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New Approach Industries, Tourism and CSR
Standardisation

Vademecum on European Standardisation

Part II

European standardisation in support of European policies

Chapter 4.2

Follow-up of Mandates

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Follow-up of mandates

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Introduction

1. Context

The original version of this document was drafted to answer the request of the Council formulated in item 25 indents 1 and 2 of its Resolution of 28 October 1999¹, relating to the development and follow up of standardisation mandates in the framework of European policies and especially under the New Approach:

"The Council asks the Commission:

- *to ensure that standardisation mandates under the new approach are prepared accurately and efficiently, affording Member States and the European standards bodies sufficient opportunity to contribute;*
- *to ensure that standardisation activities covered by mandates are subject to thorough monitoring and that appropriate measures are examined with the European standards bodies in order to ensure proper progress".*

Item 25 indent 1 is treated in a separate part of the Vademecum which deals with the role and development of the mandates. The subject of this document corresponds to item 25 indent 2, which concerns the follow-up of the mandates.

The invitation from the Council to the Commission "to ensure" the follow-up of the execution of the mandates first requires a common clarification and interpretation of the various terms used. Moreover, the different basic elements of an effective follow-up are examined and supplemented with recommendations to determine the concrete means. These must take account of the fact that the European standardisation bodies² which accept a mandate are responsible for the execution of the mandate and therefore also its daily follow-up.

It should be noted that just describing recommendations is not sufficient. They must also be implemented, which implies concrete actions by entities remaining to be specified. In any case, this implementation should be carried out in close cooperation with the European standardisation bodies.

2. Analysis of the request of the Council as given in item 25 indent 2 of the Resolution of 28 October 1999

In order to answer precisely the request of the Council, it is necessary to analyse the request as well as the missions and tasks that result from it.

We can distinguish two missions in the invitation quoted in item 25 indent 2 of the Council Resolution, each one being made up of two aspects:

¹ OJ C 141 of 19.05.2000

² see Annex I of the Directive 98/34/EC (OJ L 204, 21.7.1998, p. 37–48)

- a. *"Ensure that standardisation activities covered by mandates are subject to thorough monitoring"*. This request to the Commission aims to ensure that measures are set up to check that the activities of standardisation, as well as the resulting standards themselves, satisfactorily fulfil the terms of a mandate and the regulatory/essential requirements³ of the directive involved. Therefore we shall deal here with the follow-up on the qualitative level. Moreover we should make a distinction between the task of ensuring the existence and application of means of checking and the task of checking itself.
- b. *"Ensure that appropriate measures are examined with the European standards bodies in order to ensure proper progress "*.

Here, the Council asks the Commission to ensure, along with the European standardisation bodies, that measures are set up to see that standardisation work progresses in good time. Here we shall deal with the administrative and organisational follow-up. Again, a distinction needs to be made between ensuring the existence of means to do this and the administrative follow-up of the work.

³ The expression "essential requirements" is a specific expression used for the regulatory requirements in the framework of New Approach directives.

Chapter I

The mission "To ensure the follow-up of standardisation activities"

As pointed out above, we should make a clear distinction between the task of the Commission to ensure the existence and application of measures for follow-up and checking and the task of follow-up and checking itself. We firstly need to analyse the basic elements of a close follow-up before being able to determine what measures the Commission should implement.

1. Basic elements of an effective follow-up of standardisation activities

In order to define the nature and characteristics of the measures to be set up by the Commission, it is firstly necessary to lay down the conditions for an effective follow-up. The following elements should be specified:

- the scope of the follow-up, namely, what we understand by "a thorough monitoring of standardisation activities";
- the stages, that is, at what moment should checking and/or examination be carried out;
- the actors who are in a position to carry out such a follow-up;
- information and methods of communication.

1.1 Scope of the follow-up

A correct follow-up of the execution of a mandate from the content point of view assumes that, at appropriate stages there is an examination or check of each mandate with regards to the work programme, the standards or alternative standardisation deliverables being developed or adopted as well as the standardisation process. We can therefore quote the following points on monitoring and checking:

- the standardisation programme and each component of this programme must fit in with the Community legislation and policy to which the mandate refers;
- where the subject of the mandate is a request to develop harmonised standards, the standardisation programme has to cover in a coherent way the categories of products and the risks mentioned, as well as the regulatory/essential requirements of the directive concerned;
- the standardisation programme has to be coherent with existing programmes of the same organisation and its sister organisations;
- where the subject of the mandate is a request to develop harmonised standards, each harmonised standard being developed or adopted has to treat in a satisfactory way one or more regulatory/essential requirements. Here it will be useful to check, if possible, that a high level of safety is ensured;

- where the subject of the mandate is a request to develop harmonised standards, for each harmonised standard there should be a clear and precise indication with regard to the relationship between its content and the essential requirements covered. More precisely, it is advisable that the relationship is being established, if possible, prior to the stage of public enquiry, and that it is made available, together with the draft standard, at that stage;
- the other requirements of the mandate, for example, the request that the European standardisation bodies consult specific organisations, have to be fulfilled by the standardisation process itself.

We might ask whether some systematic check should be made to see if the activities of standardisation carried out under this mandate comply with the general principles of standardisation (openness, transparency, independence etc.) and the general guidelines on cooperation signed between the European standardisation bodies and the Commission⁴. At first sight, we can limit ourselves here to management and follow-up "by exception".

Recommendations H

1. *It is necessary to check that the programme of standardisation itself integrates well into the Community policy (or policies) quoted in the mandate, and in the case of the mandate requesting to develop harmonised standards which of the regulatory/essential requirements of the directive concerned are covered.*
2. *Each harmonised standard has to treat satisfactorily the regulatory/essential requirements that it claims to cover.*

⁴ OJ C 91, 16.04.2003

1.2 Stages at which checking should be carried out

The checking of the above-mentioned elements can be carried out at one and/or at several of the following stages:

- drawing up of the work programme;
- development of the preliminary draft of the standard or alternative standardisation deliverables;
- the public enquiry;
- the vote and/or publication of the standard or alternative standardisation deliverables by an European standardisation bodies;
- the request for publication of the references of a harmonised standard in the OJ.

Since there is a possibility of checking at these stages, we have to assume that there are also some opportunities for communicating and dealing with the comments at these times. These possibilities should form an integral part of the stages, as is already the case with the public enquiry.

Recommendation I

1. *Checking of the documents (programmes, draft standards or alternative standardisation deliverables and standards) produced by the European standardisation bodies is necessary at certain formal stages.*

1.3 Entities likely to be in charge of monitoring and checking

The actors that carry out monitoring and checking are in the first place:

- the responsible European standardisation body (bodies);
- the public authorities at national level;
- the sectoral department of the Commission responsible for the mandate.

It is useful to clearly define the role and tasks of each entity, taking into account, among other factors, the resources available. The cooperation methods between these entities also remain to be determined. For example, we can envisage the creation of an ad hoc group composed of the representatives of the European standardisation bodies concerned, a "New Approach" consultant and the Commission representatives.

Recommendations J

1. *The role and the tasks of each entity in charge should be defined clearly, as well as the cooperation between these entities.*
2. *A first check should be carried out by persons in charge of the execution of the mandate. The existence of a quality control system within the European standardisation bodies could represent an asset.*
3. *The "New Approach" consultant has a key role in checking the harmonised standards produced, especially whether relevant essential requirements are covered in an adequate way.*
4. *The sectorial committee or group of experts of the directive concerned should play a real role in the follow-up of the execution of the mandates, even if this directive does not stipulate it.*

1.4 Information and the methods of communication

Each check and follow-up requires an examination comparing the assignment (the mandate) with the resulting product (the programme and/or standards or alternative standardisation deliverables). A communication procedure should be developed taking account of the comments arising from these checks. Moreover, easy access to this information has to be ensured for the parties directly concerned.

Among others, the following elements should be examined and taken into account:

- information (the terms of reference, the documents forming the object of checking, comments on these documents);
- the availability of this information as well as the means to achieve it (such as databases accessible by Internet);
- the methods for dialogue and treatment of the comments (meetings, electronic newsgroups for exchanges of information etc.).

In particular, we need to examine whether it is possible or useful to set up a procedure for communicating fundamental comments on behalf of the official authorities, in order to avoid formal objections against the standards at a later date. Indeed, the procedure for dealing with these objections is not simple, because there must be a detailed examination of the case, as well as consultations with the various parties, a formal consultation of the Standing Committee⁵ and a

⁵ 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'

Commission Decision. This "Early Warning" system will moreover make it possible to comply with the request expressed by the Council in Item 21 of its Resolution of 28 October 1999.

Recommendations K

1. *A clear procedure should be envisaged for communication and taking charge of the comments arising from the checks.*
2. *A possibility for early warning should be set up, as requested by the Council Resolution item 21. This system should make it possible to avoid subsequent formal objections against the harmonised standards or the application of the safeguard clause.*
3. *Consideration must be given to the question of the availability of information on mandates as well as the standardisation programmes and the draft standards to the various interested parties.*

2. Measures to ensure an effective follow-up

As mentioned in the introduction, this involves formulating, and if necessary setting up, measures on behalf of the Commission for ensuring the effective follow-up of standardisation work.

It should be remembered that European standardisation bodies initially have the responsibility of ensuring the proper execution of the accepted mandates as well as the conformity of the (harmonised) standards or alternative standardisation deliverables adopted with the mandate and the directive concerned (see also Recommendation J2).

Currently, there are already several measures in force on behalf of the Commission. The main ones are as follows:

- the mandates themselves. It is important that each mandate should contain elements allowing the effective follow-up of its implementation;
- the possibilities of creating Working Parties, such as those in the fields of construction products, machines and pressure equipment;
- the meetings of the normal and enlarged Standing Committee;
- the role allocated to the sectorial services of the Commission.

In the first instance, it is appropriate to maintain these methods, but also to improve and strengthen them. If necessary, supplementary measures could also be introduced. A presentation of the actions launched by the European standardisation bodies to strengthen their own follow-up

procedure could be envisaged. This presentation could be made to the sectorial committee, to the group of experts of the directive concerned or the normal and/or enlarged Standing Committee.

The existing means are described below with, if necessary, some proposals for improvement and/or reinforcement.

2.1 Mandates

Each mandate should not solely describe which requirements and which criteria of the standards or alternative standardisation deliverables need to be satisfied, but must also include the elements allowing and facilitating the monitoring of its implementation. This makes it possible to detect possible gaps in the standardisation work compared with the mandate and the related New Approach Directive. In a separate document of the Vademecum dealing with the role and elaboration of mandates (Part 1 Chapter II par. 2), the various requirements are stipulated regarding the contents of a mandate.

2.2 Role and tasks of the "New Approach" consultants

"New Approach" consultants play a very important role in the various phases of the execution of mandates, from explaining the essential requirements to checking the harmonised standards that will be submitted to the Commission for publication of their references in the OJEU.

The reports established by the "New Approach" consultants and communicated amongst others by the European standardisation bodies to the Commission services should be mentioned here. These reports allow all concerned parties (technical and managerial entities of CEN, sectorial services of the Commission) to detect possible problems and to start, if necessary, correctives measures. It is essential that the sectorial services of the Commission use these reports with the aim of a systematic follow-up of the mandated standardisation activities.

2.3 Ad hoc groups

In the event of major problems in the execution of the mandates in a given field, an ad hoc Working Group (Task Force) can be created, as was done in the past for some mandates, e.g. mandates concerning construction products, machines or pressure equipment.

It should be noted that the creation of such an ad hoc group has to be justified, because the participation in meetings of an ad hoc group requires human resource mobilisation in an already difficult context.

2.4 Normal Standing Committee

Up to now, the normal Standing Committee has not dealt systematically with the follow-up of the mandates.

However, as is stipulated in several "New Approach" directives, this committee can be referred to "when a Member State or the Commission considers that the harmonised standards... do not entirely satisfy the essential requirements dealt with... ". In this case, the document on the

administrative procedure in the event of a formal objection against a harmonised standard clearly specifies the role of the Standing Committee as well as the role of the sectorial committee of the directive concerned.

As indicated in this document, it is unnecessary to await publication of the references of harmonised standards in the Official Journal. It is possible, and even useful for a Member State or the Commission to inform the Standing Committee on probable major objections against a harmonised standard. Such an intervention could be useful even at the draft stage of a harmonised standard, particularly if the regulatory aspects are in danger of not being taken into account in an adequate manner. However, the Standing Committee cannot be used as an appeal authority.

In the formal and informal process mentioned above, the usefulness of the participation of "New Approach" consultants should be examined.

2.5 Sectoral services of the Commission

Generally, it is the task of the sectoral service to follow the mandated work that they have requested. ENTR-Standardisation unit is only involved in the follow-up of mandates at the level of the Technical Boards of CEN and CENELEC and ETSI Board and in financial matters when there is a grant agreement.

The Commission department originating a mandate has to follow its execution in close cooperation with the persons in charge of the European standardisation body and the "New Approach" consultant(s). It is advisable that a representative of this service follows the part dealing with the aspects of the directive and/or the mandate at the meetings of the technical committee concerned. Such a follow-up makes it possible to note the possible problems on this level at an early stage.

It should be noted that the sectoral service representatives of the Commission already participate actively in the periodic meetings mentioned in item 2.4 and in the meetings of the enlarged Standing Committee.

It has to be underlined that the sectoral services have to check if the terms of references of the mandate are respected. The checking system must be based on a continuous process throughout the development of the standards or alternative standardisation deliverables. It is up to the European standardisation bodies to ensure, where appropriate by asking the help of the "New Approach" consultants, that the harmonised standards cover correctly the regulatory requirements. It is therefore not necessary, as a general rule, for the Commission services to check the technical content of the harmonised standards (cf. the procedure to follow in case of a formal objection against a harmonised standard).

2.6 Service Level Agreement

The Service Level Agreement is concluded between the unit DG ENTR-Standardisation unit and Commission services initiating mandates in the case that the European standardisation bodies request the co-funding by the Commission for the mandated work. The objective of this document is to optimise the co-operation of these services. It aims to provide each of them with a clear understanding of the tasks related to the awarding of standardisation-related grants proposed by the European Standards Organisations and their follow up.

2.7 Availability of the texts of mandates

With the aim of better transparency of the mandates addressed to the European standardisation bodies, the Commission has established a database of mandates on the Internet in which the final texts of the mandates as transmitted to the European standardisation bodies are publicly available.

This database contains all mandates issued by the European Commission to the European Standards Organisations since June 2002. It also has a significant number of earlier mandates in the numbering system M/xxx. No mandates with other numbering systems are in this database.

From M/3xx onwards, the text of the mandates is available in English, French and German. The earlier mandates are at present available in English only, but the other linguistic versions will be uploaded in due course.

The availability of this information facilitates the follow-up of the work by all concerned parties.

Chapter II

Mission "To ensure that standardisation work progresses regularly"

This chapter relates to the administrative and organisational follow-up of the work. As in the previous chapter, a distinction must be made between ensuring the means, a task, which falls mainly on the Commission, and the actual task of administrative monitoring of work, for which European standardisation bodies are mainly responsible. The latter task has to be carried out as the follow-up of a project, to be executed within a certain time and according to a previously defined timetable. Techniques of project management and monitoring should be applied by the European standardisation bodies.

1. Basic elements of the administrative monitoring of work

As stated by the Council in its Resolution of 28 October 1999, this involves carrying out a task in close cooperation with the European standardisation bodies. In fact, the planning of standardisation work, as well as its follow-up, is actually carried out by the European standardisation bodies, which must set up the means necessary to achieve these goals and perform regular reporting. The European standardisation bodies have already taken several initiatives to improve this follow-up.

The Commission Report in the Council and in the European Parliament⁶ describes the efforts of the European standardisation bodies to increase their efficiency. In its Conclusions of 1 March 2002⁷, the Council welcomes the initiatives of the European standardisation bodies, particularly those related to reducing the time to produce standards.

Without wishing to intervene in the working methods of the European standardisation bodies, the following principles should be applied:

- the execution of a mandate should to be regarded as the execution of a project. Suitable tools should be applied for the management and monitoring of the projects (such as the detailed planning of resources, monitoring and evaluation);
- the programme of the European standardisation body concerned represents the basic element of the follow-up. This programme should indicate all the subjects forming the object of standardisation as well as the completion dates;
- the development of each individual standard should be regarded as the execution of a project, so a separate workplan should therefore normally be advised for each standard;
- a systematic use of IT is required to facilitate the planning of work and its follow-up.

These resources should also lead to a more transparent process of development of the standards process, making it accessible to all interested parties:

⁶ COM (2001) 527 final of 26.09.2001

⁷ OJ C 66 of 15.03.2002

- a certain degree of harmonisation between the three European standardisation bodies is desirable in the terminology used for the follow-up of the mandates as well as the presentation of the programmes and their state of progress (for example: the completion time of a standard). This should also make it possible to obtain consistent statistics;
- care should nevertheless be taken not to intervene in the specific working methods of each European standardisation body, in view of the autonomy of these organisations and the fact that they are responsible for the organisation of their own work;
- the technical and administrative follow-up of the stages has to go together with a financial follow-up of the grant agreement (if any) for the execution of tasks related to the mandate concerned and *vice versa*.

Recommendations L

1. *The execution of a mandate and the development of standards have to be regarded as an actual project. Therefore, the techniques of project management must be applied, such as work planning, active follow-up, the introduction of corrective measures in the event of problems and project evaluation.*
2. *The independence of the European standardisation bodies must however be respected. We should be aware that they are entirely responsible for the execution of the accepted mandates and for the development of the necessary standards.*

2. Measures to ensure the administrative monitoring of work

In principle it is advisable to use the same measures as already established for the follow-up when dealing with the contents and the standardisation activities (see Item 2 of the previous chapter). These measures comprise:

- the requirements given in the mandate (programme request, indication of the completion dates, regular reporting request);
- the use, if necessary, of *ad hoc* groups;
- the Standing Committee in its normal and enlarged configuration;
- the role of the sectoral services within the Commission.

The use of tools for the follow-up of projects should enable a clear presentation of the progress of standardisation work for all the interested parties.

If necessary, the Commission can examine in even greater detail, together with the European standardisation bodies, those measures that could be strengthened or set up in order to increase the efficiency of this administrative follow-up.

* * *

Annex 1

Tasks and responsibilities of the New Approach Consultants



CEN/CENELEC Guide 15

Tasks and responsibilities of the New Approach consultants

The present guide provides guidance on the tasks and responsibilities of the New Approach consultants working with CEN and CENELEC. It was approved by CENELEC BT decision D134/C056 and by CEN Resolution BT C072/2008.



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Tasks and responsibilities of the New Approach consultants

1 Scope

This document is the CEN/CENELEC guide on the tasks and responsibilities of the New Approach consultants working with CEN and CENELEC.

It deals with the:

- Role and profile of the consultant
- Main tasks and responsibilities of the consultant
- Consultant's involvement in the development of standards
 - Involvement from the time of the creation of the NWI
 - Comments at enquiry stage
 - Advice and comments following the enquiry stage
 - Formal assessment prior to formal vote/UAP
 - Resolution of disputes
- Selection of a new consultant
- Induction and introduction of a new consultant
- Handover from previous consultant
- Reporting and evaluation of consultant's work
- Treatment of complaints

2 Background

European Directives (hereinafter called directives) contain *essential requirements*. These essential requirements shall be fulfilled by the product before it may be placed on the market.

Standardisation work related to directives is described in Mandates to the ESO's.

European Standards provide a means for manufacturers to demonstrate conformity to the essential requirements of directives. Such European Standards are referenced as *harmonised standards*.

The relevant technical body of CEN or CENELEC is responsible for deciding which technical requirements will be included in a European Standard.

The references and titles of harmonised European Standards are published by the European Commission in the Official Journal of the European Union (OJEU).

The European Commission and EFTA request that CEN and CENELEC assess the conformity of all candidate harmonised standards to the relevant essential requirements of relevant directives.

CEN, CENELEC and the European Commission/EFTA appoint independent consultants to carry out this assessment and to provide assistance and guidance to the technical bodies developing these European Standards in relation to the relevant directives and their respective essential requirements. Mandates can influence this work in particular ways. Consultants may also explain some elements of the relevant Mandates.

Many harmonised European Standards are based on international standardization according to the Vienna or Dresden Agreements. In such cases the consultant shall also be consulted with the development of such standards.

3 Role and profile of the consultant

3.1 Role of the consultant

The consultant is responsible for assisting experts to prepare harmonised standards and provides the necessary recommendations, explanation and support in relation to the relevant directive(s) and the respective essential requirements.

The consultant shall be involved with the technical bodies from the earliest possible stage in the development of a European Standard at the latest when a working draft is available in order that his/her comments may be taken into account from the beginning.

When requested by a technical body, the consultant shall obtain clarification on the scope of the directive or mandate from the Commission.

The consultant shall examine if the work programme of the relevant technical bodies covers all aspects indicated in the related directives and mandates (i.e. essential requirements, product families...) and identify any gaps which may be bridged by standards.

The consultant is **not** responsible for deciding or choosing which technical requirements will be included in a European Standard. This is the responsibility of the technical bodies.

The consultant informs the technical body on the compliance of a draft standard with the provisions of the relevant directive¹⁾; during development of the draft from the creation of the work item, through the preparation of the draft standard, during the public enquiry and before the Formal Vote or UAP.

¹⁾ Directive has to be understood in its broad sense (e.g. TSI's in case of Railway Interoperability, RID/ADR/AND agreements in the case of dangerous goods, ...).

3.2 Competence of the consultant

A consultant is required to be impartial and independent.

In order to fulfil his/her tasks, the consultant shall have:

- a deep technical understanding of the field of work of the relevant technical bodies and a recent state of the art experience of the subject;
- extensive knowledge and experience of relevant directives;
- experience of developing and implementing standards;
- knowledge of the main rules (e.g. CEN/CLC Internal Regulations, ISO/IEC Directives, different timeframes within the drafting process);
- knowledge of the Vienna Agreement, Dresden Agreement;
- social competence/interpersonal skills.

4 Main tasks and responsibilities of the consultant

The consultant's main tasks and responsibilities are:

- to explain to the technical bodies the different elements of the relevant directive(s) and mandate(s), especially the essential requirements, as far as necessary;
- to give recommendations to the technical bodies during the development of a standard with the consistency of the draft standard to the relevant directive(s);
- to identify shortcomings in the technical requirements chosen by the technical body in relation to the essential requirements in the relevant directive(s), and where possible suggest remedies, noting that the responsibility for the choice of technical requirement remains with the technical body;
- to advise whether the work programme of the technical body covers all aspects indicated in the relevant directive(s) (i.e. essential requirements, product families, risks...);
- to provide formal assessments on draft standards prior to formal vote/UAP in relation to the relevant directive(s) as requested and strictly by the deadline requested by the central secretariat²⁾;
- to keep up to date with the latest developments of the directive(s) they are contracted for;
- to identify new standardization needs and check for duplication of work.

²⁾ In this document "central secretariat" refers to CEN Management Centre (CMC) and/or CENELEC Central Secretariat (CLC/CS).

In particular, the consultant **shall**:

- ensure that candidate harmonised standards comply with the relevant essential requirements laid down by the relevant directive(s). This activity is to be maintained for the entire duration of the development of the standard, at the latest starting with the first working draft, during the enquiry (prEN) and before the formal vote/UAP;
- comment on all draft standards under his/her responsibility during the Enquiry Stage;
- give a formal assessment to all final drafts prior to the Formal Vote/UAP under his responsibility;
- check each draft standard, that is under his/her responsibility and that is in support of directive(s), for the existence and the contents of an annex (Annex Z) giving the relation between the standard and the essential requirements in the relevant directive(s);
- by mutual agreement attend meetings of technical bodies;
- be available to the European Commission (usually DG Enterprise and Industry) and the relevant Standing Committee(s) for questions related to the preparation of the standards;
- co-operate and co-ordinate with other consultants who are advising the technical body in relation to other directives or aspects of directives;
- co-operate and co-ordinate with the central secretariat for the setting of work and priorities;
- identify the need for formal assessment of draft standards by consultants responsible for other sectors.

Additionally the consultant may:

- help the technical body to identify new harmonised standards to be prepared;
- give recommendations to technical bodies in the light of what standards are being prepared or are planned in other technical bodies in order to avoid duplication of work and contradictions;
- be asked to support the central secretariat in tasks related to standardization in the field of his/her competence;

5 Consultant's involvement in the development of standards

A flowchart in Annex A is outlining the procedures described in this clause.

Each time a standard is drafted in the framework of the Vienna Agreement, the guidelines for the implementation of the Vienna Agreement apply for the involvement of the consultant.

For standards drafted in the framework of the Dresden Agreement:

- CENELEC/CS asks for the formal assessment from the consultant at CDV and FDIS stage for all projects associated with directives;
- In order to allow possible "corrective" action at IEC level, it is recommended that CENELEC should also ask an informal advice from the consultant on the CD;
- When there is a CENELEC technical body mirroring the IEC activities, it is the responsibility of this body to manage the alignment of their (upcoming) standards to the ERs of the directive. This includes possible requests for informal advice (e.g. on CD) from the consultant;
- When there is no CENELEC technical body mirroring the IEC activities - and as a support to the Reporting Secretariat – CENELEC/CS would in the future also ask for the informal advice from the consultant on the CD³⁾.

5.1 Involvement from the time of the creation of the NWI

The consultant shall be involved with the technical body , e.g. by giving written comments or attending meetings, from the earliest possible stage in the development of a European Standard and at the latest when a working draft is available in order to provide advice to the technical body in relation to the essential requirements of the directive(s).

5.2 Comments at enquiry stage

The central secretariat ensures that all relevant draft standards that are submitted to the enquiry⁴⁾ are given to the respective consultant(s).

The consultant(s) shall provide comments to the relevant technical bodies on **all** draft standards submitted to enquiry under his/her responsibility.

The technical body shall then take into account the consultant's comments along with all comments made as a result of the enquiry in order to further develop and consolidate the technical requirements contained in the draft standard.

5.3 Advice and comments following the enquiry stage

Following the closure of the enquiry the technical body reviews all comments received, including those from the consultant, and revises the draft standard accordingly.

If agreed by the technical body the consultant receives the resulting revised draft standard and further versions as necessary and provides additional comments and guidance to the technical body.

The goal of both the consultant and the technical body should be to achieve a final draft standard that when presented for formal vote or UAP will receive a positive assessment from the consultant.

³⁾ EMC issues are exempted, as these are duly coordinated through installed provisions by CLC/TC 210.

⁴⁾ For standards being developed in parallel by IEC/CENELEC under the Dresden Agreement commenting at the CD stage might be appropriate.

It is important that the technical body and the consultant work together efficiently at this stage to avoid introducing delays into the development timeframe for the standard.

To support this aim the technical body is advised to provide the final draft standard to the consultant for 'informal assessment' and take into account the consultant comments before submitting revised final draft to the central secretariat to launch the formal vote or UAP.

5.4 Formal assessment prior to formal vote/UAP

When the technical body decides that a draft standard is sufficiently mature and that there is consensus within the technical body on its technical content, it sends the draft standard to the central secretariat for submission to formal vote or UAP.

The rules require that all relevant consultants formally assess the draft standard prior to the launch of the vote.

The formal assessment provided by a consultant establishes the clear and unambiguous opinion of that consultant on whether or not the draft standard, if adopted as a European Standard, would adequately provide presumption of conformity to the addressed essential requirements of the relevant directive(s). (Template to be found on CEN BOSS and CENELEC TISS servers).

The consultant's decision to give a positive or a negative assessment shall be based **solely** on whether or not the technical requirements presented in the draft standard would provide an appropriate means of conforming to the essential requirements of the relevant directive. The consultant may have general and editorial comments on the draft standard but these shall not contribute to the result of the assessment.

In particular the consultant checks the information contained in the Annex ZA (for CEN) or Annex ZZ (for CENELEC).

The consultant shall provide the formal assessment within the set timescale⁵⁾.

When all the consultants' assessments of the draft are positive, it will be submitted for formal vote/UAP (however, see 4th paragraph of 5.5). With such a positive assessment the consultant supports that the European Standard when ratified, is submitted as a Harmonised Standard for publication of its reference in the Official Journal of the European Union under the directive(s) under which it has been assessed.

If one consultant submits a negative assessment on the draft standard, further processing is suspended, the vote is not launched and the draft standard is returned to the responsible technical body along with the negative assessment of the consultant.

The technical body (chairperson, secretary, the WG convenor and WG secretary, Reporting Secretariat, as appropriate), shall then consider the reasons given by the consultant for the negative assessment along with any proposals provided by the consultant to resolve the comments. This might imply a dialogue with the consultant.

The technical body should seek, and the consultant must provide, any clarification and explanation of the comments that lead to the negative assessment and the necessary solutions.

⁵⁾ 28 days for CEN. The consultant is given the "voting period minus 1 month" to provide his/her formal assessment in due time to CENELEC.

Subsequently, following resolution of the comments made by the consultant in the negative assessment the technical body may submit a modified draft standard to the central secretariat which then requests new assessments from all relevant consultants.

The consultants shall refrain from raising any new issues or concerns in any second or subsequent assessment of a draft standard.

Only when all the assessments of the draft standard by of all consultants involved (multiple directives) are positive, shall it be submitted for vote.

If, however, the technical body and the consultant cannot agree on how to resolve a negative assessment then one or both parties should seek to resolve the dispute as foreseen in 5.5 (Resolution of disputes).

At all times the technical body and the consultant shall work together to find agreement, whilst respecting each other's particular roles and responsibilities.

5.5 Resolution of disputes

It is important that technical bodies and the consultants work together to find appropriate agreement on the wording of draft standards. Either party can contact the central secretariat for help and guidance at any time on issues and points of difference.

In the rare instances when a consultant and a technical body cannot agree on how to resolve a negative assessment on a draft European Standard, the technical body or the consultant shall elevate the issue to the Technical Board for decision.

In this case, the consultant and/or the technical body should raise the matter with the central secretariat that will obtain the necessary positions of both parties and present them to the Technical Board with a proposal on how to proceed to facilitate the further development of the draft standard.

The often quoted "veto"-right of the consultant does not exist. As an outcome of the discussion within the Technical Board the final draft might be send to formal vote as agreed by the technical body while not adopting the consultant's comments given at the negative assessment.

There is no mandatory obligation for the technical body to adopt all comments given by a consultant.

N.B.: The Commission or the Member States may raise a Formal Objection if they consider that the standard does not comply with the essential requirements. This may end up in stopping the referencing of the standard in the OJEU.

6 Selection of consultants

CEN and CENELEC are responsible for managing the selection procedure to appoint a consultant.

The European Commission and EFTA participate in the selection process along with the central secretariats of CEN and CENELEC and representatives of the sector and/or technical bodies.

For each field the central secretariat of CEN or CENELEC launch a “call for candidates” to initiate the selection procedure. The national members publicize the calls e.g. to national (mirror) technical bodies and/or on web sites and/or in national publications.

Applicants are asked to submit details of their knowledge and experience of the relevant directive(s), the development and application of relevant standards and the daily remuneration rate sought.

The central secretariats manage the selection process consulting the

- European Commission,
- EFTA Secretariat,
- Sector representative,

and review the applications using the criteria given in 3.2, prepare a shortlist of applicants, interview selected applicants and decide the final choice of a consultant.

CEN and CENELEC appoint consultants initially for one year, renewable annually. After four years the central secretariats must launch a new call for candidates for each consultant position. Currently individual consultants must not be contracted for more than eight years in total.

7 Induction and introduction of new consultants

Following the appointment of a new consultant the central secretariat ensures that he or she is given the appropriate information in order to perform the role as a consultant and is introduced to the technical committees for which he or she will be responsible. Important information relating to discussions and decisions on draft standards in preparation is made available to the new consultant, including feedback from the previous consultant.

7.1 Induction

The central secretariat ensures that the new consultant receives information about:

- the role of a consultant and his/her rights and duties;
- the working procedures of a consultant and relevant deadlines given for his/her work;
- details of the technical bodies and their work programmes for which the new consultant will be responsible (including access to relevant database tools);
- the contact details of the technical body secretaries;
- contractual reporting requirements.

In particular, the central secretariat provides pertinent information in the form of a ‘handover dossier’ (see Clause 8).

The provision of information about outstanding negative assessments is essential to allow the new consultant and the responsible technical body to resolve the issues raised in the assessment in the most efficient manner.

If possible and appropriate the central secretariat tries to ensure that the new consultant can meet with the outgoing consultant to achieve a good handover of information and knowledge.

The central secretariat arranges (a) meeting(s) with other consultants (if any) working under the same directive. A common understanding of the consultants' tasks and responsibilities, especially of the relevant directive and the respective essential requirements should exist among the consultants working under the same directive.

7.2 Introduction to technical bodies

The central secretariat ensures that the relevant technical bodies are informed of the appointment of a new consultant at the earliest moment, including the date when the new consultant will begin work (and take over from any outgoing consultant), his/her contact details and any other information that will enhance the smooth introduction of the new consultant to these technical bodies.

As stated above, the central secretariat provides the new consultant with relevant information about the technical bodies, their work programmes and the contact details of the technical bodies secretaries.

The central secretariat facilitates initial contact between the new consultant and the technical bodies in accordance with the priorities dictated by the work programme, including outstanding negative assessments and the status of draft standards.

The central secretariat helps the new consultant to establish an initial list of missions that the consultant will undertake in order to address the priority issues and also to introduce him/herself to the technical bodies.

8 Handover from previous consultant

Whenever possible, the central secretariat tries to ensure that the outgoing or previous consultant provides a 'handover dossier' which will be given to the new consultant to help him/her to assume responsibility for the relevant work programme with the fullest knowledge of the current status of discussions and the history of relevant agreements and decisions.

Before the contract of the outgoing consultant expires, the central secretariat asks the outgoing consultant to provide a 'handover dossier' which shall include details of:

- all comments and assessments made by the outgoing consultant on draft standards that have not been adopted as European Standards at that time;
- a full and clear explanation of the basis and justification for all outstanding negative assessments;
- details of any draft standards undergoing public enquiry for which the outgoing consultant has not yet provided comments;
- particular issues, positions and agreements that were made during the development of currently adopted standards that would be essential for the new consultant for future revisions or amendments of those standards;

- 'horizontal' issues relevant to the field covered by the directive, or the technical bodies for which the new consultant will be responsible;
- particular decisions and/or policies made by the relevant EC committee of the directive.

The central secretariat provides the 'handover dossier' to the new consultant and provides additional information and support for his or her understanding, as necessary.

The incoming consultant should respect any former positive position and decision taken by the outgoing consultant on any ongoing draft work, in order not to unnecessarily delay the work.

9 Reporting and evaluation of consultant's work

9.1 Reporting

Every four months the consultant shall submit activity reports on the templates provided to the central secretariat based on the contractual requirements.

9.2 Evaluation of consultant's work

Towards the end of each annual contract the central secretariat carries out an evaluation of the performance of a consultant over the period of the contract and provides it to the European Commission/EFTA together with a recommendation on whether or not the consultant should be offered a new contract (in accordance with the overall timescales, see Clause 6).

The central secretariat monitors the development of harmonised European Standards and the performance of a consultant, in particular the:

- adherence to the planned timescales for provision of formal assessments;
- the provision of comments during the public enquiry;
- positive and negative assessments;
- compliance with Clause 4 of this Guide.

The central secretariat also takes into account the ongoing monitoring of progress of the relevant work programmes and feedback from technical body officers, other players in the standards system and organizations participating in the development of European Standards.

10 Treatment of complaints

Whenever there are complaints from either side (the consultant or the technical body) these shall be brought to the attention of the central secretariat. The central secretariat shall then try together with the involved parties to solve the problem.

Annex A Flowchart

