

Reform of European Standardization Procedures
Requirements of constitutional and European law
upon standardization through private bodies

Résumé

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with the financial support of the German Bundestag
(Technology Assessment Bureau) and the European Commission

Darmstadt / Cologne
September 1995

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Foreword

This paper summarizes the principal findings of a research project performed with the support of the Technology Assessment Bureau of the German Bundestag and the Commission of the European Communities. We have chosen to issue this résumé in English, French and German in order to permit a broad debate at the European level on the reform of the standards process.

The study summarized here makes no claim to setting the keystone in a new vault of European standardization; to be appreciated as a milestone on the path towards reform in pursuit of a vibrant democracy and a free constitutional state would be success enough.

In this matter, a crucial role can devolve upon the parliaments - both national and European. If the representation of the people should come to view the democratic crafting of processes of technological change as a part of its task, then it will of necessity find that it must devote greater attention to the workings of private standardization bodies.

Dreieich, in the September of 1995

Martin Führ

I. Introduction

Modern industrial society is inconceivable without technical standards. Almost all industrially manufactured things around us have been standardized in some way or another. It is thus no exaggeration to say that technical standards decisively stamp the face of modern society: In day-to-day practice, it is not so much the stipulations of law rather than these very technical standards that determine how a product is made (materials composition, form, various technical requirements, disposal-related issues), and in what manner polluting facilities are operated (design of manufacturing plant and its components, emissions and their monitoring). Such a standard is therefore more than just "distilled technical expertise" - it always also represents a binding decision as to whether and how society shall go ahead with a structuring of technology that is socially equitable and environmentally acceptable, and as to the manner in which the issue of the opportunities and risks associated with a specific technology is addressed and alternatives are debated.

But the process of standardization has until now maintained a very low profile, not to say a secretiveness - it has at all events eluded any broad public participation. The actors in this process keep to themselves. Only the lobbyists with a vested interest in a specific project have a say. Experience has shown that particularly at the European level lobbyists use the standards process to exert political influence upon EC legislation. Jacques Repussard, the Secretary-General of the European Committee for Standardization (CEN), postulates in his standard work "Common Standards for enterprises" (Luxembourg 1994), published in a second edition in 1995, that the standardizers have the "requisit maturity" to orient their decisions not solely to their particular interests, but also to societal considerations. Past experience, however, has failed to bear this out.

That this process permits lobbying at all is partly because standardization has long been defined and accepted as being a part of self-regulation of industry. A further reason is that the political dimension of standards has failed to be fully appreciated. The public seems to notice them only when they are absent or inadequate, typical examples being the continuing absence of a Europe-wide electric socket, or the continuance over many years of an unsatisfactory safety standard for climbing ropes.

While industry has always understood standardization to be its province, the history of the efforts of other circles and groups in society to play a role in the standardization process is short and quickly told. Among these, consumer representatives were the first to enter the arena. Their access was already debated twenty years ago and in Germany institutionally established through the

setting up of a consumer advocate council under the umbrella of the German standards body DIN. At the European level, however, consumer interests have only found representation since the middle of the 1980s. At the end of the 1980s, the labour unions finally raised their voice, demanding consideration in European standards of safety, health and hygiene at the work place. In 1994, small and medium-sized enterprises (SMEs) finally started taking an active interest in the standardization process. Last of all were the environmental associations: It was not until the end of 1994 that a first meeting came about between their representatives and the actors involved in European standardization (in this case the European Commission and CEN/CENELEC).

This is none too soon, for the import of standardization has been growing fast in recent years: More and more, European standardization is coming to replace that of individual states. To this end, the European Commission has conferred upon the European Standards Organisations (CEN, CENELEC, and ETSI) "general powers" to develop European standards and technical specifications. While standards documents drawn up by private bodies are in principle defined as being non-binding, they are in many cases linked to binding sovereign legal instruments, thus acquiring much more weight: The Community not only uses standardization in support of its technical legislation enacted under the "New Approach", but also in other areas, such as public procurement. The European Commission further issues so-called simple standardization mandates to supplement existing legal instruments (e.g. in the field of biotechnology and genetic engineering).

The standardization activities undertaken at the European and national levels have thus steadily become ever more complex - in both their legal and societal aspects. If the EC now increasingly only stipulates the framework of a Directive and leaves the formulation of the details to the standardizers, then this in effect shifts decision-making powers from the parliamentary legislator to private standards-making bodies. What makes this enormous increase in the powers of private bodies particularly problematic is that, until now, it has not been balanced on the structural side by a correspondingly strengthened representation of public-interest and environmental concerns. The legal and political debate on how to address properly this "delegation" to non-governmental organizations of the power to stipulate qualitative and quantitative requirements has, however, now come under way.

II. Appraisal method: Criteria for the design of procedures compatible with the rule of law

The question that arises is this: Which substantive and procedural arrangements must be made in order to reflect adequately public-interest concerns in the standards process? When trying to find a response to this question, the authors of this study found that before proposals for reform can be formulated at all, criteria must be developed by which to appraise this process. These criteria are derived from primary EC law, and German constitutional law.

In a first step, the authors delineate the requirements following from these two bodies of law upon the structure of standardization procedures, and develop these to legal appraisal criteria. The methodology used here is oriented to the approach developed by *Roßnagel et al.*, and transposes this from material demands upon technology development to the procedural side of technology regulation. The method breaks down into four stages, and is termed "Concretization of legal requirements upon technological development proposals", COLE ("*Konkretisierung rechtlicher Anforderungen zu technischen Gestaltungsvorschlägen*", KORA). The method is not, in principle, so much concerned with legally binding legal criteria, but rather with a technological development that is compatible with the requirements of the law. This need not exclude the possibility that, in certain constellations, the criteria also mark out the dividing line to illegality. The purpose of the method is not, however, to define this line, but to stipulate criteria for the development of technical systems.

The authors thus expressly note that while the formulated criteria are derived from (constitutional) law, an infringement of these criteria must not necessarily be given the verdict of "unconstitutional". The criteria rather set guideposts to which a "constitutionally compatible" structuring of procedures should be oriented. Or, as *Roßnagel* puts it:

"Legal statutes are stipulations of the democratic sovereign. These statutes carry the highest authority possible in a democracy. They are an expression of the striving of our society to take, in a conscious process, its development into its own hands, rather than leaving it to anonymous powers. Legal statutes draw their substance from the regulatory idea that the public good must be put forward and defended against particularist interests. It is in the service of this idea that the law wards off unconscionable encroachments upon freedoms, protects disadvantaged interests, sets out the goals of social order and development, and offers rules by which conflicts can be resolved. These functions of the law are also - and indeed particularly - requisite in the light of the capacity of technology to change the world. It is the law that is entrusted with the task of protecting those interests and values which we do not want to see jeopardized despite dynamic technological development."

It is with this in mind that the authors of the study have derived requirements for the standards process from fundamental constitutional rights, other constitutional

principles and Community law, and have further developed them to form criteria for legal appraisal. Their observance would ensure that the process of private standardization is made democratic, transparent and fair, satisfying the requirements of due process and the rule of law, and thus realizing not only interests of an economic nature, but also public-interest concerns (health, environment and consumer protection).

Criteria for legal appraisal of standardization procedures of private bodies;

On the basis of fundamental constitutional rights, other constitutional principles and Community law the following requirements for the standards process can be derived.

1. Procedural structure

- a) Timely participation of all interested circles
- b) Screening of environmental and health relevance
- c) Particular procedural rights for the minority

2. Balanced composition

- a) Pluralism of interests
- b) Pluralism of perspectives
- c) Capability of participants to formulate an opinion through provision of resources
- d) Competent representation of even "diffuse" interests

3. Transparency

- a) General availability of information on current state and further schedule of procedure
- b) Documentation of decision-making
- c) Explanation of specifications made
- d) Documentation of dissenting votes

4. Review of results

- a) Periodic review of conformance with public interests
- b) Specific testing in individual cases

5. Continuous adjustment

- a) Right to initiate review
- b) Periodic review

III. Standardization practice in Europe

In the second section of their study, the authors show how complex a process the formulation of a European standard is. As the necessary groundwork for the application to the standards process of the above appraisal criteria, they initially give a status-quo analysis of the current process. Here they delineate the content and objectives of the standards process as pursued by private bodies, and then sketch the work of the principal European Standards Organisations, CEN and CENELEC. They show that, according to the definition recognized by the International Organization for Standardization (ISO) and the UN Economic Commission for Europe (ECE), the goal of standardization is to give "maximum benefit to the public" - this would indeed suggest that the issuance of standards should not only be driven by the interests of industry, but at least equally by other public-interest concerns, too.

In practice, however, this is by no means the case: There is a glaring lack of adequate procedural structures that might ensure that public-interest concerns - environment, health and intergenerational equity - receive adequate representation. This is confirmed by the analysis of two case studies of standardization mandated by New Approach legislation (namely the EC Building Products and Packaging Directives).

The authors selected these two Directives for exemplary examination because both explicitly name the objective of "environmental protection", and because practical experience is already available with both at the various stages of procedure. The application of the appraisal criteria to the two procedures reveals that both fail to satisfy most of them, partly or completely. As regards the specific situation of environmental associations, the authors find that these have until now only made little experience with European standardization, and that wherever they are or have been involved, the assessments of the process are largely negative. One cause for this is that the representatives of the environmental side are generally not viewed as interested circles with an institutionalized claim to participation. Indeed, they are viewed as "troublemakers" who unsettle the established balance in the interplay of forces between conventional standardization interests. In the case of European standardization on packaging in particular, it became apparent that standards processes at the European level have a distinctly informal character, and that the procedure itself is determined less by expertise than by political and strategic orientations.

IV. Conclusions for the strengthening of environmental concerns

The implications of the above analysis for any successful participation of environmental organizations, or the successful transport of environmental concerns into the standards process, are:

1. An effective participation of the representatives of environmental interests needs formally secured procedural rules, to which these representatives can refer without having to struggle for them every time anew.
2. The environmental organizations must be adequately prepared and "equipped" with physical resources, information and staff, if they are to be able to participate and hold their ground in the complex decision-making network of European standardization.
3. Within the environmental organizations themselves, the organizational and political preconditions to an effective participation in standardization work must be created. The current European umbrella structures are neither organizationally nor procedurally in a position to ensure an appropriate and regular input to the process. As standardization activities also have a highly political character, the environmental organizations must enter into an intensive debate on whether and under which conditions they are politically prepared to enter the standardization arena.
4. The less the participation of environmental advocates is perceived to be the particular interest of a single organization, the more success it will have: The likelihood that environmental interests can be enforced rises greatly, if environmental representatives from the competent public authorities participate together with the environmental associations.

The two case examples led the authors to a further, pivotal finding: In European standardization, beside the actual standards process within the standards-making bodies, the so-called "political" level is of great import. The Directives themselves already embody substantive and procedural preliminary decisions that set the course for the further standardization work. Very early on, i.e. before the standards process as such actually commences, preliminary decisions are taken in the form of "basic requirements", "basic documents", or "standardization mandates". Here EC committees are partly involved. Environmental representatives must be placed in a position to influence already these preliminary decisions. The likelihood that environmental aspects receive more consideration in the standards process then rises greatly.

V. A model for reform

To remedy the deficits that they found, the authors formulate a model for reform. The aim of this model is to give greater weight to public-interest concerns and to allow transparency and democratic control, without, however, overburdening the procedure or overstressing the resources of the actors on the public-interest side. The intention is not to put forward a comprehensive concept for revision of the process in every detail. The authors are rather concerned with the fundamental elements of reform. The proposals are guided by the following precepts:

- The direct responsibility of the participants in the standards process should be maintained, and reinforced with due regard to the public-interest concerns touched upon in the particular procedure.
- The established course of the standardization procedure should be altered as little as possible. The proposals are based on the existing structures.
- The stipulations concerning the course of the procedure and the forms of participation are geared to creating a transparent structure. This benefits the whole standards process.
- There should be no institutionalized external control of non-mandated standardization work. Instead, internal review is to be accorded greater weight.

The analysis focuses on the European level. The proposals thus initially address that level. The national level, however, can by no means be excluded, for the principle of national representation provides that the individual national positions put forward in the European Standards Organisations are defined at the national level. It is thus of crucial importance that public-interest aspects already find representation in the standards process at that level.

A. Modification of the standardization procedure

The authors put forward a series of modifications to the standardization procedure. The most important of these are:

1. Each standardization procedure could commence with a "screening stage". This would serve to institutionalize a form of "ascertainment of public-interest relevance" within the body concerned (Technical Committee, Working Group etc.). The members - recognized experts in their fields - would be obliged to apply their expert knowledge to examine whether and in what degree public-interest concerns are affected by their standardization project.

As a tool for this, an examination catalogue could be drawn up that is applied, as a matter of principle, to all procedures. In order to avoid burdening the procedure with a variety of different catalogues, a unified catalogue should be used that covers all the public-interest concerns. This could then be supplemented for certain areas of standardization by more specialized catalogues, such as the current draft ISO Guide for the Inclusion of Environmental Aspects in Product Standards (ISO/CD 10060; soon to be ISO Standard 10060). External actors to whom the outcome of the screening has been made accessible could then more easily assess the public-interest relevance of individual standardization projects, and decide more rapidly on the form their participation is to take. The authors are aware that a screening stage entails an increased workload. They argue, however, that a timely integration of public-interest aspects is well worth its while - not only because it benefits the standards process itself, but also because it improves the social acceptance, and in particular the marketing, of products and services conforming with the thus drafted standard.

2. Furthermore, in the interests of transparency, a general access to working documents and to work scheduling should be introduced. This would albeit mean a departure from the previous obligation to maintain the confidentiality of working documents. On the other hand, however, procedural and substantive deficits could then also be revealed by such actors that are not directly involved in the standardization procedure. This would make it possible to introduce points of criticism at an early stage in the work programme, and actors not involved until then would be able to decide whether and in what form they wish to participate in the procedure.
3. In the event of disagreement over an issue, the minority should have the right to formulate a dissenting vote.
4. The course of standardization work should be documented and published. This should include the list of participants and their professional affiliations, and the main considerations that have led to the final specifications. It should further describe the outcome of the screening stage, and the way in which the points raised in that stage were taken into consideration in the final standard. The dissenting votes and the debates on the positions voiced therein are also a component of this documentation.

B. Institutional changes

On the institutional side, the authors propose the following measures (see also the schematic at page 14):

1. The European and national standards bodies should establish - as already done by the German standards institution DIN in the form of its *Koordinierungsstelle Umweltschutz* - internal environmental coordination bureaus (Coordination Office for Environmental Protection - CO-EP). These would be charged with, inter alia, identifying environmentally relevant standardization projects, and working towards the realization of environmental requirements in these projects through ensuring the implementation of the corresponding procedural and substantive rules. This is in fact a task already entrusted to the "Environment" Working Group within CEN Programming Committee 7 - but as the group is expected to pursue the whole range of environmental concerns in practically every standardization project, its failure is a foregone conclusion.
2. The representatives of the European environmental protection associations should receive a formal observer status ("associated member") in the European Standards Organisations (CENELEC, ETSI and CEN). They would thus be able to attend in an advisory capacity the sessions of the Technical Committees and Sub-Committees, and also to participate in the work of the Programming Committees and Sectoral Technical Bureaus.
3. In order that the environmental organizations can participate at all in a qualified manner in the standards process, they must receive the physical resources requisite for such participation. While suitable arrangements already exist for the consumer associations and the labour unions, the environmental side has until now been deprived of such support. To create appropriate structures, the authors propose the following arrangement: The Community should provide the funds necessary to establish a European technical coordination bureau of the environmental organizations ("TEB" in the schematic, page 14), and to permit an input from outside experts. The European bureau must be complemented by technical bureaus at the national level in order to ensure a feedback to the debates in the individual Member States. This is essential to guarantee that environmental concerns play their part in the definition of the individual national positions represented in the standards process, and thus influence the decision-making in the European Standards Organisations.

C. Standardization mandated by New Approach legislation

The above elements of reform should - in view of the high factual importance of standards in the regulation of both the development and application of technology - be applied, as a matter of principle, to all standardization projects at the European level. Insofar as there is, however, a particular link to legal instruments of the European Communities (i.e. within the "New Approach" or in

standardization work mandated by the Community that has a particular relevance to the realization of the goals of Article 130r of the EC Treaty), the authors propose additional reforms within the EC institutions (i.e. at the political level):

1. Following existing models in other fields, such as in health and safety at the work place, a "Advisory Board for Environmentally relevant Standardization" (AB-ES) constituted on a basis of parity should undertake a "monitoring" of the course and outcome of the standardization procedure. This committee would be charged with accompanying the whole standardization process - from the preparatory consultations, over the formulation of the mandates, through to the evaluation of whether the standardization process and outcome conform to the stipulations of Community law and the standardization mandate. This should place the various social groups in a position to participate, within an institutionalized regulatory body and in all relevant phases, in the debates on subject and content of the standardization process.
2. The authors also consider the involvement of the European Parliament to be called for where the above link is given. It should be examined in each individual case whether the intervention of the standards organizations is really necessary - in the light of the democratic principle that fundamental decisions should be taken in the form of Community legal instruments. If this examination should show a - partial - delegation to the European Standards Organisations to be indispensable, then the loss of decision-making power of the Parliament would have to be compensated by disclosure requirements upon the European Commission. These requirements would cover the agenda and course of debate in the committees, the planned standardization mandates, the content of such mandates, and a presentation of the possibilities to make opinions heard.
3. As the European Commission has until now refused to examine the conformity between the stipulations of Community law and those of the standardization documents, the authors demand a formal evaluation of conformity. This should examine both the observance of procedural rules, and the implementation of substantive stipulations. The authors note that the evaluation criteria must, on the one hand, leave enough leeway for standards specifications that allow technical and functional innovation, while on the other hand safeguarding the adequate consideration of relevant public-interest aspects.

D. Implementation of the reform model

In order to transpose into law the elements of reform described above, one necessary measure is the amendment of the EC Treaty: Beside the future role of the European Parliament, it must also be established that "substantial" decisions must be taken by the institutions of the Community and not by private standards bodies. Criteria determining under which conditions a delegation is permissible must be enshrined in the Treaty.

At the level of secondary Community law, the authors suggest that a legal instrument be enacted which implements the elements of the reform model. As the purpose is mainly to define procedural requirements at the Community level, this can only take the form of an EC Regulation pursuant to Article 189, para 2 of the EC Treaty. The enactment of a Standardization Regulation would create a binding instrument giving guidance to all actors - including those in the Community institutions. The content of the Regulation would be concerned with general requirements upon the course of the standardization procedure, and substantive requirements upon environmentally relevant standardization in fulfilment of the stipulation of Article 130r, para 2, sentence 3 of the EC Treaty that "environmental protection requirements must be integrated into the definition and implementation of other Community policies". As a minimum, it should be determined that, with respect to environmental protection, standards must comply with a certain level of protection (such as the "high level of protection" cited in Articles 100a, para 3, and 130r, para 2 of the EC Treaty), and must observe certain material points. Further points of regulation should be:

1. The introduction of a mandatory "screening stage".
2. Creation of transparency of course and outcome of the procedure (establishment of a publicly accessible information system, documentation of decision-making, obligation to state reasons for decisions).
3. Participation rights for public-interest advocates at the European and national levels; here the framework conditions of institutional support must also be addressed.
4. Establishment of Environmental Coordination Bureaus within the standards bodies, at both the European and national levels.
5. Introduction of an evaluation of conformity (of standardization to Community law and mandates) within the standards organizations, whereby this must also be accessible to public-interest advocates.

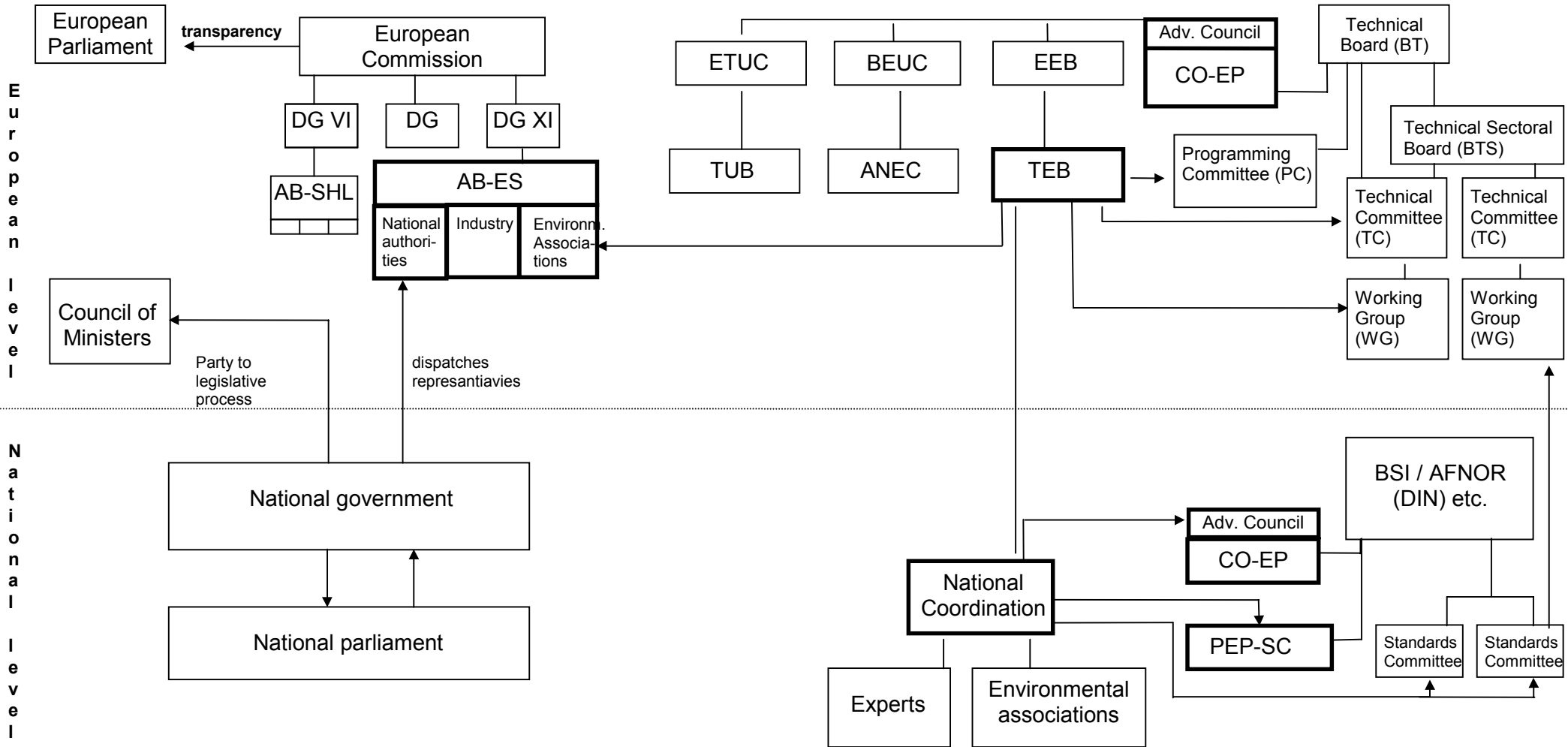
6. For environmentally relevant standards mandated by the European Commission, an Advisory Board for Environmentally relevant Standardization (AB-ES in the following schematic) should be set up; this would, inter alia, cooperate in the formulation of mandates and in the evaluation of conformity.

In a further step, the procedural and substantive requirements proposed at the level of Community law would have to be transposed by the standards organizations into their internal articles. This transposition should take place through the rules of procedure of the European Standards Organisations, and the rules of procedure of the national standards bodies.

„Political“ institutions

Public-interest representatives

Standards Institutions



AB-SHL: Advisory Board für Safety, Health and Protection of Labour
 AB-ES: Advisory Board for Environmentally relevant Standardization
 BEUC: European Bureau of Consumer Unions
 DG: General Directorate
 ETUC: European Trade Unions
 EEB: European Environmental Bureau
 CO-EP: Coordination Office for Environmental Protection
 PEP-SC: Principles of Environmental Protection Standards Committee
 ANEC: Technical Coordination Bureau of the Consumer Unions
 TUB: Technical Coordination Bureau of ETUC
 TEB: Technical Coordination Bureau of the EEB

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 (with support by the European Commission)
 in collaboration with U. Brendle (nova-Institut)

**Overview of actors and institutions
 in the process of European standardization**

Reform Proposal
 by M. Führ / ELNI

VI. Concluding note

With the reform model formulated here and its legal implementation, we can not claim to fully remove all existing constitutional and democratic deficits. Compared to the status quo, however, the realization of the proposed reforms would provide significant improvements. While this would not on its own ensure the independent representation of environmental and other public-interest concerns at all levels and in all areas, it would at least introduce the rudiments of greater "self-regulation" and "self-binding" of the other actors, and would permit the representatives of environmental protection interests to give a regular and qualified input to particularly relevant standardization procedures. As the reform debate, in Germany just as in the other European states, is as yet at a relatively early stage, further probing - such as an in-depth comparative legal study - into the issues touched upon in this paper is called for before a final position can be formulated on the type and extent of the necessary reforms.