect of a product (see the Guide to the New Approach Directives, paragraph 8.3.2). It deals only with cases of formal objections to standards.¹

However, 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 standard. In this context reference must be made to the texts of the New Approach Directives. The Commission shall bring the matter before the 98/34 Committee and shall initiate the procedure for a formal objection to the standard in the following two cases:

- when the Commission considers that, on the grounds of a shortcoming in the 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 standard, does not require the separate introduction of a formal objection to this standard, but nor does it exclude it.

2. General context

It must be stressed that it is part of the New Approach concept that standardization remains a voluntary process based on consensus achieved in the framework of

¹ It has to be noted that the directive on construction products contains more specific and constraining rules (compare its Article 5.1):

- a formal objection may be introduced not only against a standard, but also against European technical approval or even a mandate;
- a formal objection must be notified to the committee set up by this directive;
- this committee has to deliver an urgent opinion.

In the light of the opinion of this committee, and after consultation with the 98/34 committee, where it concerns harmonized standards, the Commission has to inform Member States if the standards concerned should be withdrawn in the publications.

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 and respect for the principles embodied in the general guidelines agreed upon by the Commission and the European standardization bodies. What is more, additional procedures have been introduced, such as checking by independent consultants within the context of standardization. Similarly, to monitor the correct execution of the mandate, the public authorities may participate in the standardization process via its instruments and procedures.

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 standardization 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 harmonized 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. Confirming the existence of such a shortcoming is no longer the act of a single Member State, but is based on the opinion of a 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 98/34 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 standardization and is not subject to the provisions or procedures established by the standardization bodies. It cannot be invoked with respect to a document that has not yet received the status of a harmonised standard.

3. Earliest date possible for introducing an objection

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

- (a) the standard, qualified as a harmonized standard, has been **ratified** by the European standardization body concerned. In fact the text of a standard is only definitive when it is ratified.

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 standardization bodies, with the request to include the standard in their national collection, there is nothing to stop those who are aware of the ratified, harmonised standard from already formulating a formal objection;

- (b) a **request** has been made to the Commission by a European standardization body **to publish the references** of this harmonised standard in the Official Journal of the European Communities (OJEC), in the C series. Indeed, it is always possible that the European standardization body concerned is of the opinion, after its final examination, that the 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.

3.2 The question has been raised as to whether, on the basis of existing directives, the references of a standard must have been published in the Official Journal before a formal objection can be introduced. 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 standard has been published. However, the two conditions indicated in 3.1 must be met, i.e. the standard must have been ratified 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 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.

4. How may the Member States introduce a formal objection?

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 may also send a copy to the Commission service responsible for managing the Directive concerned (see "contact points" in the New Approach Guide).

A Member State may forward any documents concerning a formal objection to a standard in one of the official languages. The Commission services will ensure that these documents are made available in at least one of the working languages used by the 98/34 Committee.

However nothing impedes a Member State from bringing a formal objection before the Committee 98/34, in conformity with the internal rules of this Committee.

Withdrawal of a formal objection must be notified using the same channels as those used for introducing an objection.

5. 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 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 standard (number, year and title);
- precise details as to the part of the 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 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 Committee 98/34 should be delivered, having regard for the respective consultation procedures of this 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.

6. Procedure for dealing with objection files

The texts of the directives require that the 98/34 Committee and *a fortiori* the Commission take urgent action. This urgency is justified, either because complying with the 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.

6.1. The 98/34 Committee

As laid down in the New Approach directives, it is up to the Committee of Directive 98/34/EC to give an opinion on any formal objection to a standard. The Commission services handling contacts with the Committee Secretariat on standardization issues will forward the file and useful information to this Committee².

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 98/34 Committee is sought. This will help save time by precluding situations such as this Committee simply

² See also footnote 1

sending back the file to the sectoral group concerned at its first meeting on the subject.

The service responsible for the Secretariat of the 98/34 Committee for standardization questions will submit the proposal of measures to be taken to the 98/34 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. As indicated by the directives, the 98/34 Committee will deliver an urgent opinion.

6.2. 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 standards 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 assessment³ 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 98/34 Committee as soon as possible.

7. Decisions and publications

- 7.1. Every formal objection introduced with regard to a standard will be the subject of a decision (acceptance or rejection) on the part of the Commission once the consultation procedures have been completed. No decision will be taken if the formal objection has become irrelevant meanwhile. An example would be if the standard had already been reviewed and was now regarded as satisfactory.
- 7.2. The Commission decision will be addressed to the Member States.
- 7.3. Any Commission decision regarding the acceptance of a formal objection to a 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 OJEC of references to the 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 standard, the publication of this decision in the Official Journal will be the only way of informing all the interested parties.

³ See also footnote 1

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

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

7.4.1. Case where the references of a standard have not yet been published in the OJEC

In order for those parts of the 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 standard that will not give presumption of conformity, and indicating the reasons why.

7.4.2 Case where the references of the standard have already been published in the OJEC

In order to allow the manufacturers to continue to confer presumption of conformity for the uncontested parts of the standard, the Commission will carry out a "partial withdrawal". This will comprise a Commission decision specifying the part of the 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.

- 7.5 The annexed table shows the various possibilities as regards both, the publication of the standard’s references in the OJEC and the publication of the decision concerned.

8. Request to review the standard

Whenever the Commission has agreed with a formal objection to a standard, it will forward a precise mandate to the European standardization body concerned to review the standard in question. This mandate will be the subject of an opinion delivered by the 98/34 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 standardization 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 98/34 Committee will be kept informed on a regular basis of progress with the respective standardization work .

A mandate of this kind could, moreover, also be conferred when a formal objection has been rejected, but the Commission and the 98/34 Committee are of the opinion that it is nevertheless necessary to (partially) review the standard.

9. 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 standardization 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 standardization work and its results, which are not guaranteed in advance. Although it has to be recognized that close cooperation between the public authorities and the European standardization bodies 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 standardization body concerned to solve the problems raised by its formal objection

10 Advance communication from the public authorities regarding a problem with a standard

The formal objection procedure does not undermine the rights of Member States to communicate to the Commission, or directly to the 98/34 Committee, any problem related to the application of the essential requirements in a standard, even before it has been ratified. In some cases the problem could be serious enough for a formal objection to be introduced at a later stage. Such advance communications could therefore avoid a formal objection at a later stage. These communications do not have any legal consequences.

In this context it may be useful for a Member State to express its intention to introduce a formal objection. It would permit the Commission to exercise a certain vigilance when it receives the request from a European standardization body to publish the standard's references in the OJEC. The Commission can take it into account in the internal procedure for requesting a publication of this kind, without the Member State in question in any way being released from its own political responsibilities as regards surveillance. However, the communication of an intention will not be treated as a formal objection.

For such a communication to be usefully taken into consideration, it must concern a ratified standard, include the same information as that requested for a formal objection (cf. 5) and there must be a clear indication of the deadline by which the formal objection will be introduced.

In their correspondence with the Commission, Member States are asked to distinguish clearly between the introduction of a formal objection file and other types of communications, such as the intention to introduce such an objection.

11. The continuous checking of the standardization process.

The procedure for a formal objection and notification of the intention to introduce such an objection, do not preclude the Committee 98/34 from examining, in the framework of its work, the progress of standardization 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.

12. Informing the 98/34 Committee

The 98/34 Committee will be informed regularly and systematically of the way the procedure described above is progressing and its results for each formal objection file. It will also be informed of every communication expressing an intention to introduce a formal objection. Commission services are studying the possibility of putting the decisions taken on a Commission website. At that point this information will be available to all interested parties.

Annex: Table

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

Case			Commission decision		Example of a concrete case
N°	Conclusion following consultations		Have the standard’s references already been published?	Subject of the decision	
	Formal objection	Is the standard deficient?			
1	The objection to the standard is accepted	Totally	Yes	Complete withdrawal from publication of the standard’s references	Yes
2			No	The standard’s references will not be published	
3		Partially	Yes	Partial withdrawal of the publication of the standard’s references	
4			No	Partial publication of the standard’s references	
5	The objection to the standard is rejected	-	Yes	Publication of the standard’s references is not withdrawn	No
6		-	No	Publication of the standard’s references	

- NB:
1. Partial publication means the publication of the standard’s references with an indication as to the parts, which do not confer the 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.