Kommission
Arbeitsschutz und
Normung

30e

Accreditation of testing and certification bodies

Verein zur
Förderung
der Arbeitssicherheit
in Europa

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KAN Report 30e

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1 About this report

The Commission for Occupational Health and Safety and Standardization (KAN) was founded in 1994 to assert German interests in OH&S matters, especially with regard to European standardization. KAN is composed of representatives of the social partners, the federal state and the Laender, the Hauptverband der gewerblichen Berufsgenossenschaften (HVBG, German federation of institutions for statutory accident insurance and prevention) and the German Standards Institute (DIN). One of KAN´s tasks is to focus the public interests in the field of occupational health and safety and to exert influence on current and future standardization projects by delivering opinions on specific subjects.

KAN procures studies and expert opinions in order to analyse occupational health and safety aspects in standardization and to reveal deficiencies or erroneous developments in standardization work.

This study was based on the following task in hand:

1.1 Background

A precondition for a properly functioning European Single Market is the elimination of barriers to trade. The free movement of goods within the European Union can be impaired by differences in national regulations and testing, certification and surveillance procedures. Confidence in the technical competence, capability, impartiality and integrity of bodies performing conformity assessments is of great importance for the Single Market and also for relations between the EU and third countries. This is true both of the area subject to statutory regulation and that not subject to such regulation. The accreditation of bodies conducting examination, calibration, certification (of products, quality systems and personnel) and inspection is to be regarded as a confidence-building measure for industry and public bodies. Accreditation procedures, i.e. the formal and technical assessment and recognition by an authority or for that matter by a private body of the competence to perform special tasks, continue to exhibit substantial differences at national, European and international level. The ongoing development of international standards and their consistent application is therefore of great importance in this area. It must be ensured, however, that the standards do not contravene requirements resulting for example from EU Single Market Directives.

Council Decision 93/465/EEC gives rise to a presumption of conformity with the requirements of the EU directives provided testing/certification bodies meet the requirements of the harmonized standards. At present, the Member States apply supplementary criteria for the designation of bodies, in addition to EN 45000.

In order for the presumption of conformity to be created in fact, standards are therefore required which fully cover the requirements of the directives, are harmonized pursuant to the directives, and are published in the official journal.

In addition, it is desirable for international agreement to be reached with regard to these requirements. Once this has been achieved, the mutual recognition of conformity assessment bodies designated by the Member States enshrined in statute in the agreements between the EU and third countries (MRAs) and the protocols governing the mutual recognition of conformity assessments between the EU and the candidate countries for EU membership (PECAs) could then also be based upon these requirements.

Neither the EN 45000 nor the relevant ISO/IEC Guides meet these requirements at the present time. Furthermore, the structure of these series of standards and ISO/IEC guides exhibits redundancies which could be eliminated in the course of a revision.

1.2 Objective of the study

The objective of the study is to clarify the extent to which revision of the international body of ISO CASCO standards, which is generally adopted unchanged in the EN 45000 ff. series of standards, could have implications for the European/national accreditation and designation system, and which elements of Community law are to be regarded as indispensable requirements for adoption of the standards.

To this end, all directives in which notified bodies play a part were to be considered. The study was further to consider European and international standards and draft standards, guidance documents such as ISO/IEC Guides, including the guidance documents drawn up by the European Co-operation for Accreditation (EA) for application of the EN 45000 series, and guidance documents of the European Commission (e.g. Blue Guide, Certif, SOGS documents, MEDDEV).

The study was to establish the following facts:

The principles of German accreditation and designation systems

A description of the current principles and features in the areas subject and not subject to statutory regulation

The principles of the accreditation and designation systems of European countries

Model compilation of the principles and systems of other European countries

International framework agreements

Presentation of the relevant international framework conditions and proposals, e.g. agreements between the EU and third countries (MRAs), PECAs, WTO-TBT, UN ECE, OECD, TABD, etc., and their possible effects upon the European system.

Possible changes to the principles of accreditation and designation

Identification of the potential effects of revision of the international body of standards (ISO CASCO) and their adoption into the EN 45000 ff series of standards upon the European/German system of accreditation and designation.

Recommendations

Development of proposed arrangements for international standards governing conformity assessment (accreditation, certification, inspection, examination/calibration) which give rise to a presumption of conformity for the area subject to statutory regulation. For this purpose, requirements should be formulated for the content and structures of the standards which are necessary for the most uniform possible application in the area subject to statutory regulation and that not subject to such regulation.

Proposals for the series of standards should contain requirements for the bodies seeking accreditation/designation, including for their surveillance, and for the accreditation bodies/designating authorities, and should be equally suitable for application in the area subject to European harmonization (EU directives/regulations), the area subject to international harmonization (MRAs, PECAs), and the area not subject to statutory regulation. The proposals should identify the relevant distinctions.

KAN thanks the authors for performance of the project and for presentation of the report, and the following experts for their support in evaluation of the study:

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The following summary of the study and the recommendations were adopted by KAN in April 2003.

Summary of the study

I) Terms of reference of the study - background and description of the problem

Realization of the **fundamental economic freedoms** enshrined in the EC Treaty (formerly the EEC Treaty) has, since the signing of the Treaties of Rome, been the European Union's must pressing objective. Realization of these fundamental freedoms involves realization of the free movement of goods, of the free provision of services, of the free movement of employees, and of the free movement of capital **in observance of health protection, occupational health and safety, and consumer and environmental protection**.

The realization of these freedoms is subject essentially to the creation of secondary community law, i.e. the drafting of directives and regulations. Primary community law - in this context the EC Treaty - is not of itself sufficient for assurance of the fundamental freedoms. Without secondary community law, the Single Market would not progress beyond a juxtaposition of independently regulated national markets, the members of which would be permitted reciprocal access, but not complete freedom of action. This situation can be described only as "resembling" a single market.

The Single Market involves more, however. With the conclusion of the EC Treaty, the Member States have assumed more far-reaching obligations which are to be met through legal harmonization. Harmonization of the **free movement of goods** is of key significance in this context. This fundamental freedom, probably the most important in the EC Treaty, was realized by the **New Approach** - the most significant project for realization of the Single Market. The New Approach was presented in 1985 in the European Commission's white paper[1] and established in law by a Council Resolution.[2]

The proposed approach for the creation of free movement of goods within the territory of the EU/EEA[3] was new: since complete harmonization of legislation, including harmonization of all technical safety requirements, proved to be excessively protracted and consequently virtually impossible, the Commission pursued the strategy of **minimum harmonization.** The chief principle behind this strategy is that the relevant regulations in the various Member States are largely equivalent, and that **reciprocal recognition of the national regulations would therefore suffice** in principle.

The model for these considerations was provided by the ECJ; the most famous case is probably that of the "Cassis de Dijon" in 1979[4]. In this decision, the ECJ ruled import bans to be incompatible with the EC Treaty, irrespective of whether the primary legislation governing the free movement of goods (the EC Treaty) was already supported

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1 European Commission white paper on the completion of the internal market, COM (85) 310 - final, 14.6.1985

2 Council Resolution of 7 May 1985 setting out a new approach to technical harmonisation and to standardisation, OJ C 136, 4.6.1985, p. 1

3 The New Approach applies not only to the territory of the EU, but also the EFTA states Iceland, Norway and Lichtenstein. This territory is designated the EEA (European Economic Area). The territory subject to the New Approach will however be referred to in the present study principally as the "EU", in accordance with the usual convention.

4 ECJ/E 1979, p. 649, see also Moench, C.: NJW 1982, p. 2690 ff.

by directives and regulations. The ECJ's ruling was based upon goods being able to circulate freely once the twelve-year transitional period for creation of the Single Market had passed (1970) except where, in exceptional cases, this freedom contravened important national reservations, such as requirements concerning the protection of health and safety.

The Commission adopted this view and developed, in its white paper, the concept of minimum harmonization (through directives) with the greatest possible recognition of tlegal provisions of other European countries. The white paper states that its activity for the harmonization of statutory provisions concerning the distribution of products, the Community should in future limit itself essentially to the formulation of minimum criteria for conformity assessment bodies and of **basic requirements** for products. The basic requirements refer - depending upon the function of the directives to be adopted - to requirements for safety, health, environmental protection, consumer protection, etc.

The minimum degree of harmonization is however only a "half-way house". The minimum degree of harmonization was and remains a means for swift realization of the Single Market; it is not, however, a suitable concept for a sustainable solution. The Commission has also recognized this fact. For many areas, including areas in which harmonized directives do not exist, provision was therefore made within the New Approach for further harmonization by the **creation of harmonized standards**. These standards are not legislative in nature; their observance is nevertheless not merely optional. Where the standards are complied with, the Member States are obliged to assume that the products and (manufacturing) processes for which such compliance is declared satisfy the minimum requirements set forth in the directives (presumption of conformity). Pressure is thus exerted upon companies to act in compliance with the standards.

The third essential element of the New Approach for assurance of the free movement of goods within the European Single Market is the **reciprocal recognition of certificates of conformity**. The principle applicable here is that barriers to trade would be restored should the national surveillance authorities fail to recognize evidence, produced in other Member States, of the observance of directives and/or standards. In the past, the national authorities - or, in the area not subject to statutory regulation, the purchasers - have frequently demanded retesting or even certificates issued in the country of destination for imported products or implemented management systems. The consequence has been a reinforcing of barriers to trade.

In order to eliminate such barriers to trade, it was necessary to create a system by which certificates issued by independent bodies were recognized reciprocally by the Member States. The acceptance of a system of this kind is based essentially upon sufficient **confidence** in the results of conformity assessment produced by bodies in other Member States, specifically confidence in satisfactory health protection, occupational health and safety, and consumer and environmental protection.

These considerations led the Commission to develop its **Global Approach**[5], which was intended to provide transparency of the conformity assessment systems and

5 The work of the Commission following adoption of the New Approach was completed in July 1989 with the following Communication to the Council: "Global approach to certification and testing" (OJ

comparability of the competence of the testing, certification and monitoring bodies, in order for the concept of recognition to be functional. The essential idea here was to lay down uniform and transparent minimum requirements not only for products, but also for the activity of the conformity assessment bodies. Prior to adoption of the Global Approach, the EU New Approach directives contained conformity assessment procedures which differed from each other and were not harmonized. The Global Approach consequently embodies

(1) harmonization of the requirements for products and conformity assessment procedures to be observed by the manufacturer,

(2) harmonization of the regulations governing the organization and *modus operandi* of the national testing, certification and surveillance bodies,

(3) harmonization of the regulations governing the organization and *modus operandi* of the testing, certification and surveillance bodies stated under (2), which are often under national control

(4) harmonization of the national systems which designate the bodies responsible for licensing of the bodies stated under (2).

An essential advantage of the New Approach in conjunction with the Global Approach is the **relevance for all conceivable cases of the movement of goods** in Europe. Conformity assessments may be necessary either because national or European statutory provisions require certain technical specifications, or in order to meet a demand from the market. In the first case, the legislators require evidence of conformity which the manufacturer may have to furnish for reasons of occupational health and safety, protection of health, the environment, safety, etc., before he may distribute the products. In the second case, testing of the products is required by purchasers upon conclusion of a business agreement; the test is a result of the company's competition strategy. The system described takes all the cases stated into account, namely:

- the "area subject to harmonized statutory regulation", i.e. the area for which harmonized EU directives exist,
- the "area subject to statutory regulation", for which national regulations exist, but EU directives do not (at this stage), and
- the "area in the private sector not subject to statutory regulation", in which requirements and control methods are exclusively the prerogative of contracting parties, and which the Commission or the ECJ may influence only by providing the contracting parties with a structural and organizational supporting framework.

The European Commission, the national authorities, the conformity assessment bodies, the companies, and numerous other parties have now gathered several years' practical experience in the implementation of the New Approach. This experience has shown the

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C 267, 19.10.1989). This communication developed into the following documents: "Council Resolution on a global approach to conformity assessment", OJ C 010, 16.1.1990 and "Council Decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives", OJ L 380, 31.12.1990.

New Approach to be a successful instrument for the establishment and initial development of the Single Market. Over the course of time, however, certain essential **problem areas** and issues have arisen in relation to the instruments of the New Approach.[6] These formed the impetus for the present study, which is intended not only to identify and examine the the problem areas, but also to draw up proposals for improvement.

A *preliminary* essential weak point concerns both the legal relevance and substance of the legislation and standards supporting the New Approach, and the actual implementation of these regulations within the individual Member States. For example, the terms governing the **minimum criteria for notified bodies** enshrined in the various EU New Approach Directives in particular appear to be too abstract and too divergent. The Member States are granted enormous discretionary powers in the application of these criteria, which may result in discrepancies in the level of competence of the testing and certification bodies.

In addition, the **EN 45000 series of standards** (principles of conformity assessment) listed in Council Decision 93/465/EEC (the "Modules Decision") no longer appears to be mandated by the European Commission; furthermore, the minimum requirements stated in the European directives are not always transposed correctly and precisely within these standards. In addition, the application of certain individual standards within this series to specific areas of testing and certification is not always clearly regulated; the Member States may apply different standards for the designation of a body with one and the same conformity assessment function.

As a result, on the one hand, the **presumption of conformity ascribed to these standards**, according to which a body is presumed to possess competence in compliance with the directive provided it complies with a corresponding harmonized standard, is called into question. This presumption of conformity ceases to apply as soon as different standards are applied for conformity assessment procedures which are in fact equivalent, and for which doubts may also be raised regarding whether the standards satisfy the requirements of the directive. At the same time, the statutory relevance of these harmonized standards and the order of priority of the directives, decisions and standards is not always regulated clearly and unambiguously.

This uncertainty **damages the confidence** in the system of conformity assessment, and with it the confidence in the free movement of goods and in the standard of protection of health, occupational health and safety, and environmental and consumer protection. Should divergent criteria and procedures apply in Europe for conformity assessment, both of products and of bodies, criteria and procedures which may not necessarily even meet the minimum criteria enshrined in the EU directives, the resulting loss of confidence may lead individual parties to call the complete system into question, and in the worst case bring down the entire New Approach. Without confidence in the technical competence, skill, impartiality and integrity of bodies performing conformity assessments, the free movement of goods within the Single Market cannot be maintained.

A *second* weakness concerns the **terminology** employed in relation to the New Approach: the terms "designation, "accreditation", "notification", including the associated procedures and their significance and operative effect, are defined and applied differently from one Member State to another.

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6 For background and more information on problem areas, see also: SOGS N426 EN: Draft DG Enterprise Consultation Document on the review of the New Approach, 28.01.2002

Thirdly and finally, **efforts are currently underway at international level by ISO/CASCO** regarding essential standards - the EN 45000 series governing testing/certification/accreditation - with a view to having these international standards adopted as CEN/CENELEC standards in identical form in the near future. In order for these standards to be applied within the New Approach in a manner which gives rise to a presumption of conformity, it must then be assured that the requirements of the European Single Market and specifically of the New Approach are reflected in these international bodies of standards, in order to assure the essential conditions for the free movement of goods within the EU. A revision of this European system must include approaches to solutions for avoidance of the deficiencies stated, and at the same time the results of the ISO/CASCO activity must be anticipated and influenced.

Based upon the numerous existing statutes, directives, standards, guidance documents, comments, field reports and recommendations, the present **study** analyses the principles of German and European accreditation and designation systems, in order to identify their inherent weaknesses with reference to meaningful examples. International agreements concluded between the EU and third countries in the area of conformity assessment are examined, as are the efforts of ISO/CASCO to reform the international body of standards.

The objective of the study is to develop, on the basis of the status quo identified by the analysis, proposals for the development of a uniform and inherently consistent body of regulations for the conformity assessment of bodies, proposals which create an accepted presumption of conformity and assure adequate health protection and occupational health and safety. These proposals primarily take account of the requirements of the Single Market, i.e. the New Approach, for functional, free movement of goods, and could also be applied in the area not subject to statutory regulation. The question of how the proposals formulated here might be implemented in legal terms is also addressed.

II) Results of the study

Presumption of conformity

According to the results of the study, the EN 45000 series of standards may now **no longer be regarded as giving rise to the presumption of conformity**[7].

A **comparison of the content** of the EN 45000 series of standards with the provisions of the EU New Approach directives shows that not all standards cover all requirements of the directives. By way of example, the criteria for the bodies' independence differ. Liability insurance is not mandatory. The conformity assessment procedures described in the standards are not unreservedly suited to covering the conformity assessment procedures of the modules, and the conditions governing subcontracting are not identical in all cases.

7 With regard to the presumption of conformity created by the standards, refer to the detailed examination of their form and content in Chapter 3.2.2.3, p. 57 ff.

In addition, the standards are not clearly referenced in the individual conformity assessment modules: for almost every module, the Member States may make reference to several standards with significant differences in content for assessment.

The study also examines whether the provision containing the presumption of conformity does in fact have a **binding effect upon the Member States**. The presumption of conformity can be found in the "General Guidelines" annex of **Council Decision** 93/465/EEC. A "decision" of this kind is classified in the legal literature as a *sui generis* legal instrument. Such legal instruments must be properly promulgated; such promulgation is *sine qua non* for legal instruments which, like Council Decision 93/465/EEC, are directed at external parties. In the case of the Modules Decision, this was effected by publication in the Official Journal. The "General Guidelines" are incorporated into Article 1 of this Council decision in the form of a reference which defines a rule of law and is therefore binding. The reason for this is the facility thus created for a departure from the guidelines in justified exceptional cases. The party to which the "General Guidelines" are directed, in particular by virtue of the 2nd sentence of Item I.A.k), are the Member States. In consequence, the decision together with the "General Guidelines" and the presumption of conformity is **legally binding upon the Member States**.

The presumption of conformity concerns **harmonized standards in the EN 45000** series, which were originally developed in response to a European Commission mandate. The standards as originally drafted have since been revised several times; several of them are no longer in force. For these reasons, doubts may be raised as to whether the presumption of conformity is currently (at least) *formally* in force. The EN 45000 series of standards may however be deemed still to have **mandated status** if the view is taken that the revision of a harmonized standard need not be based upon a standardization mandate. This is the view taken by the authors, since in accordance with prevailing legal opinion, a standard may be incorporated into a statute by the reference "in the latest version". An **essential precondition** must however be fulfilled in this case, namely that the revised edition does not contravene the original standardization mandate, and that the Commission fulfils its **responsibility to review the standards** at regular intervals.

The fact that the EN 45000 series of standards has not yet been published in the Official Journal does not contravene a presumption of conformity with regard to the form, owing to the explicit reference in the published Modules Decision 93/465/EEC. Should, however, the future ISO 17000 series of standards also give rise to a presumption of conformity, it will require a "**constitutive action**" by the Commission (such as amendment of Council Decision 93/465/EEC).

The study reveals that the presumption of conformity remains valid for the form, but by no means for the content. The **European Commission** is requested to restore the presumption of conformity for the content, but also to establish it more firmly with regard to the form.

Designation and accreditation practice in Europe

Besides examining the terms of the European New Approach directives and standards, the study also provides a comprehensive analysis of the current designation and accreditation systems in Europe.[8]. Notable features and **deficiencies** were identified, in

8 For details, refer to Chapter 3.3, p. 68 ff.

particular in the following four areas: "designation and notification procedures", "accreditation", "monitoring of the notified bodies", and "requirements placed upon designating authorities", viz.:

1. Within the current statutory framework, the designation of bodies is solely the responsibility of the Member States. It is their prerogative to select bodies for designation in the context of a New Approach directive and to notify them to the European Commission and to the other Member States. For a long time, no binding provisions existed governing how the Member States should in practice implement the **designation and notification procedures**, and in particular the act of assessment. The logical consequence was that each Member State was able to develop its own system for designation of the bodies, which, owing in particular to the lack of transparency which has been observed, gave rise in recent years to doubts concerning the viability of the New Approach; confidence, including confidence in the safety level of the products, has already suffered as a result.

A **comparison between European countries** reveals, for example, that the terms "designation" and "notification" are not employed uniformly, and in some cases are even used ambiguously. In addition, the range of requirements placed upon bodies to be notified extends from formulations such as "at the discretion of the ministry concerned" through "requirements of Certif documents and EU directives" to the frequent formulation "minimum criteria of the directives and EN 45000 standards". In some countries, guidance documents for designation and monitoring or similar provisions governing implementation exist; these guidance documents differ in the requirements which they set forth.

2. In the view of the European Commission, **accreditation** in accordance with the EN 45000 series of standards is valuable for designation in the area subject to harmonized statutory regulation but is not sufficient without an assessment of the capabilities required by the European New Approach directives. In contrast to the usual understanding of accreditation in the area not subject to statutory regulation, the conformity assessment bodies must not only conduct their examinations in accordance with standards, but must also possess the competence to verify compliance with the generally formulated safety and performance requirements as required by New Approach directives.

In practice, accreditation bodies exist in all Member States; they are generally central "national accreditation bodies", whose legal status differs. The scope of and conditions for accreditation differ substantially, in fact, from one Member State to the next. Only in a small number of countries, for example, does an obligation exist for the bodies to be notified to be accredited in accordance with the EN 45000 series of standards - generally without more precise indication of the standards against which accreditation is to be performed. Some countries regard the existence of accreditation as "helpful". Others state that accreditation in accordance with the EN 45000 series of standards cannot of itself be regarded as satisfactory demonstration of competence.

3. The tasks of the Member States are not limited to designation and accreditation. Each Member State is also responsible, following designation of a notified body, for **surveillance**, i.e. for assuring that the notified body permanently possesses the technical competence required of it by the New Approach directives. This requirement can be traced back to Council Decision 93/465/EEC. The New Approach directives do not fully implement this concept, however: the Member State is (only) required to withdraw the notified status should it establish that the body no longer meets the specified criteria.

These requirements reveal a **deficiency** of the New Approach, as the existing statutory framework contains neither a binding legal obligation for regular monitoring, nor a time limit for validity of notification.

4. Owing to the scope granted to the Member States for implementing the designation and notification processes and the accreditation and monitoring systems, no uniform standards exist in Europe. **Comparable requirements placed upon accreditation bodies and designating authorities** could contribute towards the requisite enhancement of transparency and of reciprocal confidence in the New Approach. The study reveals that few specific, legally binding provisions exist in this respect and that this system is also structured differently in each country.

The results of the study generally reveal the statutory requirements governing the designation and notification processes, the accreditation and monitoring systems and the designating authorities in Europe to be inconsistent, and also imprecise. As a result, serious discrepancies exist between the various systems established at national level. The confidence in the New Approach and in an adequate system of occupational health and safety and health and environmental protection is thus undermined.

"Common elements" as a solution to the problem

According to the results of the study, the presumption of conformity of the EN 45000 series of standards can no longer be justified; in addition, different requirements exist between Member States regarding virtually all procedures for and parties to the New Approach. These **deficiencies** are **eliminated** by the "common elements" proposed by the present study.

These "**common elements**", i.e. generic, common requirements governing bodies to be notified, incorporate in part the minimum criteria - previously harmonized[9] - of the EU directives, and specify these criteria precisely and uniformly for all bodies to be notified. These criteria are formulated in the study in such a way that they can be applied comprehensively within the area subject to statutory regulation, i.e. both in the context of the New Approach, and in the context of agreements between the EU and third countries. The "common elements" - a summary of which is not practical at this point - are divided into those which place requirements upon the structure, the resources, the process, and the management system of the body. They are described in Chapter 5.2 (p. 112 ff.).

The "common elements" proposed in the present study must be implemented **swiftly**, in order to restore confidence in the New Approach. **The "common elements"** may be implemented by establishment in European secondary legislation (directives or regulations), in the form of standards, by a European guidance document, or with the aid of "common technical specifications"[10]:

1. In order to ensure a consistent and binding safety standard and a level playing-field for competition throughout the European Union, the "common elements" proposed in the present study could be enshrined directly in European **secondary legislation by means of directives or regulations**. Owing to the high level of precision of the "common elements"[11], a proposal of this kind would however mean a departure from the

9 For details, refer to Chapter 5.1, p. 110 ff.

10 In Chapter. 5.3, p. 126 ff., the respective advantages and disadvantages of these four alternatives are described in detail.

11 See Chapter. 5.2, p. 112 ff.

philosophy of the New Approach (minimum degree of harmonization with support from detailed standards). Conversely, it would clearly be beneficial to enshrine the minimum criteria from the existing EU directives which are harmonized in the present study[12] in a horizontal directive. Should this prove not possible, the minimum criteria could also be harmonized by a verbatim annex in all sectoral New Approach directives.

2. In line with the New Approach, the "common elements" for bodies to be notified must then be implemented in **standards**. Two alternatives for implementation are conceivable in this case: in ISO/CASCO standards only, or with supplementary European standards.

With the close co-operation of CEN, WG 23 of **ISO/CASCO** is currently drafting its own "common elements" for the 17000 series of standards for accreditation bodies and conformity assessment bodies. The "common elements" proposed in the present study[13] **must** be included in the activities of this working group, in order for the requirements of the European Single Market - and specifically those of the New Approach - to be addressed adequately *in the terms and structure* of this international body of standards, which will be valid worldwide.

ISO/CASCO has however decided to retain the existing form of standards geared to the assessment body, i.e. separate standards for laboratories, inspection bodies, certification bodies for products, systems and personnel, and for accreditation bodies. For this reason, the "common elements" are unlikely to be implemented in a manner appropriate to the *structure* of the New Approach, as it must for example be possible for the ISO standards to be applied in Europe to the individual modules.

The "common elements" can thus be implemented most suitably by dedicated **European standards**; this solution fulfils in both terms and structure the requirements of the New Approach, which has now been in place for several years; eliminates the deficiencies identified in the present study; and assures an adequate level of occupational health and safety and of health and environmental protection. An **unequivocal Commission mandate** to CEN/CENELEC would be indispensable for this solution.

This does not prevent European and international standards from having identical terms; on the contrary, in order for the terms to be harmonized to the greatest degree possible, ISO/CASCO and CEN/CENELEC should agree on an identical "kit" of "common elements", which should be based as far as possible upon the proposals put forward by the present study.

3. The advantage of a **guide** to implementation of the "common elements" lies in its comparatively swift and economical realization. The chief criticism are the doubts concerning its legal force, which is clearly inferior to that of standards. The objective of creating a Europe-wide, coherent system of designation and monitoring based upon equivalent requirements cannot be attained by this means. One level further down - for detailing of the generic principles for the specific directives - guidance documents may however be useful, as is shown by the example of the MEDDEV 2.10/2 document.[14]

4. A further option which, owing among other things to a dearth of practical experience, should however be regarded as inferior, would be for the "common elements" to be

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12 These can be found in Chapter 5.1, page 110

13 The differences (only minor in substance) between the "common elements" of ISO/CASCO and the "common elements" of the present study are described in detail in Chapters 2.1.2. and 5.3.2.

14 MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices

implemented in the form of "**common technical specifications (CTS)**". This new class of normative documents was created in the form of EU Directive 98/79/EC on in vitro diagnostic medical devices. In terms of their binding force, CTS are superior to standards but inferior to directives. CTS are adopted jointly by the Member States; this would make them a useful instrument, firstly for reflecting the Member States' responsibility for designation and monitoring of the bodies on their territories, and secondly for approaching the objective of a coherent European system by the creation of a jointly established catalogue of requirements.

Harmonization of the designation and notification process

Besides harmonization of the requirements placed upon bodies to be notified, a need also exists for harmonization where possible of the assessment and designation procedures, and in particular for these procedures to be made transparent: legally binding provisions governing the procedures for designation and, in particular, assessment and monitoring of the notified bodies do not yet exist. For this reason, the study proposes the following **improvements**:

In order for a transparent system of equivalent designation to be put in place, provisions are required at different levels. These provisions concern designation (more precisely, the requirements placed upon the body in conjunction with designation), the notification phase, monitoring, and the common **requirements placed upon the designating authorities**/accreditation bodies. The latter may be based for the greater part on the "common elements" currently being drafted by ISO/CASCO for bodies to be notified. These "common elements" were partly adopted, partly adapted or in some cases, for example in the section on "independence and impartiality" of the "Structure" sub-item[15], completely revised in the study for the requirements applicable to designating authorities.

The improvements to the **designation procedure** are chiefly addressed by three recommendations[16]. They deal firstly with the application procedure, in which in addition to the application itself, various documents are to be required from the body to be notified concerning organization, resources, QM system, and the conformity assessment activities for which application is being made. Secondly, the assessment procedure could be harmonized by means of the general requirements, proposed in the study, for bodies to be notified and designating authorities in conjunction with standards (e.g. EN 45003 and EN 45010). Thirdly, it is essential that during establishment of the competence and during designation proper that the requirements governing "reports" are uniform and that conditions can be imposed in conjunction with designation.

Three proposals for improvements are likewise made with regard to the **notification phase**[17]. Practical experience has shown firstly, that the scope of designation must be defined clearly with regard to the products and technologies to which it applies; in the past, this relationship has been laid down inconsistently and without verification by the Commission. Secondly, the practical experience gained regarding improvement and harmonization should also be exploited in the area of notification, in order for example to avoid the assignment of multiple identification numbers to a body[18]. Thirdly, in the

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15 For details, refer to Chapter 6.4, p. 144 ff.

16 Details of these proposals can be found in Chapter 6.1, p. 136 ff.

17 Discussed in detail in Chapter 6.2 (p. 140 ff.)

18 For example, Prüf- und Forschungsinstitut für die Schuhherstellung e.V. has been assigned the identification numbers 193 and 713, and LGA Bayern the identification numbers 125 and 780.

Internet age, and in consideration of the infrequency with which the notified bodies have been published in the Official Journal in the recent past, efforts should be made, in addition to reviving the traditional procedure of publication in the Official Journal, to make publicly accessible online databases available.

In the area of **surveillance** of conformity assessment bodies, to which insufficient attention has been paid in the past, the following aspects are of importance[19]: existing deficiencies could be eliminated by mandating and publication of ISO/IEC 17011, which contains general provisions governing surveillance, and by the drafting of provisions in respect of specific directives. These provisions should also extend to measures which the designating authorities are entitled to take as a result of monitoring, for example the attachment of conditions, and suspension and revocation of designation.

Harmonized terminology and definitions

The study reveals considerable differences in the use of the terms "accreditation", "assessment"; "designation" and "notification".[20] Harmonized terminology and definitions are however indispensable if the New Approach is to be able to function. The study contains proposals for terminology. The proposals have been selected such that they may be applied comprehensively both in the New Approach, and in the area of agreements between the EU and third countries. The following definitions form the basic framework of the terminology[21]:

- **Accreditation**

  Determination by an impartial third party that a body satisfies defined requirements and is competent to perform defined conformity assessment activities (without competence to designate).

- **Assessment (of a conformity assessment body)**

  Procedure by which the designating authority evaluates whether a body satisfies the requirements set forth in laws and regulations regarding

  competence for generic (non-product-specific) aspects

  2. the specific technical competence

  in order to be able to perform conformity assessment activities.

- **Notified body**

  Body authorized to perform defined conformity assessment activities within the scope of European directives.

- **Designating authority**

  Body established or charged by a Member State and authorized to designate or to monitor conformity assessment bodies falling within its jurisdiction, to suspend designation, to lift suspension, or to withdraw or revoke designation.

- **Designation**

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19 For details, see Chapter 6.3, p. 142 ff.

20 For details, refer to Chapter 3.3 (p. 68 ff.) and Chapters 4.1 and 4.2 (p. 101 ff.).

21 Only the most important definitions are listed here; the remainder can be found in Chapter 4.3, p. 107 ff.

Formal decision by a Member State which, following successful assessment of a body, authorizes it to conduct defined conformity assessment activities within the scope of laws and regulations.

Note: authorization is subject to the prior assent of the opposite party to the agreement in the case of agreements between the EU and third countries.

- **Notification**

  Procedure by which a Member State informs the European Commission and the other Member States of the designation of a body.

Effects of the "common elements" and the definitions upon agreements with third countries

Besides realization of the Single Market with the aid of accreditation, designation and notification procedures, the EU also aims to improve the international movement of goods. The central concern in this instance is the elimination of technical barriers to trade. In this respect, the **MRA** and **PECA** reciprocal agreements are essential. The EU concludes MRAs with third countries which possess a comparable level of technical development and comparable procedures for conformity assessment. PECAs are supplementary protocols to the Europe Agreements concluded with candidate countries for EU membership in Central and Eastern Europe.[22]

An important **difference** identified in the study between the MRA/PECA systems and the New Approach is the **point in time** at which the conformity assessment body may commence its activities. It may perform conformity assessments only once it is **authorized** to do so[23].

In the **European Single Market**, authorization is dependent upon whether notification of the other Member States subsequent to designation is declaratory or constitutive in nature: in other words, whether or not the Commission possesses the means to conduct a material examination of the result of assessment. Where designation is based upon successful accreditation, notification is only declaratory in nature; the European Commission is obliged to accept designation. The conformity assessment body may commence its activities upon designation. The responsible authority should however state at designation that the responsible authorities in the other Member States may request information prior to publication in the Official Journal.

Notification is constitutive in nature if the European Commission is at liberty to reject communication of the designation. In cases in which accreditation has not been carried out or is not successful, the European Commission and the Member States are granted the right to require the submission of relevant evidence. Designation is not certain in this case; without the acceptance of the European Commission, it would be without effect within the European Single Market.

In the case of **MRAs and PECAs**, designation is likewise essential for authorization of the conformity assessment body. Designation is however without effect vis-à-vis the conformity assessment body until the opposite party to the agreement has assented to the designation. The conformity assessment body may commence its activities within the scope of the MRAs and PECAs only once it has been included by way of decision in the

22 For a detailed analysis of MRAs and PECAs, see Chapter 3.4, p. 78 ff.

23 This issue is discussed comprehensively in Chapter 4.1, p. 101 ff.

sectoral annex following the assent of the opposite party to the agreement. Publication in the Official Journal is only declaratory in nature.

The definitions proposed in the present study in connection with the “common elements” take into account the differences stated above[24] and **resolve problems specific to certain agreements**.[25] The reciprocal recognition of the conformity assessments within the **MRAs** is based upon the assessment of the technical competence of the conformity assessment bodies. Introduction of the "common elements" into the MRAs establishes a uniform standard for the requirements placed upon bodies to be notified. If the conformity assessment bodies are examined on the basis of the "common elements", a contribution is made towards the elimination of the differences in standards between the conformity assessment systems in the territories of the parties to the agreement.

Further discrepancies exist in the definitions of "designating authority" and "designation" in the agreements themselves; these definitions are contradictory in certain MRAs. The "common elements" represent a landmark for the required adaptation if they are considered in the MRAs. They are not considered directly, but instead by amendment of the texts of the agreements by the parties to them. The more an amendment retains the existing structure and substantial framework of the agreement, the greater its probability.

The third countries with which the EU has concluded a **PECA** within the context of a bilateral Europe Agreement must bring their relevant regulations into line with the technical regulations of the European Community and with the European standards. They further undertake to observe Community law; they must therefore adopt amendments to Community law in their national legislation. With the implementation of the "common elements" within the EU, the latter must also be considered in the national regulations of third countries. The reason for this is the progressive political and economic integration of these third countries into the EU. The same benefits which the "common elements" accord the European Single Market are thus also applicable in the context of the PECAs.

Recommendations by KAN

Recommendations to the European Commission

KAN requests that the European Commission

- take measures to eliminate the other problem areas identified; these include, for example, the currently inconsistent application of the requirements placed upon accreditation bodies and designating authorities including the procedures for assessment, accreditation, designation, notification and surveillance.
- take steps to ensure that the standards based upon the "common elements" for conformity assessment bodies and designating authorities are considered during revision of the agreements between the EU and third countries governing reciprocal recognition of conformity assessment. Harmonization of the terminology employed

24 These differences are reflected for example in the definition of "designation".

25 For details of the effects of the "common elements" upon MRAs and PECAs, see Chapter 7, p. 150 ff.

with that commonly used internationally should be made an objective in order to eliminate difficulties of understanding, in particular with third countries.

Recommendations to DIN

KAN requests that DIN take efforts to ensure that the study is made available without delay through the responsible standards committee to the ISO/CASCO working group currently concerned with drafting of its own "common elements". It is essential that the "common elements" proposed in the study be incorporated into this activity by ISO/CASCO in order to ensure the greatest possible conformity. This is also necessary in order to avoid European enterprises being placed at a disadvantage.

Should, however - as is probable - discrepancies be found between the terms of the "common elements" drafted in the present study and the "common elements" actually included in the ISO/CASCO body of standards, preference should be given to additional European standards. DIN is then requested to ensure that the proposals are considered during standardization activity by CEN/CENELEC.

The study should, however, also be made available to the European standards organizations from the outset, in order for the progress of international standardization activity to be monitored in consideration of European interests.

Recommendations to the German Federal Ministry of Economics and Labour (BMWA)

KAN requests that the BMWA

- introduce the study and its findings in political discussions and committees at national and European level (such as the SOGS – Senior Officials Group on Standardization and Conformity Assessment Policy and the technical advisory group 133[26]. Parallel to the results agreed by these bodies, the further recommended measures should be promoted.
- restore the presumption of conformity of the relevant standards, which at present can no longer be sustained. This should be achieved (1) *for the terms*, by harmonization of the requirements placed upon conformity assessment bodies and (2) *for the form*, by a legally binding act.

  Concerning 1) *Harmonization of the terms:* the minimum criteria for conformity assessment bodies should preferably be regulated in a binding manner for all sectors within a horizontal directive. Alternatively, the minimum criteria could also be harmonized by a verbatim annex in all sectoral directives. The considerably more comprehensive "common elements", which serve to support the minimum criteria for bodies to be notified, should be implemented if at all possible as European standards

26 Committee responsible for Article 133 of the EC Treaty, which is concerned with international trade policy.

or series of standards in their own right. A mandate from the European Commission to CEN/CENELEC is indispensable for this purpose.

Concerning 2) *Legally binding (constitutive) act:* amendment of Council Decision 93/465/EEC or adoption of a horizontal directive as described above assures that the relevant standards (ISO 17000/EN 45000 series of standards) formally give rise to the presumption of conformity.

- ensure that DAR and KOGB acknowledge the study and consider its recommendations and findings in their joint discussions concerning further development of the German accreditation, recognition and designation system.

Recommendations to the industry bodies

KAN requests that the industry bodies affected by this issue acknowledge the study, evaluate its results, and introduce its findings into the relevant discussions and committees.

Recommendations to the KAN Secretariat

The KAN Secretariat should make the study available to the bodies charged with dealing with the issues which the study addresses. The KAN Secretariat should prepare the results of the study for parties at European and international level. An English translation would be useful for this purpose.

1 Principles of conformity assessment

A key factor for success in the realization of the Single Market and in particular of the free movement of goods was the "**New Approach** to technical harmonisation and to standardisation"[27]. This novel system – which, in contrast to previous arrangements, did not aim to regulate each and every technical detail, and which made provision for unanimous adoption by the Council – was based upon the four following four **basic principles**[28]:

- Harmonization of legislation is limited to the establishment of basic safety requirements which must be fulfilled by the products at distribution in order to assure the free movement of goods.
- The technical specifications of the minimum requirements for products stated in the directives are set forth in harmonized standards. The European standards organizations receive a mandate from the European Commission for the drafting of these standards.
- Application of the standards remains voluntary.
- Where products are manufactured in accordance with harmonized standards, they are presumed to meet the essential requirements set forth in the relevant directive.

In order to assure genuine freedom of movement of goods, these four principles must be supplemented by further mechanisms which assure reliable conformity assessment[29]. In addition, they must also be recognized by all Member States since, should a Member State implement its own regulations and regulatory procedures for assessing the fulfilment of the basic requirements of the directives and standards, the advantage of the New Approach would effectively be lost.

The result of these considerations was the "**global approach** to certification and testing"[30], the objective of which was the formulation in Community legislation of minimum criteria to be observed throughout Europe not only for products, but also for the conformity assessment bodies. This global approach has now resulted in **two types of conformity assessment procedure** being introduced in the Single Market: firstly, the examination of products, services, processes, systems and persons by laboratories or inspection/certification bodies, and secondly, the examination of these bodies by the Member States responsible for them.[31]

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27 Council Resolution of 7 May 1985 setting out a new approach to technical harmonisation and to standardisation, OJ C 136, 04.06.1985

28 Cf. European Commission: Guide to the Implementation of Directives Based on New Approach and Global Approach, Luxembourg 2000, p. 7f. ("Blue Guide")

29 OJ C 267, 19.10.1989, p. 3

30 Communication from the Commission to the Council on a Global Approach to Certification and Testing (OJ C 267, 19.10.1989) and the Council Resolution on a global approach to conformity assessment (OJ C 10 16.1.1990).

31 OJ C 267, 19.10.1989, p. 23: It is the task of each Member State to designate them and notify them to the Commission and to the other Member States.

Before these two types of conformity assessment are presented (Chapter 1.2), this chapter will first consider the basic objectives of and conditions for conformity assessment (Chapter 1.1). These two aspects, like the existing reciprocal agreements in the context of conformity assessment (Chapter 1.3), form the basis for the considerations which follow; the study is based upon these concepts and principles.

1.1 Objectives of and conditions for conformity assessment

The **essential objective** of the New Approach in conjunction with the Global Approach is the avoidance of technical barriers to trade, both in the area subject to harmonized statutory regulation and in that not subject to statutory regulation, for assurance of the free movement of goods within the Single Market in consideration of satisfactory minimum standards for consumer, environmental, and health protection.

Article 100a (3) of the Single European Act already contained the principle that a high standard of legislation is to be assured for industrial products with regard to health, safety, and protection of the environment and the consumer. The target elements summarized above are however reflected at numerous points in the arguments for the New Approach[32].

This objective is to be achieved by the system stated above, comprising

- New Approach directives governing the minimum requirements placed both upon the products, services and processes, and upon the competence of the conformity assessment bodies (in the form of general minimum criteria),
- Supplementary standards for specification of the stated minimum requirements,
- And by reciprocal recognition of conformity assessment results, with regard to both the products and the (conformity assessment) bodies involved.

In order for this system to find acceptance among the individual Member States, the standards, legislation, and administrative and testing procedures of which all differed, certain **conditions** had to be met. As with the three elements stated, it is important in the first instance that the criteria for products and bodies set forth in the directives do in fact assure a satisfactory minimum standard of health, environmental and consumer protection.

These minimum criteria, which for the most part are highly abstract, must now be supported in the harmonized standards in such a way that the user is able to work with them in an intelligent manner, and that the minimum standard enshrined in the directives is not violated.

Of decisive importance is the **confidence** in the system of the New Approach and the Global Approach, which is particularly important in the context of the third element in the system, that of reciprocal recognition of the results of conformity assessments:

> *"The necessity for a globlal approach to certification, inspection and testing thus arises out of this basic need to create conditions that are conductive to confidence,*

32 See for example: OJ C 136, 4.6.1985, Annex I, Annex II.1 and Annex II.B.III.

and, to that end, to bring the structures and procedures involved in these activities more closely into line."[33]

A key condition is thus the confidence in competence and quality, viz.[34]

- Confidence in the quality of the products,
- Confidence in the quality and competence of the manufacturer of these products,
- Confidence in the quality of testing and certification bodies,
- Confidence in the quality of the bodies licensing and conducting surveillance of the testing and certification bodies, i.e. those responsible for their designation and accreditation.

Although the Global Approach is to reinforce confidence in quality and competence explicitly by **transparency** – for example by way of certain information processes[35], a basic suspicion on the part of individual Member States has existed and continues to exist regarding procedures and their results from other Member States. In the early years of the Global Approach, this suspicion was directed particularly at certain Southern European Member States, and is currently directed at the Eastern Europe candidate countries for EU membership.

The European Commission had already anticipated this suspicion prior to implementation of the Global Approach, and proposed at its adoption a number of **measures and instruments for confidence-building**. These measures (should) still apply:[36]

In the area subject to harmonized statutory regulations, examinations performed in a Member State are recognized reciprocally as a matter of course. Although, in accordance with the New Approach guidelines[37] the state authorities remain responsible for the safety (and the other requirements stated) in their jurisdiction, they have an obligation to permit the distribution without checks of products which meet the established requirements. Against this background, the Commission expressed a wish for a change in the responsibility of Member States for the bodies: the Member States should, in the Commission's view, now accept political responsibility for ensuring that the notified bodies meet and continue to meet the minimum criteria stated in the directives.

In the area not subject to harmonization, the Commission extended the ECJ judgement on "biological products"[38] in order to reinforce confidence in that it now interpreted and elaborated the central issue regarding equivalent examination. The ECJ ruled, long before the advent of the New Approach, that examinations performed in products' countries of

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33 OJ C 267, 19.10.89, p. 5

34 Hansen, W.: Zertifizierung und Akkreditierung von Produkten und Leistungen in der Wirtschaft, p. 4f.

35 Regarding Commission proposals on this subject, see: OJ C 267, 19.10.1989, p. 18 ff.

36 For details, see: OJ C 267, 19.10.1989, p. 3 ff. and p. 15 ff. and Hansen, W.: Zertifizierung und Akkreditierung von Produkten und Leistungen in der Wirtschaft, p. 5f.

37 OJ C 136, 4.6.1985, Annex II

38 ECJ judgement of 17.12.1981, digest 1981, p. 3277

origin in accordance with the statutory requirements of the products' country of destination must be accepted by the country of destination in such cases where the examination in the country of origin is equivalent. The Commission regards equivalence as given when the examinations are performed by accredited testing bodies on the basis of internationally relevant assessment criteria.

This ruling goes hand-in-hand with the Commission's recommendation to the Member States to employ the instrument of accreditation, preferably on the model of the United Kingdom's central accreditation system. Accreditation organized in this way should, according to the proposal by the Commission upon adoption of the Global Approach[39] – be performed on the basis of the EN 45000 series of standards; universally recognized equivalent examination would thus be assured.

In the domain of business enterprises, the Commission considers the establishment of quality management systems in accordance with European standards to be a further important instrument for the building of confidence within the Global Approach.

A final point concerns the area in the private sector not subject to statutory regulation, in which the Commission or the ECJ has only limited scope for intervention. In this case, the Commission proposes the establishment of a European infrastructure for certification in order to promote the conclusion of voluntary agreements between parties concerning the reciprocal recognition of certificates.[40]

That the objective of the Global Approach described above continues to apply is beyond dispute. Valid reservations are nevertheless now held regarding certain conditions and instruments for the building of confidence which were formulated in 1989. The objective of the present study is to address and analyse these doubts and to dispel them in the future by means of suitable proposals for improvement.

1.2 Types of conformity assessment

The New Approach is based, in conjunction with the Global Approach, upon conformity assessment at two levels. The first level is the examination of products, services, processes, etc. with regard to their compliance with the requirements of the directives, and where applicable, of standards; the result is a declaration of the products as having been manufactured in accordance with the directives or standards, as the case may be.

Since the quality of these products etc., and thus also the standard of safety, environmental protection and protection of health is, however, directly dependent upon the quality and competence of the body examining the products, the Global Approach introduced examination at a second level: conformity assessment of the bodies performing testing.

Both forms of conformity assessment are absolutely essential for the implementation of the New Approach, and are outlined below.

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39 OJ C 267, 19.10.1989, Annex, Chapter IV, Part 1 No. 3, p. 19

40 For further details, see OJ C 267, 19.10.1989, Annex, Chapter IV, Part 4, p. 25

1.2.1 Conformity assessment of products, services, processes, systems and persons

In conjunction with the harmonization of legislation, **conformity assessment on the first level** serves to demonstrate that a product, a service, a process, a system or a person complies with certain legislation or other technical specifications or criteria.

In the area subject to harmonized statutory regulation, the purpose of conformity assessment is to ensure that the **basic requirements of the appropriate directive** are observed. Where legislation contains references to standards (New Approach directives), products etc. are assumed to comply with it in particular when their compliance with relevant standards is established. As the harmonized standards to which the directives refer are not binding upon the enterprise, the latter must be provided with the opportunity to demonstrate compliance with the directive by other means.

All **sectoral directives**[41] in accordance with the New Approach possess a **uniform structure** with largely verbatim standard articles; they correspond to the guidelines approved by the Council on 7 May 1985[42]. The guidelines also set out when the involvement of third parties for the issuing of certificates should be required by the directives, and what criteria the Member States should consider for the recognition of various certificates.

At the time of adoption of the guidelines, a uniform concept for the **assessment procedures** themselves did not exist. The procedure for conformity assessment of products etc. was set out by the Council of the European Communities in December 1990 in Council Decision 90/683/EEC "concerning the modules for the various phases of the conformity assessment procedures"[43]. The **"modular concept"** was drafted on the premise that the entrepreneur should be offered alternative means within the scope of Community law for demonstration of compliance with the technical harmonization directives.

The standardized concept created by the Council with its Decisions of 13 December 1990 and 22 July 1993[44] encompasses eight different procedures for the assessment of the individual products. These are described as **"modules"**.[45] These procedures concern the examination of the products at two different stages of production, namely the design stage and the production stage. Certain procedures refer to both stages; others are applied only to one of the stages, but can or must be combined with others. The individual measures which must be observed by the manufacturers - and also by the assessment bodies, should the procedure make provision for conformity assessment by third parties - are listed under each of the eight procedures.

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41 The New Approach directives are described in the Blue Guide (p. 75f.). An up-to-date list can be found at http://www.newapproach.org/directiveList.asp

42 Council Resolution of 7 May 1985, OJ C 136, 4.6.1985, p. 1

43 OJ L 380, 31.12.1990, p. 13

44 In conjunction with the arrangement for EC marking, the Decision of 31 December 1990 was repeated by the Council without substantial change on 22 July 1993, OJ L 220 30.8.1993.

45 For details of the modules, see Chapter 3.1. Only an overview and an explanation of the relationships will be provided at this point.

The new harmonization directives make reference to this modular concept and determine which of the individual modules of the conformity assessment procedure are available for the individual products[46]. The selection is made in accordance with the potential risk posed by the products, and their nature. It may be stipulated for example that a manufacturer's declaration may suffice for affixing of a conformity mark (CE marking), or, conversely, that unit verification or approval of a QA system must be performed; generally, the enterprise may also choose from a number of conformity assessment procedures.

Where conformity assessment by a third party is a requirement in such a case, this assessment (irrespective of where it is performed) must be conducted by a third party of a(ny) Member State. The manufacturer or importer may select any of the bodies in the EU notified by the Member States and published in the Official Journal of the European Communities.

Provided the product passes one of the assessment procedures available to the manufacturer, the manufacturer is entitled to issue a manufacturer's declaration and to apply to his product the **CE marking** provided for in the New Approach directives. For distribution of the products subject to a New Approach directive, the issuing of the manufacturer's declaration and affixing of the CE marking to the product by the manufacturer are mandatory requirements. Where the involvement of a notified body is a further requirement, the certificate issued by this body must be available before the product may be distributed.

The **provisions governing the application and relevance of the CE marking** are not regulated uniformly in the directives enacted prior to application of the standardized assessment procedures. For this reason, the Commission submitted a proposal to the Council for a regulation "concerning the affixing and use of the CE mark of conformity on industrial products" on 5 June 1991[47] which was implemented by the corresponding Council Decision 93/465/EEC of 22 July 1993[48] which harmonized the provisions governing this issue.

In this decision, the **significance of the CE mark** is defined as follows:

> *The CE marking affixed to industrial products symbolizes the fact that the natural or legal person having affixed or been responsible for the affixing of the said marking has verified that the product conforms to all the Community total harmonization provisions which apply to it and has been the subject of the appropriate conformity evaluation procedures.* [49]

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46 Within these modules, it may be necessary to subject processes, systems or persons to examination in order for compliance to be demonstrated for a product in the area subject to harmonized statutory regulation. For the area governed by national legislation and the area of the private sector not subject to statutory regulation, separate conformity assessment procedures are also possible for processes etc. This option will not be considered in greater detail in this chapter; the focus here is upon the modular concept which has been developed for the area subject to harmonized statutory regulation.

47 OJ C 160, 20.6.1991, p. 14

48 OJ L 220, 30.8.1993, p. 23

49 OJ L 220, 30.8.1993, Annex I-B-b), p. 26

Should a body have been involved for monitoring, the identification number of the body concerned appears after the CE marking. Other markings may be affixed [50]provided they do not impair the legibility of the CE marking and are clearly distinguishable from it. Provisions concerning the typeface of the CE marking, its minimum size, and the method by which it is affixed are contained in the Decision.

The standardized conformity assessment procedures of the Global Approach are not intended for the area not subject to statutory regulation, for which neither harmonization directives nor harmonized standards exist.

1.2.2 Conformity assessment of bodies

The **second level of conformity assessment** extends beyond product assessment: it addresses examination of the bodies which assess the products, processes, systems, etc. The philosophy behind this measure is firstly, that the quality of these bodies has a substantial influence upon the product safety, and secondly, that a uniform quality standard of these bodies is a prerequisite for confidence in the New Approach system.

The Commission thus recommends, in its Global Approach, the **creation of central national networks for the second level of conformity assessment**. The objective here is to enhance transparency of the activities of test laboratories and certification bodies, both in the area subject to statutory regulation, and in the area not subject to statutory regulation, in order for confidence in these bodies to be improved. These networks are national **accreditation systems** both for test laboratories, and for monitoring and certification bodies.

In contrast to the area not subject to statutory regulation, in which conformity assessment bodies and the results of conformity assessments are recognized reciprocally on a voluntary basis, accreditation and designation is of key importance in the area subject to harmonized statutory regulation (New Approach directives). The terminology of designation and accreditation is currently subject to variations in usage. In the present context, "designation" refers in very broad terms to authorization of a qualified body by a Member State to perform conformity assessments on the first level, and "accreditation" to an instrument for the assessment of the qualification of these bodies.[51]

The **designation of the national bodies** remains the prerogative of the individual Member States; the bodies must be legal persons resident in the territory of the Member State. In order to prevent unqualified parties from declaring the conformity of products with the relevant directives, a need exists for the state to be satisfied that the testing and certification bodies are competent. The Member State, in its sovereign capacity, is responsible for designation of the bodies falling within its jurisdiction. To this end, it must establish a designating authority (e.g. an authority within its administrative structure, or an independent private enterprise charged with fulfilling state functions). This body "designates" the body once it has ascertained the body's competence (itself or through other institutions).

In all cases, the Member State concerned is responsible vis-à-vis the other Member States and the institutions of the EU for the competence of the bodies. Examination within the

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50 For example an eco-label.

51 Cf. Chapter 3.3; Chapter 4.3 contains proposals for new, harmonized definitions

harmonized area is performed in accordance with the minimum criteria enshrined in the directives and with the requirements of the conformity assessment procedure concerned; the notified bodies must at all times satisfy the following **criteria**[52]:

- availability of personnel and equipment,
- independence and impartiality vis-à-vis the subject of the examination,
- technical competence with regard to the product under examination and the associated conformity assessment procedure,
- integrity, including with regard to observance of professional secrecy,
- taking out of liability insurance.

The relevant series of European standards, EN 45000, is to be employed for the **detailed specification of these minimum criteria**. Accreditation in accordance with these standards is not mandatory, but is of assistance with regard to the technical component of designation. The EN 45000 series of standards distinguishes between certification, testing and surveillance bodies which, according to their area of activity, are assigned to the following **standards**:

	Certification bodies	**Test laboratories**	**Surveillance bodies**
Criteria for the assessment and accreditation of bodies to be notified	EN 45010	EN 45002 EN 45003	EN 45010
Criteria for the procedure	EN 45011 EN 45012 EN 45013	EN 45001	EN 45004

Fig. 1: Standards from the EN 45000 series relevant to bodies to be notified[53]

Should the Member State or the organization charged by it conclude during assessment of the body to be notified that all significant requirements are met, either by accreditation and observance of the standards, or by alternative, equivalent means, the body concerned is designated and notified. By **notification**, the Commission and the other Member States are informed that a body satisfies the requirements and is competent to carry out conformity assessment procedures. Designated and notified bodies are published by the Commission in the Official Journal of the European Communities[54].

A body which has been designated and notified does not retain its status automatically and indefinitely, but must submit to regular examination of whether the requirements placed at the time of designation are still met in full. Should reasonable doubts exist

52 Blue Guide, p. 40

53 Fig. from: Blue Guide, p. 41

54 A relatively up-to-date list of all notified bodies can also be found on the Commission's web pages, Enterprise Directorate-General: http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies.htm (7.11.2002)

regarding the quality and competence of a notified body, the Commission or a Member State may initiate a **procedure for the revocation or suspension of designation**. Should the suspicion be confirmed and all legal remedies be exhausted, the responsible national designating authority - and only this authority - revokes designation.

The **duties** of notified bodies are not limited to reliable performance of the conformity assessment procedures for which they are licensed, but also include[55]:

- Provision of relevant information to the designating authorities and to the market surveillance authorities.
- Participation in standardization activity and co-ordination activity between the Commission, Member States, and other notified bodies.
- Should the notified body transfer, as it is permitted to do, a part of its activities to subcontractors, it remains fully responsible for the subcontractors' competence, independence, objectivity and transparency.

1.3 Reciprocal agreements in conformity assessment

Reciprocal agreements are concluded on a voluntary basis between accreditation bodies, or on a statutory basis between countries or between countries and nongovernmental organizations, for the purpose of simplifying the free movement of goods. The purpose of the agreements is the reciprocal recognition or adoption of the results of conformity assessments and the associated avoidance of duplicate or multiple conformity assessments of the same subject.[56]

1.3.1 Between accreditation bodies

Accreditation bodies conclude reciprocal agreements in order to enhance the acceptance beyond their respective national borders of the results from conformity assessment bodies accredited by them. The agreements are voluntary, but are for example also used in the context of reciprocal agreements between countries[57].

Reciprocal agreements between accreditation bodies in the form of multilateral agreements (MLAs) which are not legally binding exist at regional or international level. In **Europe**, the accreditation bodies have united to form the European co-operation for Accreditation (EA)[58]in order to conclude MLAs. The agreements are based upon the European standards governing accreditation bodies and conformity assessment bodies[59] and the guidance documents developed by the EA[60]. Accreditation bodies which have demonstrated their competence for the area of accreditation concerned in the evaluation procedures organized by the EA may be party to the MLAs. The EA publishes parties to

55 Blue Guide, S. 44 ff.

56 Note: ISO/IEC Guide 68 "Arrangements for the recognition and acceptance of conformity assessment results" is currently being drawn up by ISO/CASCO.

57 Cf. Chapter 3.4

58 The issues of competition and cartels currently being discussed in on European political committees in this regard in the area not subject to statutory regulation are beyond the scope of the present study.

59 Cf. Chapter 2.2

60 Cf. Chapter 2.3.2

the MLAs in its publication EA-1/08[61] Further regional reciprocal recognition agreements exist, e.g. at APLAC (Asia Pacific Accreditation Co-operation), IAAC (Interamerican Accreditation Cooperation) and PAC (Pacific Accreditation Cooperation).

At **international level**, the accreditation bodies have set up two organizations which also organize MLAs or whose guidance documents form the basis for MLAs:

- IAF (International Accreditation Forum) in the sphere of accreditation of certification bodies (products, systems, personnel)
- ILAC (International Laboratory Accreditation Cooperation) in the sphere of accreditation of testing and calibration laboratories.

The MLAs are based upon international standards[62] and upon the guidance documents developed by IAF and ILAC[63]. Evaluation procedures, in which broad consideration is also given to the regional evaluations, are also essential for participation in the MLA. In recent years, co-operation between IAF and ILAC has been stepped up with the objective of merging the two organizations. A joint committee already exists for the sphere of accreditation of inspection bodies.

1.3.2 Between national governments and nongovernmental organizations

The essential concern of the European Commission within the context of the New Approach in conjunction with the Global Approach is the **elimination of technical barriers to trade** in observance of adequate minimum standards for consumer, environmental and health protection[64]. For businesses resident in Europe, the objective of the free movement of goods is however of great importance, not only with regard to the Single Market, but also beyond its borders in the **international movement of goods** with other major trade partners such as Japan, the USA, or Australia.

As a component of its foreign relations, the EU has for several decades been pushing ahead with activities which simplify world trade, i.e. activities which are intended to break down barriers to trade worldwide. These measures equally include agreements with certain countries, and the support of nongovernmental organizations concerned with the simplification of trade, with the aid for example of reciprocal agreements for the conformity assessment of products and bodies. At this point the study will consider in greater detail the WTO-TBT Agreement as a central, international framework for the avoidance of technical barriers to trade, and the organizations supporting activities in the area of conformity assessment, namely UN ECE, OECD and TABD.

Of importance in this context are however primarily the "**MRAs**" (**M**utual **R**ecognition **A**greements) and "**PECAs**" (**P**rotocols to the **E**urope Agreements on **C**onformity **A**ssessment and Acceptance of Industrial Products). The former are concluded by the EU, on the basis of Article 133 of the EC Treaty, with third countries who possess a comparable level of development and comparable procedures for conformity assessment.

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61 . This publication can be accessed through the EA web site at www.european-accreditation.org.

62 Cf. Chapter 2.1

63 Cf. Chapter 2.3.1

64 Cf. also Chapter 1.1 in this regard

The latter are supplementary protocols to the Europe Agreement which are concluded with Central and Eastern European candidate countries for EU membership. Owing to the significance of MRAs and PECAs in the EU's current system of conformity assessment and also with regard to the recommendations for future arrangements, the two types of agreement are described in detail in Chapter 3.4.

1.3.2.1 The WTO-TBT Agreement

The World Trade Organization (WTO) is based upon the multilateral **General Agreement on Tariffs and Trade** (GATT), established in 1947. GATT was characterized by two fundamental principles, those of most-favoured nation treatment[65] and of national treatment" and was supplemented in 1979 in the area of conformity assessment by an **Agreement on Technical Barriers to Trade**[66] in which it was agreed that international standards be used to the extent possible.[67]

This agreement proved inefficient, however, not least owing to the small number of parties to it: it was signed by only 40 countries. In addition, its terms were deficient in places. This led to negotiations over a reform of GATT being held in Uruguay in 1988.[68]

The result of the Uruguay Round was the **establishment of the World Trade Organization** (WTO) which replaced and reformed GATT by incorporating not only GATT, but also GATS (governing services) and TRIPS (governing intellectual property) as the new cornerstones of the WTO. During the Uruguay Round, numerous agreements were concluded for the most diverse areas of trade; of key significance for the area of conformity assessment was the conclusion of a WTO Agreement concerning technical barriers to trade. This agreement not only replaced the GATT agreement mentioned above, but also substantially extended it and placed it on a stronger and broader footing. This agreement received the name "**T**echnical **B**arriers to **T**rade".[69]

As not only the Member States of the EU are members of the WTO - which currently has a total of 144 members - but also the EU itself, each of the numerous WTO agreements was integrated into European law by Council Decision 94/800/EC of 22 December 1994 "concerning the conclusion on behalf of the European Community, with regard to matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations"[70]. Like all other agreements, the WTO-TBT Agreement came into force on 1 January 1995.

The legal relevance and **binding effect of the WTO-TBT Agreement** derive from the WTO regulations governing the creation and adoption of policy: WTO decisions and agreements are generally adopted only by consensus between all members, and must in addition be ratified by the national governments and parliaments. The governments are

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65 GATT, Article I: (...) any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties

66 OJ L 71, 17.3.1980, p. 29

67 Osterheld, B.: Abkommen der Europäischen Gemeinschaft über die gegenseitige Anerkennung von Konformitätsbewertungen, p. 93f.

68 Volz, G.: Die Organisationen der Weltwirtschaft, S. 70 ff.

69 Osterheld, B.: EU agreements, p. 95

70 OJ L 336, 23.12.1994, p. 1

thus bound to conduct their trade policy within the limits set forth by the WTO agreements.[71]

The parties to the WTO-TBT Agreement agreed, in over 13 pages, upon detailed rules and procedures for the drafting, adoption and application of technical rules, standards and conformity assessment procedures. These contain not only rules corresponding to the principles of the GATT Agreement described above, but also formulations for example setting forth the **priority of international standards** over national and European standards. On this basis, the EN 45000 series of standards could also be replaced by the corresponding ISO 17000 series of standards within the foreseeable future.

Despite the priority given to international standards, it cannot be inferred that the ISO 17 000 standards can be adopted clearly and irrevocably into the EN body of standards; this is shown for example by the following paragraph of the WTO-TBT Agreement:

> *"Where international standards exist [..], the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection [..]"*[72]

These exceptions clearly relate to unsatisfactory standards of health, safety, environmental protection and national security even where mentioned in a different context - as justification for unilateral national action in the absence of international regulations or where major differences exist between national and international provisions.[73]

The priority accorded to international standards was however established in earlier agreements between the different standards institutions, for example between CEN and ISO in the 1991 Vienna Agreement.[74]

Furthermore, Article 5 of the WTO-TBT Agreement contains **rules governing the harmonization of conformity assessment procedures**; the definition in Article 5.5 for example is as follows:

> *"With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures."*

The term "conformity assessment procedure" is defined, like the other key terms, in Annex 1 of the agreement. The important reciprocal **recognition of the results of conformity assessment procedures** is addressed in Article 6. These results must consequently also be recognized in cases where the procedures differ, but where confidence exists in their mutual equivalence. A key aspect of this confidence is an

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71 WTO: The World Trade Organization in brief, p. 1; http://www.wto.org/english/res_e/doload_e/inbr_e.pdf (30.10.2002)

72 Article 4.1 in conjunction with Annex 3 Item F of the WTO-TBT Agreement

73 Article 2.10 of the WTO-TBT Agreement

74 See in this regard ISO/CEN: Agreement on technical cooperation beteween ISO and CEN, http://www.cenorm.be/boss/supmat/refdoc/archive/ms/ms002.htm (23.12.2002), Chapter 4

"adequate and enduring technical competence of the relevant conformity assessment bodies [..]; in this regard, verified compliance, for instance through accreditation, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence."[75]

The WTO-TBT Agreement thus provides the **essential basis** for international harmonization of technical regulations and standards and for the reciprocal recognition in this context of conformity assessment procedures, including their results. MRAs and PECAs in particular are based upon this agreement; Article 6.3 explicitly encourages contracting parties to conduct negotiations over such agreements.

For the organizations considered below, too, the WTO-TBT Agreement is the framework in which they develop, specify, interpret and publish provisions concerning various aspects: although the WTO-TBT Agreement represents the basis described, it does not, for example, describe the exact form a harmonized standard should take or how a conformity assessment procedure is to be conducted.

1.3.2.2 UN ECE

The "United Nations Economic Commission for Europe" (UN ECE) is a **commission** of the "Economic and Social Council" (ECOSOC) **of the UN**, by which it was founded in 1947. ECOSOC is responsible within the UN for the realization of a higher standard of living, maximum possible employment, and an adequate level of social and economic progress. ECOSOC encompasses five regional commissions - for Europe, Africa, South America and the Caribbean, Asia and the Pacific, and Western Asia - each of which reports to ECOSOC.

UN ECE is a forum of 55 countries and 70 nongovernmental organizations. Its purpose is to improve **economic co-operation between its members and the provision of information**. Key aspects of the work are economic analyses, statistical evaluations, technical assistance, and harmonization efforts in the areas of the environment, sustainable energy, trade and industry, transport, and forest exploitation. To date, EN ECE has proposed over 30 agreements and protocols and over 250 guidelines and standards in these areas, many of which have been implemented in the national legislation of the EN ECE member states or in the ISO body of standards[76]. For example, the sectoral annex governing motor vehicles of the MRA concluded with Australia[77] refers at several points to UN ECE regulations and agreements (in particular the 1958 agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles[78]) which the parties to the agreement are to use.

These proposals are developed by dedicated institutions for the subjects concerned which in turn are divided into working groups. As one of seven UN ECE Committees, the

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75 Article 6.1.1 of the WTO-TBT Agreement

76 Cf. UN ECE: Mandate and Role; http://www.unece.org/oes/about/mandate.htm (30.10.2002) and ECOSOC (eds.): About ECOSOC; http://www.un.org/esa/coordination/ecosoc/about.htm (30.10.2002)

77 OJ L 229, 17.8.1998, p. 51 ff.

78 For details, refer to the documents on the ECE web site: http://www.unece.org/trans/main/wp29/wp29regs.html

"Committee for Trade, Industry and Enterprise Development" is responsible for the area of conformity assessment and harmonization of technical regulations. This committee in turn is divided into four working parties, of which the **WP.6 "Working Party on Technical Harmonization and Standardization Policies"**[79] deals with the issues addressed by the present study.

WP.6 also regards itself, like the UN ECE as a whole, as a **forum for the discussion of problem areas.** WP.6 recognizes that the member states possess full sovereignty in issues of health protection, safety, environmental protection and the public interest. The function of WP.6 is therefore to draft (legally non-binding) proposals and "to attract attention to unnecessary obstacles and to help Governments achieve a reasonable balance between national measures taken and the impact of these measures on international trade and cooperation".[80]

In the sphere of conformity assessment, attention may be drawn to the following **activities** and documents of WP.6, which were reviewed for their potential to make a substantial contribution to the study. Documents of this kind will be referred to in the study at a later stage, as and when required by the context[81]; they are not considered in greater depth at this stage owing to their scale:

- Drafting of an "ECE Standardization List" compendium[82], which lists the sectors in which national governments identify a need for action in the area of standardization, including the area of regulation and the organizations responsible for and involved in it.
- Publication of a collection containing proposals for international harmonization of standards policy[83] which discusses, among other things, the following specific documents:
  - A. Further developments in international cooperation on technical harmonization and standardization policies
  - B. Coordination of technical regulations and standardization activities
  - C. International harmonization of standards and technical regulations
  - F. Creation and promotion of international agreements on conformity assessment
  - G. Acceptance of conformity assessment results
- Setting up of an ad-hoc team with the name "START" (Standardization and Regulatory Techniques) in 1999, in order to study the relationships between national and international standards, and their facility for further development. The first result of the START team was a proposal for an

79 Refer in this regard to the web pages of this WP.6: http://www.unece.org/trade/tips/wp6/wp6_h.htm (30.10.2002)

80 UN ECE WP.6: Providing an International Forum; http://www.unece.org/trade/tips/wp6/wp6_h.htm (30.10.2002)

81 This procedure and principle may also be applied to the documents and activities of the organizations OECD and TABD, which are dealt with below.

82 UN ECE WP.6: ECE Standardization List, ECE/STAND/20/Rev.5

83 UN ECE WP.6: Recommendation on Standardization Policies, ECE/TRADE/17/Rev.4

"international model for technical harmonization[84] which was included in the above list under "L" with recommendations in the area of standardization policy.

1.3.2.3 The OECD

The "Organization for Economic Co-operation and Development" (OECD) was created in 1961 from the OEEC (Organization for European Economic Co-operation), which in turn had had the function of assisting the USA and Canada in the **reconstruction of Europe** under the Marshall Plan following World War II. The objectives of the OECD are the creation and optimization of strong market economies in the member states (now 30), the **expansion of free trade**, and the support of both industrial and developing countries.

Like the UN ECE, the OECD also regards itself as a **forum** in which areas of economic and social policy may be discussed and developed further. By the **exchange of experience and co-operation**, members and also non-members are to be supported in identifying sustainable concepts and responses to the challenges presented by the globalized world economy. The results of these discussion processes may be legally binding documents between individual members or between all members, or non-binding recommendations. In both cases, non-members are at liberty to enter into the agreements or to implement the recommendations.

Although the highest body of the OECD is the Council, the Secretariat in Paris has a decisive role in the OECD's operational activities. Within dedicated committees concerned with particular issues, almost 2,000 scientists gather data, observe trends, produce studies, evaluate statistics, and formulate predictions in the areas of trade, the environment, agriculture, technology, and fiscal matters[85]

The subjects related to conformity assessment and the harmonization of technical standards are developed within the "**Trade Committee**", which has as its objective the promotion of strong and liberal world trade. It regards the WTO's regulations as a basis for this activity; the focus of the OECD Trade Committee, however, lies less in the negotiation of specific agreements than in the interdisciplinary analysis of problems and publication of the results[86]

Once again, only an excerpt of the noteworthy **activities and publications** of the OECD Trade Committee will be presented here which are of interest for the subjects of relevance to the present study:

- In March 2000, the Trade Committee organized a conference on the subject of technical barriers to trade which was attended by over 130 experts from standards organizations and consumer protection and industry bodies, and government representatives.[87]

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84 UN ECE WP.6: "An international model for technical harmonization based on good regulatory practice for the preparation, adoption and application of technical regulations via the use of international standards", UN ECE Recommendation "L"; http://www.unece.org/trade/tips/docs/wp6_01/model-17r4e.doc (30.10.2002)

85 OECD: Overview of the OECD/About OECD; http://www.oecd.org/ (30.10.2002)

86 OECD: About the Trade Committee, http://www.oecd.org/ (30.10.2002)

87 For details, see OECD: Special meeting on technical barriers to trade – summary report by the secretariat, TD/TC/WP/RD(2000)1/FINAL, April 2000

- An OECD study conducted in 2000 examined the extent to which different technical standards and procedures for conformity assessment exert a financial influence upon the companies concerned.[88]
- A further study conducted in 1999 dealt with the status quo in the area of accreditation, certification and conformity assessment. Groups involved were identified, and agreements and existing model proposals (e.g. MRAs) analysed. These experiences and the WTO-TBT Agreement formed the basis for proposals for solutions.[89]
- The existing standards and standards activities in the sectors of electrical appliances and electromagnetic compatibility, pressure equipment, construction machinery and machine safety within the WTO, the EU, Japan and the USA were examined closely with regard to their strengths and weaknesses. The experiences gained by the parties involved were documented, and proposals made for improvements.[90]
- The activities of the OECD in the area of good laboratory practice (GLP), good manufacturing practice (GMP) and good clinical practice (GCP) are worthy of particular mention. These concepts were developed under the leadership of the OECD with the involvement of other organizations such as the European Commission, WHO and ISO.[91]

1.3.2.4 The TABD

The TABD (Transatlantic Business Dialogue) is a product of **institutional convergence between the EU and the USA** following the end of the Cold War, beginning with the 1990 Trans-Atlantic Declaration. Besides non-binding declarations of intent, for example concerning sustainable development or the war against terror, consultation mechanisms such as the six-monthly EU-US summits were agreed.

At the initiative of the European Commission and the US government, business representatives from both sides met in November 1995 in Seville for a conference under the heading "Trans-Atlantic Business Dialogue". A long list of requirements was adopted in which the governments were challenged to remove obstacles to trade and investment on a comprehensive scale. In the wake of the Seville conference, the greater part of the demands made were adopted in the "New Transatlantic Agenda", the TABD was established as an institution, and the conference set up as an annual meeting of high-ranking business leaders and government representatives.[92]

The TABD is co-chaired by one US and one European business representative. These representatives are generally the CEOs of large corporations; Jürgen Strube (BASF) and Jürgen Schrempp (DaimlerChrysler) served as the European Chair for example in the

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88 OECD: An assessment of the costs for international trade in meeting regulatory requirements, TD/TC/WP(99)8/FINAL, February 2000

89 OECD: Regulatory reform and international standardization, TD/TC/WP(98)36/FINAL, January 1999

90 OECD: Standardization and regulatory reform: selected cases, TD/TC/WP(99)47/FINAL, February 2000

91 For details, see: Ettarp, L.: An Overview of International Conformity Assessment Systems, SWEDAC DOC 97:10, Chapter 4.7.2

92 Schomaker, A.; Detken, D.: Die EU und die USA, in: Röttlinger, M.; Weyringer, C. (Eds.): Handbuch der Europäischen Integration, p. 536ff.

years 1996 and 1998 respectively. The Chair is supported by a Leadership Team which is likewise co-chaired, a secretariat, and a number of groups of experts.

The objective of the TABD is the **promotion of transatlantic trade** and scope for investment by the **elimination of barriers to trade**, including the avoidance of inefficiencies and duplicate efforts caused by excessive regulation and procedures.[93] This objective is achieved by jointly drafted recommendations which are intended for implementation by the governments. By strict pursuit of its objectives and the involvement of high-ranking business and government representatives, the TABD has become an influential negotiating forum.

At its annual conference, the TABD sets out its **chief areas of activity**, which are then addressed by groups of experts. In addition to topics such as the capital market, e-commerce, business networks and data protection, emphasis is also placed upon the harmonization of technical rules and conformity assessment procedures[94]:

- For 2002, for example, a chief concern on the agenda was regulatory policy. The TABD's aim here is to study the effects of international standards upon trade and business, including the moves towards harmonization in US/EU systems and procedures.
- In 2002, an expert group concerned with "Conformity Assessment" conducted its activities, on which Mr Gürtler (Siemens) represented Europe.
- At the Berlin conference in 1999, the group "Conformity Assessment and Product Marking" (CAPM) (which is no longer in existence) presented proposals for the elimination of technical barriers to trade. The proposals concerned the subjects of harmonization and international standardization, worldwide recognition of testing, conformity assessment procedures in the area subject to statutory regulation, and product marking.[95]
- The 1996 conference held in Chicago was dominated by the idea of an MRA between the USA and the EU, which was strongly pushed forward and influenced by the parties.

1.3.3 Between conformity assessment bodies

Reciprocal agreements have been reached between conformity assessment bodies, for example in order for **products** which are to be distributed regionally or internationally **to be tested only once**. The voluntary reciprocal agreements concluded in the electrical sector are of great importance for European and international trade:

- The CCA procedure in Europe
- The CB procedure internationally

Certification bodes for electrical products who have demonstrated their competence by **peer assessment** may employ both procedures. Parties to the CCA and CB reciprocal

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93 TABD: The TABD in 2002, http://www.tabd.org/about/about.html (30.10.2002)

94 Cf. TABD: The TABD in 2002, http://www.tabd.org/about/about.html (30.10.2002) and TABD History 1995-2002, http://www.tabd.org/history.html (30.10.2002)

95 TABD: CEO Conference Conclusions, Berlin 1999, S. 10; http://www.tabd.org/recommendations/Berlin99.pdf (30.10.2002)

agreement certify electrical products on the basis of tests performed by another parties to the agreement. The advantage of the agreements for manufacturers is that they can employ the certificates and markings of different product certification bodies on the basis of a single test, and can thus respond flexibly to regional or national market demand.[96]

96 Note: ISO/IEC standard 17040, "General requirements for peer assessement of conformity assessment bodies" is currently being drawn up by ISO/CASCO.

2 Normative requirements placed upon accreditation bodies and conformity assessment bodies

General requirements for accreditation bodies and conformity assessment bodies are contained in normative documents (standards and other normative documents, such as guidance documents or technical rules) which are drawn up and published by standards organizations on the basis of consensus. The normative documents set out uniform **criteria for the bodies and their activities**. The application of normative documents by the bodies is voluntary. Compliance with them may however be a condition for participation in reciprocal agreements[97] or constitute a demonstration of competence for recognition in the area subject to harmonized statutory regulation[98].

The requirements placed upon accreditation bodies and conformity assessment bodies set forth in normative documents are supported by guidelines, the objective being for accreditation procedures to be conducted uniformly. The guidance documents are based upon the "no more, no less" principle, i.e. they may not contain requirements which are more or less stringent than the documents upon which they are based. Compliance with these guidance documents is a requirement for example for MLA membership[99].

2.1 International standardization (ISO/CASCO)

The normative documents for accreditation bodies and conformity assessment bodies are drafted by **CASCO**, the ISO committee responsible for conformity assessment, and published as ISO/IEC documents. Until recent years, the normative documents drafted by CASCO were published only in the form of guides. Since 1997, a distinction has been drawn between standards and guides. CASCO documents are generally published in the form of standards when their content is prescriptive and as guides when it is descriptive.

2.1.1 Current situation

The requirements placed upon accreditation bodies and conformity assessment bodies are contained in the following currently valid CASCO documents. Although these documents are for the most part guides, their content - for example on the basis of the terminological distinction made in 1997 - is in all cases prescriptive. They therefore all have the character of standards.

Requirements for **accreditation bodies**:

- ISO/IEC Guide 58:1993 — Calibration and testing laboratory accreditation systems - General requirements for operation and recognition (corresponds to EN 45 003:1995, see Chapter 2.2)

97 See Chapter 1.3

98 Cf. the comments upon the presumption of conformity in Chapter 3.2.2.3

99 Cf. Chapter 1.3.1

•ISO/IEC Guide 61:1996	General requirements for assessment and accreditation of certification/registration bodies (corresponds to EN 45 010:1998, see Chapter 2.2)
•ISO/IEC TR 17010:1998	General requirements for bodies providing accreditation of inspection bodies

Requirements for **conformity assessment bodies**:

•ISO/IEC 17025:1999	General requirement for the competence of testing and calibration laboratories (corresponds to EN 17025:2000, see Chapter 2.2)
•ISO/IEC 17020:1998	General criteria for the operation of various types of bodies performing inspection (corresponds to EN 45 004:1995, see Chapter 2.2)
•ISO/IEC Guide 65:1996	General requirements for bodies operating product certification systems (corresponds to EN 45 011:1998, see Chapter 2.2)
•ISO/IEC Guide 62:1996	General requirements for bodies operating assessment and certification/registration of quality systems (corresponds to EN 45 012:1998, see Chapter 2.2)
•ISO/IEC Guide 66:1999	General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS)

A complete list of the current ISO/CASCO guides and standards can be found in Annex A.

2.1.2 Further development

The normative CASCO documents for accreditation bodies and conformity assessment bodies will be published in future only in the form of standards in the ISO/IEC 17 000 series.

The following **standards projects for accreditation bodes** and conformity assessment bodies are currently in preparation at CASCO:

• ISO/IEC 17011:	General requirements for bodies providing assessment and accreditation of conformity assessment bodies This standard will replace ISO/IEC Guides 58 and 61 and ISO/IEC TR 17010.
• ISO/IEC 17021:	General requirements for bodies operating assessment and certification of management systems This standard will replace ISO/IEC Guides 62 and 66.
• ISO/IEC 17024:	General requirements for bodies operating certification of persons

- ISO/IEC 17025 — General requirements for the competence of testing and calibration laboratories

  The existing ISO/IEC 17025:1999 will merely be adapted to the new ISO 9001:2000.

For future development of the 17000 series of standards, the following **CASCO decisions** are particularly relevant:

- CASCO has established a working group (WG 23) with the task of developing **common elements** for standards in the 17000 series governing accreditation bodies and conformity assessment bodies to be amended in the future. The common elements are intended to ensure that identical requirements are described uniformly in future standards, in order to improve the mutual compatibility of the standards and to simplify their application by the accreditation bodies and conformity assessment bodies. Common elements are formulated for example for the structure of the bodies, their independence, their confidentiality, their complaints and appeals procedures, and their management system.

  The common elements to be developed by ISO/CASCO differ in part from the common elements proposed in the present study[100]. Should ISO/CASCO harmonize common elements of the ISO/IEC 17 000 series of standards during amendment of this series, "common elements" in the context of the present study is intended to mean common requirements placed upon bodies to be notified. The terms of the common elements proposed in the present study extend somewhat beyond those of ISO/CASCO; they are however broadly identical[101]. The term "common elements" is therefore applicable in both cases.

- CASCO has opted to take the **functional approach** in further development of the ISO 17000 series of standards. The conformity assessment procedures set forth in the standards for accreditation bodies and conformity assessment bodies are to be laid down in accordance with this approach. The principles of the functional approach are to be described in the terminological standard 17000, "Conformity assessment - general vocabulary and functional approach", which is currently being drafted by CASCO Working Group 5 (WG 5). This working group proposes the following functions (see also Fig. 2):
  - Selection (e.g. sampling)
  - Determination (e.g. testing, auditing, assessment)
  - Review and attestation (e.g. certification, accreditation)
  - Surveillance

100 Refer in this regard in particular to Chapter 5.2

101 For differences and common features, refer also to Chapter 5.3.2

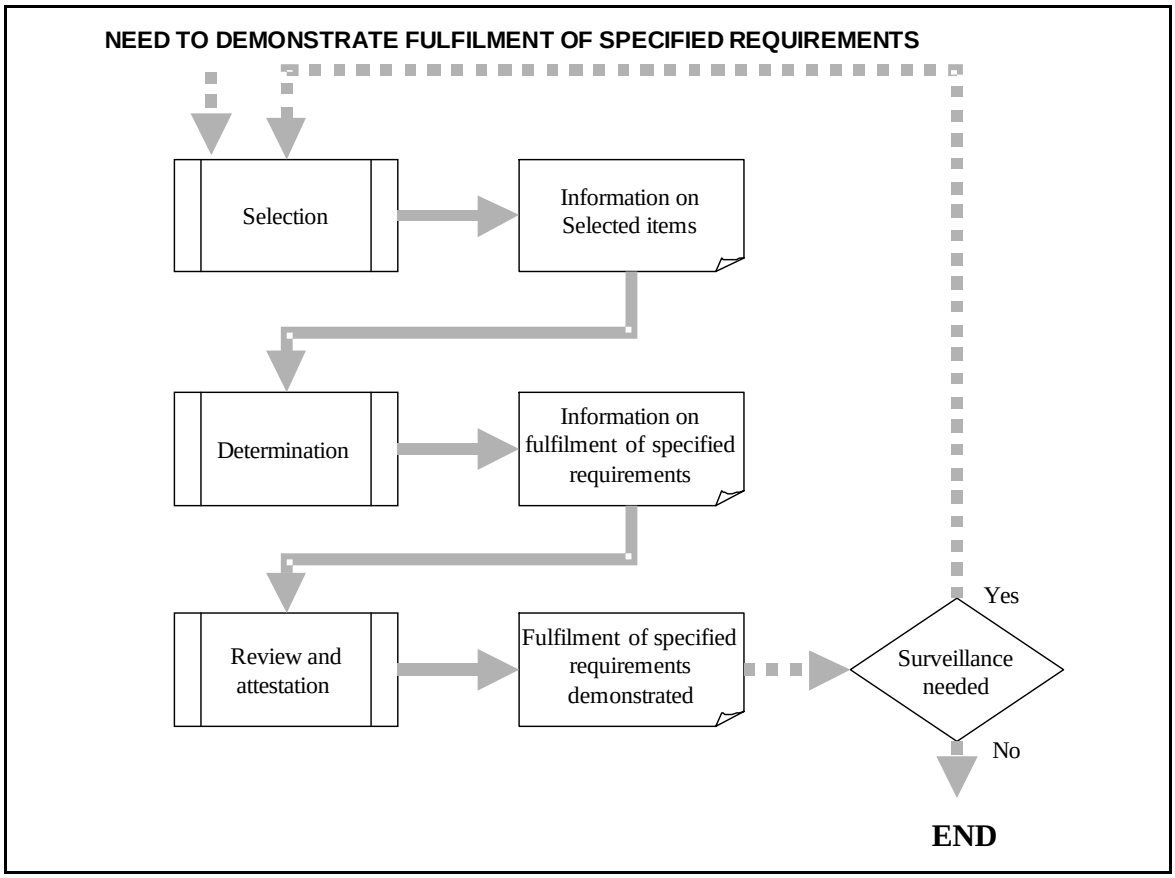

Fig. 2: Functional approach[102]

2.2 European standardization

The European standards organizations CEN and CENELEC are responsible for drafting and publishing European standards (EN) governing accreditation bodies and conformity assessment bodies. The committee with responsibility for the standards is CEN/CLC TC 1. Unlike ISO/CASCO, the European normative documents for accreditation bodies and conformity assessment bodies have always been published in the form of standards, not guides. These standards, although identical in content to the ISO/IEC guides, are therefore more binding in character than the guides, with their recommendatory character.

2.2.1 Current situation

The following EN standards placing requirements upon accreditation bodies and conformity assessment bodies are currently in force:

Requirements for **accreditation bodies**:

- EN 45 002:1990 General criteria for the assessment of testing laboratories

102 Fig. from ISO/IEC DIS 17 000 (Draft 2), Annex A, p. 8

- EN 45003:1995 — Calibration and testing laboratory accreditation systems - General requirements for operation and recognition

  (corresponds to ISO/IEC Guide 58:1993, see Chapter 2.1)

- EN 45010:1998 — General requirements for assessment and accreditation of certification/registration bodies

  (corresponds to ISO/IEC Guide 61:1996, see Chapter 2.1)

Requirements for **conformity assessment bodies**:

- EN 17025:2000 — General requirements for the competence of calibration and testing laboratories

  (corresponds to ISO/IEC 17025:1999, see Chapter 2.1)

- EN 45004:1995 — General criteria for the operation of various types of bodies performing inspection

  (corresponds to ISO/IEC 17020:1998, see Chapter 2.1)

- EN 45011:1998 — General requirements for bodies operating product certification systems

  (corresponds to ISO/IEC Guide 65:1996, see Chapter 2.1)

- EN 45012:1998 — General requirements for bodies operating assessments and certification/registration of quality systems

  (corresponds to ISO/IEC Guide 62:1996, see Chapter 2.1)

- EN 45013:1989 — General criteria for certification bodies operating certification of personnel.

With the exception of EN 45004 and EN 45013, all normative documents were drafted by CASCO and subsequently adopted by CEN/CENELEC as EN standards. For the standard governing inspection bodies, ISO/CASCO reversed the procedure, publishing the EN 45004 as ISO/IEC 17020. For certification bodies for personnel, no normative document has been published to date by ISO/CASCO. ISO/IEC 17024 is however currently in preparation by CASCO[103], which is then intended to replace EN 45013 as EN 17024.

All standards/guides containing requirements for accreditation bodies and conformity assessment bodies are identical in their European and international forms. This has major benefits for worldwide recognition of the results of these bodies, and thus for world trade as a whole.

2.2.2 Further development

The responsible European standards committee, CEN/CLC TC 1, has taken the decision to have standards governing accreditation bodies and conformity assessment bodies drafted exclusively by ISO/CASCO in the future, in order to continue to have **uniform**

103 See Chapter 2.1.2

requirements worldwide for these bodies. ISO/CASCO and CEN/CENELEC nonetheless continue to work closely together towards the same objective, with influence from CEN/CENELEC which is also not unsubstantial. The standards are adopted in accordance with the 1991 Vienna Agreement[104] in parallel voting by ISO and CEN members. As international approval and European rejection of the same draft standard is improbable, adoption will result in the medium term in the EN 45000 series of standards being replaced by the 17000 series of standards.

2.3 Guides by accreditation bodies

Groups of accreditation bodies develop guides in the form of **application documents** for the international and regional standards/guides for accreditation bodies and conformity assessment bodies, firstly in order to harmonize the accreditation procedures, and secondly to serve as a basis for reciprocal agreements[105]. The IAF (International Accreditation Forum) and the ILAC (International Laboratory Accreditation Cooperation) are international unions of accreditation bodies. The European accreditation bodies have united in the EA (European co-operation for Accreditation). The guides are drafted by committees in which the affected parties - in particular representatives of the conformity assessment bodies (testing, inspection and certification bodies) have observer status. The principle of preferential treatment for international documents (IAF/ILAC) and their adoption as EA guides also applies during drafting of the guides at EA. The IAF/ILAC and EA guides may not contain stricter or less strict requirements than the standards/guides (ISO/IEC or EN) which they support.

2.3.1 International (ILAC, IAF)

The IAF has developed and published guides to the ISO/IEC Guides 61, 62, 65 and 66. Details can be found on the IAF web site (www.iaf.nu). ILAC has also developed a range of guides for testing and calibration laboratories: these can be found on the ILAC web site (www.ilac.org).

2.3.2 European (EA)

The EA has published guides for accreditation bodies and conformity assessment bodies for the following standards in the EN 45000 series[106], which in some cases have been adopted from IAF guides:

- on EN 45010 — guide EA-3/08 (July 2002): EA Guidelines on the application of EN 45010

104 Refer in this regard to Chapter 1.3.2.1 and ISO/CEN: Agreement on technical cooperation between ISO and CEN, http://www.cenorm.be/boss/supmat/refdoc/archive/ms/ms002.htm (23.12.2002), Chapter 4

105 Cf. Chapter 1.3.1

106 The guides can be downloaded from the EA web site (www.european-accreditation.org).

• on ISO/IEC TR 17010	guide EA-3/10 (November 2001): EA Guidance on the application of ISO/IEC TR 17010
• on EN 45004	guide EA-5/01 (August 2001): Guidance on the application of EN 45004
• on EN 45011	guide EA-6/01 (June 1999): EA Guidelines on the application of EN 45011
• on EN 45012	guide EA-7/01 (December 2001): EA Guidelines on the application of EN 45012
• on EN 45013	guide EA-8/01 (September 1995): Guidelines on the application of EN 45013.

3 Conformity assessment under the New Approach in the EU

The underlying principle of the EU's New Approach is the **creation of free movement of goods**. This is achieved by conformity assessment and is based upon the principle of minimum harmonization by means of EU directives. The EU directives are based in this context upon the following principles: statutory harmonization is limited to the essential requirements. Only products which meet the essential requirements may be distributed or placed in service. Technical details are governed by harmonized standards, the application of which, however, remains voluntary. Where harmonized standard are observed, compliance with the corresponding directives is to be assumed to the extent in which the standards regulate the requirements of the directives. Manufacturers - whose own responsibility has been extended considerably by the New Approach - have the choice between a number of conformity assessment procedures for which provision is made in the relevant EU directives. These conformity assessment procedures are based upon eight basic modules, which are described in Chapter 3.1.

In order for the concept of the Single Market to be implemented, the conformity assessment must be performed by the manufacturer of the product, in some cases with the additional involvement of a third party. A further cornerstone of the concept is the reciprocal recognition of conformity assessments. This necessitates the assignment of clearly defined functions and requirements to the bodies charged with performance of the conformity assessments. Analysis of the status quo, including the question as to whether the presumption of conformity continues to apply to the terms and form when standards in the EN 45000 series are observed, forms the subject of Chapter 3.2.

The bodies must be designated and notified to the other Member States within the context of the EU directives in order for the system of reciprocal recognition to function. The nature, terms and course of the current accreditation, designation and notification procedures are examined in Chapter 3.3.

In addition to the reciprocal recognition of conformity assessments within the European Single Market, this concept is also applied between the EU and selected third countries. The reciprocal recognition of conformity assessments is based in this case upon agreements. An analysis of these agreements forms the subject of Chapter 3.4.

3.1 Conformity assessment modules

Product manufacturers are provided in the sectoral directives with a choice of **standardized procedures** for each product type. It must be ensured here that where the procedures available for selection are applied, the products comply with the basic requirements of the directive.

In the conformity assessment procedures, the underlying principle is that selection of the most suitable procedure for assessment of conformity should as far as possible be the manufacturer's prerogative. The options may be restricted by the level of hazard presented by the product, and by the provisions of the relevant EU directive.

Each EU directive developed since adoption of the Global Approach states, for its **scope**, the procedures which may be employed by the manufacturer in accordance with the Global Approach. The modules which the manufacturer may select or combine for fulfilment of conformity are dependent in part upon the type of product, the product area, and also the method of production. Presentation of the individual modules must therefore be preceded by the provision that the options available to the manufacturer for selection exist only to the degree permitted by the relevant directive. The individual modules may be combined to form a complete process. Several modules may be provided in a directive for one and the same function, in which case the results should exhibit a certain level of equivalence. Fig. 3 provides an overview of the **essential alternatives**.

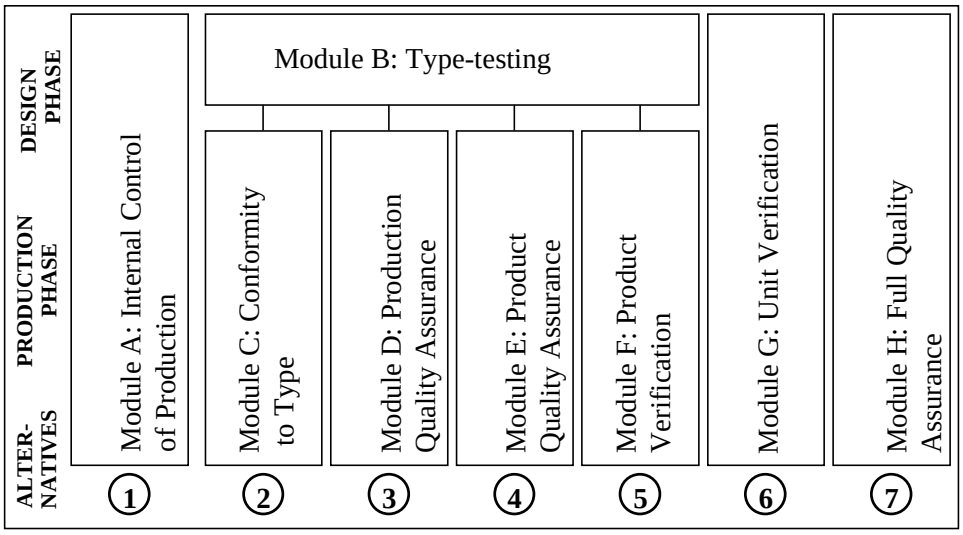

Fig. 3: Options for combination of the modules

During development of the individual modules, it was assumed that the conformity assessment for a manufacturing process refers in all cases to **two stages**, namely:

- the development stage, and
- the production stage.

Three of the standardized procedures make provision for conformity assessment by means of **quality assurance**/quality management systems. The manufacturers of these products should however be offered at least one procedure in the directives which does not require them to operate a quality assurance system. Should a manufacturer decide to operate a quality assurance system, the system must be tested and monitored. Provided manufacturers observe the relevant harmonized standards in application of the system, the requirements placed upon the quality assurance systems for the procedures must be assumed to be met. The relevant standard for this purpose is DIN EN ISO 9001:2000,

amended in 2000.[107] Compliance with it is however not a condition for compliance with individual modules; each manufacturer may also have his own systems certified, provided their quality corresponds to that of the above series of standards.[108]

The standardized assessment procedures available[109] - i.e. the **eight basic modules**[110] described in greater detail below[111] – can be found in the annexes of the sectoral directives under the following headings:

- Internal Control of Production (Module A);
- Type-testing (Module B);
- Conformity to type (Module C);
- Production Quality Assurance (Module D);
- Product Quality Assurance (Module E);
- Product Verification (Module F);
- Unit Verification (Module G);
- Full Quality Assurance (Module H).

When the complete conformity assessment procedure has been successfully completed, the **CE mark** must be affixed to the product.[112] This generally takes place at the end of the production phase. Depending upon the procedure, a notified body may be involved during the development phase, the production phase, or both phases. Where a notified body is involved during the production phase, the **identification numbers** of this body **must** appear after the CE marking.[113]

Module A: Internal Control of Production

This module concerns both the design and the production stage. The manufacturer declares here, without the involvement of third parties, that the products meet the requirements of the relevant directive, and makes technical documentation available which reveals the design, manufacture and operation of the product. The technical documentation must be retained for inspection by national authorities for at least ten years following production of the last product. The manufacturer applies the CE mark to the products and issues the declaration of conformity.

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107 The issues described in Chapter 3.2.2.3 for the EN 45000 series of standards also apply here with regard to the presumption of conformity created by compliance with DIN EN ISO 9001:2000.

108 Blue Guide, S. 37

109 Provided a positive result is yielded by one of the assessment procedures available to the manufacturer, he is entitled to issue a manufacturer's declaration and to affix the CE mark valid for all New Approach directives to his product; for details, refer to Chapter 1.2.1.

110 In addition, variants of the basic modules exist which are not considered by this overview; refer in this regard to the Blue Guide, p. 36

111 See Ensthaler, J.: Zertifizierung, Akkreditierung und Normung für den Europäischen Binnenmarkt, p. 30ff and Edelhäuser, R: Konformitätsbewertungsverfahren und Normung, in: Anhalt, E.; Dieners, P. (Eds.): Handbuch des Medizinprodukterechts, Paragraph 1ff.

112 See also Chapter 1.2.1

113 Blue Guide, p. 50f.

Module B: Type-testing

This module refers only to the design stage, and must therefore be accompanied by one of Modules C to F. A notified body attests and certifies that a sample representative of planned production complies with the requirements of the applicable directive. It reviews the technical documentation required for demonstration of conformity with the provisions of the directive. The notified body must limit its examination to the minimum required for demonstration of conformity, before issuing an EU type-examination certificate. CE marking is not affixed in this phase.

Module C: Conformity to Type

This module applies only to the production stage the design stage of which has been assured by the type-examination certification described above. The manufacturer attests and declares that the product concerned complies with the type described in the EU type-examination certificate and that it satisfies the requirements of the relevant directive. The manufacturer then affixes the CE mark to the products and issues the declaration of conformity. The directive may require spot testing of the products.

Module D: Production Quality Assurance

The module refers only to the production stage. Where applied without EU type examination, the parts of Module A must be inserted in order for the technical documentation to be included in this module. The manufacturer attests and declares that the products concerned comply with the type described in the EU type-examination certificate and that the basic requirements are met and are in compliance with the applicable directive. The manufacturer maintains a QA system for manufacturing, final acceptance and testing. The manufacturer affixes the CE mark to the products and issues a declaration of conformity.

Module E: Product Quality Assurance

This module also refers only to the production stage. It is generally applied in conjunction with EU type examination, but may be applied under the same conditions as for Module D, either alone or in conjunction with parts of Module A. The manufacturer attests and declares that the products concerned conform to the type described in the EU type-examination certificate, or that the basic requirements are met and that the products satisfy the requirements of the applicable directive. The manufacturer maintains a licensed QA system for final acceptance and testing in accordance with which all products are inspected and tested individually. The manufacturer affixes the CE mark to the products and issues a declaration of conformity.

Module F: Product Verification

This module only concerns the production stage. It is normally applied in conjunction with an EU type examination, may however be applied under the same conditions as for Module D alone. The notified body conducts testing and certifies that the products concerned conform to the type described in the EU type examination certificate, or that the basic requirements are met and the requirements of the applicable directive complied with.

The manufacturer may opt here either for testing of each individual product unit or for statistical testing. Should he choose statistical testing, he must take all necessary measures to ensure a uniform manufacturing process; the manufacturing process must conform to the type described in the type examination and guarantee that production is conducted in accordance with the technical documentation. The CE mark is supplemented by the mark of the notified body. The CE mark is affixed to the product either by the notified body or by the manufacturer himself in accordance with the provisions of the directive. The notified body issues the declaration of conformity.

Module G: Unit Verification Module

This module concerns both the design and the production stage. It is normally applied to products in once-off manufacture or small production runs. The notified body conducts inspection and certifies that the product concerned satisfies the requirements of the relevant directive(s). The notified body affixes the CE mark and issues a declaration of conformity. The CE mark is supplemented by the mark of the notified body.

Module H: Full Quality Assurance

This module for full quality assurance concerns both the design and the production stage. The manufacturer attests and declares that the products concerned satisfy the requirements of the applicable directive. He maintains a licensed QA system for design, manufacture, final acceptance and testing. The directive may, in certain cases, require the manufacturer to charge a notified body with inspecting and attesting compliance of the design with the requirements of the directive. The manufacturer affixes the CE mark to the products and issues a declaration of conformity. The CE mark is supplemented by the mark of the notified body performing this inspection.

This concept was modified with the advent of Directive 98/79/EC on in vitro diagnostic medical devices insofar as for "List A" products specified precisely in this directive, inspection of the manufactured products by way of dedicated batch approval by a notified body was introduced in addition to the comprehensive quality assurance.

3.2 Notified bodies

The Member States designate bodies within their jurisdiction for cases in which bodies must be involved in accordance with EU New Approach directives. The tasks to be assumed by the notified bodies in conjunction with the conformity assessment procedures and the requirements which they must consequently satisfy are described below.

3.2.1 Tasks

The New Approach directives require the involvement of a notified body in a number of conformity assessment procedures. The tasks to be assumed by the notified bodies are

described in the conformity assessment procedures set forth in the directives concerned[114]. The tasks concerned include in particular:

- type examination and the issuing of type-examination certificates
- design examination and the issuing of design-examination certificates
- recognition and control of QA systems
- performance of spot testing.

An **essential distinction** is drawn with regard to conformity assessment procedures between[115]

- conformity assessment systems (general description of a conformity assessment procedure) - e.g. the EU type examination described in the Modules Decision 93/465/EEC - and
- conformity assessment programmes (product-related description of a conformity assessment procedure) - e.g. the EU type examination for cardiac valves.

Each conformity assessment body is required to create **conformity assessment programmes** for the conformity assessment activities for which it wishes to be designated. The programmes are to be set up in accordance with the functional approach[116].

Details of **conformity assessment processes** and of their elements and functions can be taken from the relevant EN standards. Descriptions of the individual functions can be found for example for

- selection and sampling in EN 45004 and EN 17025,
- determination and testing in EN 17025, inspection in EN 45004 and auditing in EN 45012,
- review in EN 45004, EN 45011 and EN 45012,
- attestation and certification in EN 45004, EN 45011 and EN 45012,
- surveillance in EN 45004, EN 45011 and EN 45012.

In addition, a number of dedicated subject standards exist[117], which the conformity assessment bodies may employ for direct description of the conformity assessment processes and for the creation of conformity assessment processes.[118]

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114 Cf. in this regard also Chapter 3.1

115 Cf. for example: ISO/IEC DIS 17000 (Draft 2): Conformity assessment – General vocabulary, 2.1.7 and 2.1.8

116 See Chapter 2.1.2

117 For example in the area of quality management and statistics

118 Chapter 5.2.3 describes the essential requirements placed upon a conformity assessment body in the area subject to harmonized statutory regulation.

3.2.2 Requirements placed upon bodies to be notified

3.2.2.1 Minimum requirements imposed by the directives

The New Approach directives which make provision for the involvement of notified bodies also set out the minimum criteria for the notification of bodies. Observance by the Member States of these criteria, which are specified in the annex of the directive concerned, is mandatory. The criteria are essentially requirements concerning the body's independence and that of its personnel, the body's competence and reliability and that of its personnel, access to the equipment required for testing, liability insurance, and confidentiality. The **annexes** to the individual directives containing the minimum criteria **differ in their formulations**, however, as can be seen from the selected examples in Annex B.

3.2.2.2 Requirements imposed by modules

The EU directives generally contain, in addition to the annex containing minimum criteria, further requirements for notified bodies. These requirements can be found firstly in the articles of the directive governing the notified bodies[119], and secondly, within the conformity assessment annexes. The **conformity assessment procedures** laid down in the annexes of the relevant New Approach directives contain, in cases where provision is made for the involvement of notified bodies, further provisions, criteria and procedures which are binding upon the notified bodies. The following examples are taken from the Modules Decision 93/465/EEC[120], which describes the conformity modules to be employed in the New Approach directives:

- Subcontracting: this is permissible on the basis of formulations such as "The notified body must perform or have performed the appropriate examinations and necessary tests" (Modules B 4.2 and 4.3). Similar formulations can be found in Modules A Supplementary Requirements Part 2, C Supplementary Requirements Part 2, D 4.4, E 4.4 and H 4.4.
- The use of submitted test reports is possible and in some cases a requirement (Module B Footnote 3, Module G Footnote 3, Module H Supplementary Requirements 2)
- Competence of the assessment team (QA systems): at least one member of the assessment team must possess experience with assessment of the product technology concerned (Modules D 3.3, E 3.3 and H 3.3)
- Appeals procedures are required (Module B 5)
- Reporting requirement: reporting to other notified bodies (Modules B 7 and 8, C 6, E 6, H 6 and H Supplementary Requirements 5)
- Documentation retention requirement (Module B 5)

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119 Cf. for example Article 16 of Directive 93/42/EEC concerning medical devices or Article 14 of Directive 87/404/EEC concerning simple pressure vessels, which make provision for specific obligations to provide information and codes of practice in defined cases

120 OJ L 220, 30.08.1993, p. 23

3.2.2.3 Provisions of Council Decision 93/465/EEC – presumption of conformity and harmonized standards

The Member States must establish compliance with the requirements for notified bodies set forth in the New Approach directive[121]. Corresponding provisions can also be found in **Council Decision 93/465/EEC**, for example in Annex "General Guidelines", under Item I.A.k:

> *"for the purposes of operating the modules, Member States must notify on their own responsibility bodies under their jurisdiction which they have chosen from the technically competent bodies complying with the requirements of the directives. This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks"*

Under Item I.A.m) of the "General Guidelines", this is supplemented as follows:

> *"Notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives. Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45 000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out."*

According to the text of Item I.A.m) cited above, the Member States are obliged to assume that notified bodies satisfy the requirements of the directives (minimum criteria, requirements ensuing from the conformity assessment modules) when their compliance with the harmonized standards of the EN 45000 series is demonstrated by an accreditation certificate or other document (**presumption of conformity**). Should such evidence not be forthcoming, equivalent evidence of compliance is required which the Member States are required to present to the Commission at the latter's request.

In the New Approach directives, e.g. in Article 12 (2) of the Pressure Equipment Directive (97/23/EC)[122] – the intent of the provisions of the first sentence of I.A.m) is confirmed by the following formulation:

> *"Member States shall apply the criteria set out in Annex IV (minimum criteria to be met when designating notified bodies) for the designation of bodies. Bodies meeting the criteria laid down in the relevant harmonized standards shall be presumed to fulfil the corresponding criteria in Annex IV (minimum criteria to be met when designating notified bodies)."*

These provisions of Section I.A.m) concerning the Member States give rise to a number of **problems** which are of decisive importance for application in practice:

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121 Cf. for example Article 16 (2) of Directive 93/42/EEC concerning medical devices: "Member States shall apply the criteria set out in Annex XI for the designation of bodies."

122 Cf. also Annex B2.

1a) Legal consequences of Council Decision 93/465/EEC

of 22 July 1993; the material competence of the Council of Ministers in this area derives from Article 95 (1) of the EC Treaty, as the terms of the decision relate to the Single Market.

The document does not fall within the category of ”decision” as included in the list of secondary legislation in Article 249 (formerly Article 189) of the EC Treaty.[123]. In addition, Article 1 (1) of the decision text itself contains the formulation that "the modules listed in the Annex" and "the general guidelines in the Annex." should apply.

Like the General Guidelines, the modules are also contained in the annex to the decision. The modules themselves are therefore as binding as the Modules Decision; the annexes constitute part of the decision. The reference to them is in support of a rule of law. The particular feature of the reference is that the substance upon which the reference is based is formulated only incompletely within the element of the "statutory" rule; recourse must further be made to the technical or other regulation referred to in order for the specific terms of the statute to be determined.[124]

1b) Legal consequences of the guidelines referred to in the above Council Decision 93/465/EEC

These "general guidelines" are stated in Article 1 (1) of the Modules Decision, together with the modules; the decision is thus expressly supplemented (i.a.) by the content of the "general guidelines". The reference is therefore one in support of a rule of law in the sense described above.

An argument may be made against this interpretation by questioning the purpose of such a reference mechanism. In other words, it might be questioned why, at least with regard to the directives, the guidelines were not included in the text of the decision as the surest way of assuring their legally binding status. By the same token, it could be concluded that the fact that the guidelines are not included in the text of the decision calls their legally binding status into question.

The answer lies in the jurisprudential analysis of such a reference "in support of a rule of law", an analysis which is confirmed by the 2nd sentence of Article 1 Paragraph 1 of Council Decision 93/465/EEC. The prevailing view in jurisprudence is that the technique of reference described here has the function only of giving rise to a rebuttable presumption of agreement between the standard - or guideline - to which reference is made and the requirements set forth by statute (decision).[125]

This interpretation is confirmed by Article 1 (1) 2 of the Council decision, which states:

> *"These procedures may only depart from the modules when the specific circumstances of a particular sector or directive so warrant."*

The Council decision consciously only makes reference to the "general guidelines"; they were not included in the decision itself. The reason for this is the facility for a departure from them in justified exceptional cases.

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123 It is nevertheless sometimes argued that this Council decision may be a decision in accordance with Article 249 of the EC Treaty; cf. in this regard 2a) of the present chapter.

124 Cf. in this regard Breulmann, G.: Normung und Rechtsvergleichung in der EWG, p. 132; Ensthaler, J.: Zertifizierung, Akkreditierung und Normung für den Europäischen Binnenmarkt, p. 16

125 Breulmann, G.: Normung und Rechtsvergleichung in der EWG, p. 132

Interim conclusions regarding 1):

Both the Modules and the General Guidelines are as binding as the provisions of the Council Decision 93/465/EEC itself.

The binding nature is subject to the possibility of departures from it both in accordance with the wording of the decision (Article 1 (1) 2) and on the basis of general principles.

2a) Binding nature and party to which the decision is directed

Decisions of this category are not included in the list of secondary legislation in Article 249 (formerly Article 189) of the EC Treaty. Although decisions are mentioned, decisions such as the module decision cannot be regarded as fulfilling the relevant criteria. A generally accepted feature of a decision in accordance with article 249 is that it is directed either at *individual* private bodies or at *individual* Member States. A decision does *not* constitute the legal mechanism by which a measure intended to be binding upon *all* Member States is issued. Were this not the case, no distinction would exist between it and a directive or regulation.[126]

A decision such as the modules decision is classified in jurisprudential literature as a ***sui generis* legal instrument**.

Community practice exhibits a body of "undesignated" legal acts which is extensive, diverse, and has not yet been substantially analysed in legal terms. Such decisions primarily concern Single Market regulations, i.e. rules of procedure, organizational provisions, etc. Single Market or Internal Market law is of internal consequence only; it therefore represents self-engagement on the part of the institution concerned or of all institutions of the EU.

The term "decision", however, also includes decisions which are intended to be legally binding upon external parties. Neither the jurisprudential literature nor the ECJ raises objections to such legal acts; they need only - in the case of legal instruments with external effect, imperatively - be properly announced/published.

This took place in the case of the 1993 Council decision; the decision was announced in the Official Journal.

2b) Internal and external effect of the decision

The General Guidelines are directed at the Member States. They are legally binding upon the Member States in particular in the Annex to the Modules Decision, Item I.A.k), Sentence 2. The Member States are further addressed in the General Guidelines under Item I.A.m): they are obliged to assume that notified bodies satisfy the requirements of the directive i.a. when the latter demonstrate their compliance with the harmonized standards of the EN 45000 series by way of a certificate of accreditation or by other documentation (presumption of conformity).

Interim conclusions regarding 2):

The decision including its annexes (Modules, General Guidelines) is thus binding upon the Member States; it is directed at the Member States.

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126 Cf. also below: Oppermann, T.: Europarecht, Paragraph 487

3a) Legal background to the concept of the presumption of conformity

The Modules Decision makes direct reference to the technical harmonization directives. The procedures stated in these directives for conformity assessment are (essentially) selected from those contained in the modules. These New Approach directives describe what must be performed for this conformity assessment; this in turn is detailed and harmonized by the modules.

The quality requirements concerning the conformity assessment bodies are not referred to directly in the Modules Decision; they are however stated in the "General Guidelines", which form a binding annex to the Council decision, and in the New Approach directives. The guidelines state in this respect under Item I.A.m): "notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives".

It is debatable whether the EN 45000 series of standards remains suitable for creation of the presumption of conformity, i.e. to serve as ground on the basis of which accredited/notified bodies are competent to issue correspondingly valid certificates of conformity.

These grounds must be considered first by analysis of the **relationship between harmonized standards and the presumption of conformity** conceived in the New Approach; this must begin by definition of the term "harmonized standard": "Harmonised standards in the meaning of the New Approach are deemed to exist when the European standards organisations formally present to the Commission the European standards elaborated or identified in conformity with the mandate"[127].

Identifying standards means, in this context, that standards organizations may make recourse to existing standards, which may have to be revised. Where recourse is made to existing standards, such standards need not be European standards.

Harmonized standards enjoy **particular significance**, derived from their significance as regulations substitutive of legislation within the framework of the Single Market. This characteristic was considered in Council Decision 83/189/EEC of 28.3.1983[128], which states that for the creation of European standards which are intended to support directives, the Commission issues standardization mandates to the European standardization institutes. The purpose of these mandates is to enable directives to be adopted which contain references to standards. In accordance with this function, the following requirements apply:

- the subjects must be ascertained in respect of which harmonization of the national standards is deemed necessary, and essentially:
- the standard to be created must satisfy the needs of the basic safety requirements contained in the directive.

In conclusion, harmonized standards are seen to have the function of supporting directives, and the Commission is seen in this context to have the function of declaring, at issue of the mandate, which areas are to be regulated, or covered, in this regard.

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127 Blue Guide, p. 30

128 This directive has since been abolished in accordance with Article 13 (1) in conjunction with Annex III Part A of Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards, and replaced by the directive indicated.

Harmonized standards are consequently merely standards which have been influenced by the Commission such that their intended functions are evident.

The standardization procedure[129] outlined in the "Blue Guide"[130] in accordance with the New Approach is comprehensive and contributes to **the creation of** the **presumption of conformity** by the substance, i.e. terms, of the standards.

This is necessary, as a substantial element of the "New Approach" is that the conformity of products with the relevant directives shall not be declared by unqualified bodies. For this reason, Council Resolution of 7 May 1985 states that each Member State must inform the Commission and the other Member States of which national bodies may issue test marks or certificates of conformity[131].

This point further states: "The bodies [...] must carry out their duties according to recognized international practices and principles and especially in accordance with ISO Guides". The Member States are responsible for monitoring the activities of these bodies.

This Council Resolution was followed (with intermediate steps) by Council Decision 93/465/EEC of 22 July 1993, the annex (General Guidelines) of which state under Item I.A.m) that observance of the EN 45000 series of standards is of particular significance for the presumption of conformity. This series of standards is presented there as a **harmonized series of standards**. In accordance with the significance of the New Approach for the presumption of conformity, a series of requirements are set out under the heading of "Standardisation procedure under the New Approach" (harmonized standards), including:[132]

- a standardization mandate is issued following hearing of the Member States,
- the standardization mandate is issued to the European standards organizations,
- the European standards organizations accept the standardization mandate,
- the European standards organizations and national standards committees organize a public inquiry,
- the technical committee reviews comments, etc.

These requirements all indicate that standards in this series are **"substitutive of legislation"** with regard to the presumption of conformity. As an institution of the EU, the Commission is to be integrated into the standardization process; it is to be ensured that standards are developed which are suitable for substitution for "statutory" regulations. Of particular importance here is the fact that a standardization mandate must have been issued to the relevant standardization institute for the resolution of a particular

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129 Blue Guide, p. 30

130 Drafting and adoption of harmonized standards is based upon the guidelines for co-operation between the European standardization organizations and the European Commission. These guidelines were signed on 13 November 1984, and are currently undergoing revision. The basic principles set forth in these guidelines have however been reaffirmed on several occasions: for example, in the Commission report on efficiency and accountability in European standardisation, COM (1998) 291 (final)

131 OJ C 136, 4.6.1985, Annex II, B.VIII, No.3-2.

132 Cf. Blue Guide, p. 30f.

task. This ensures that the standard concerned complies with the requirements for the presumption of conformity.

With regard to the EN 45000 series of standards, it may be established in this respect that the individual standards were developed by the European standards organizations in response to a Commission mandate, that these standards as originally drafted are, however, with one exception (EN 45013) no longer in force; EN 45003 and EN 45004 were not, in fact, published until after the 1993 Modules Decision by the Council.

The EN 45000 series has **not yet been published** by the Commission in the Official Journal[133]. Owing to the explicit reference to them in the published Modules Decision 93/465/EEC (and that of the "General Guidelines", which are also included), this fact is immaterial as regards their significance for the presumption of conformity.

3b) Current status of the non-mandated standards in the EN 45000 series in the context of the presumption of conformity

A **mandate** was originally issued for the development of standards in this context[134]. Corresponding standards were then mandated. According to the rules of procedure of the standards institutes (in particular CEN), the European standards institutes consider their standards to be subject to revision at intervals of not more than five years, irrespective of whether or not revision is in response to a standardization mandate[135].

The Commission has now stated (in the Blue Guide, p. 32), that revision of a harmonized standard must be in response to a standardization mandate, in order to assure the possibility of conformity assessment.

This may apply in principle. It stands in contrast however to the (binding) annex of Council Decision 93/465/EEC, which contains references at several points to the EN 45000 series of standards, without distinguishing between mandated and non-mandated standards, or a particular issue of the standards being indicated.

At the time of this decision, the standards organizations were known to review their standards for the need for revision at intervals of at most five years, irrespective of whether a standardization mandate had been issued or not. The Blue Guide further states: "Unless the contrary can be deduced from the original mandate, the terms and conditions of the original mandate apply also for the revision of the harmonised standard".[136].

This clarifies sufficiently that the respective revised version of a standard in the 45000 series is adequate for **upholding of the presumption of conformity**.

This interpretation is of course subject to limits. The Commission is entitled at any time to issue new standardization mandates or to declare revised versions of the series of standards to be no longer suitable for upholding the presumption of conformity. At the same time, there is no reason from a jurisprudential perspective why a standard should not be incorporated in substitution for a statute in a manner by which its latest version takes effect. Nor is this instrument of referencing uncommon in other areas of jurisprudence. This instrument does of course not release the Commission from its duty

133 Cf. in this regard the correspondence between Blüm, N. (dated 22.12.1995) and Bangemann, M. (dated 20.3.1996).

134 BC/CEN/87/14

135 Refer to the explanation in the Blue Guide, p. 34, Footnote 89

136 Blue Guide, p. 32

to establish whether the revised versions are still compatible with the original standardization mandate.

Fittingly, the Blue Guide states, as indicated above, that unless suggested to the contrary in the original standardization mandate, its terms also extend to the revision of the harmonized standards. There are no grounds for objection to this procedure.

The anticipated **replacement in full of the EN 45000 series by the ISO 17000 series** is however not possible without a "constitutive act" on the part of the Commission, for example by amendment of Council Decision 93/465/EEC, if the presumption of conformity is to be upheld. The ISO 17000 series was not mandated by the Commission.[137]

Interim conclusions regarding 3):

The 45000 series of standards may continue to be regarded as mandated if the view is taken that the revision of a harmonized standard need not be based upon a new standardization mandate in order to uphold the facility for the presumption of conformity.[138]

This interpretation is to be accepted, within limits. The prevailing view of jurisprudence is that a standard may be incorporated into a legal provision by the reference "in its latest version" provided it is ensured that the revised version does not contravene the original standard or the original standardization mandate. According to this interpretation, referencing is therefore possible provided the Commission's duty of review is maintained. This view is shared by the Commission[139]. This duty to conduct regular review[140] must also be fulfilled by the Commission if the presumption of conformity is to be created without doubt.

4) Classification of the standards to the relevant conformity assessment procedures (modules)

Each of the standards in the EN 45000 series covers certain areas of conformity: product certification (45011), quality management system certification (45012), product inspection (45004), product testing (45001/17025). Item I.A.m) does not reference the standards to the conformity assessment procedures (modules). This assignment must be effected by the Member States in consideration of the conformity assessment procedures specified in the modules. In its "Blue Guide", which is recommendatory in status, the Commission has compiled, in the Figure in Section 6.1, the relationship between the individual standards and the respective modules. The Member States may employ this relationship in order to reference the standards to the modules:

137 Cf. in this regard also: European Commission - Enterprise Directorate-General: Methods of referencing standards in legislation with an emphasis on European legislation, p. 8

138 View of the Commission, Blue Guide, p. 32

139 Cf. Blue Guide, p. 32f.

140 Cf. also Council Resolution of 28 October 1999 on the role of standardisation in Europe, OJ C 141, 19.5.2000, No. 25

Module	EN 45000 standard(s) applicable
Aa1, Aa2	EN 45001 (+ Ability to evaluate and decide on conformity), or EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)
B	EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)
Cbis1, Cbis2	EN 45001 (+ Ability to evaluate and decide on conformity), or EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)
D, Dbis	EN 45012 (+ product-related knowledge)
E, Ebis	EN 45012 (+ product-related knowledge)
F, Fbis	EN 45001 (+ Ability to evaluate and decide on conformity), or EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)
G	EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)
H	EN 45012 (+ product-related knowledge)
Hbis	EN 45012 + EN 45004 or EN 45011

Fig. 4: Referencing of standards in the EN 45000 series to the modules[141]

Interim conclusions regarding 4):

This cross-referencing of the applicable standards in the EN 45000 series to the individual modules, which is contained in the "Blue Guide" and which is not legally binding, neither has any basis in fact, nor is it conducive to a uniform standard in Europe. In some cases, standards are offered for selection for one and the same module the terms of which are not compatible, i.e. which do not govern the same facts. A selection between standards, particularly standards the terms of which are not comparable, may lead to substantial differences in quality between the Member States. It allows a presumption of conformity to be neither inferred, nor created.

5) Agreement between the terms of the standards and the requirements of the directives

A comparison between the standards and the provisions of the directives (minimum criteria, modules) reveals that discrepancies exist, and that not all standards satisfy all requirements of the directives. For instance:

- the criteria for independence differ,
- liability insurance is not mandatory in the standards,
- the conformity assessment procedures described in the standards are not suitable, without qualification, for fulfilment of the conformity assessment procedures of the modules (for example, the result of conformity assessment according to EN 45012 is the conformity of quality management systems; by contrast, directives require attestation of product conformity),

141 Fig. taken from Blue Guide, p. 41

- the conditions for subcontracting are not identical in all cases.

Interim conclusions regarding 5):

Comparison of the EN 45000 series of standards with the EU New Approach directives reveals frequent discrepancies in the detailing of the minimum criteria set forth in the annexes to the individual directives. The wording and in some cases the terms of the minimum criteria differ[142]; furthermore, the standards do not take into account all requirements of the directives. No objective reasons for this deficit are evident. In conclusion, it may be stated that owing to this lack of conformity, the presumption of conformity cannot be upheld[143], a fact which has already been established by SOGS/WG 1.

6) Suitability of the "accreditation certificates" or "other documentary evidence" as proof of conformity

Section I.A.m) does not clearly state who is authorized to issue "accreditation certificates" or "other documentary evidence" and on what basis proof of compliance may be furnished.[144] The use of the term "certificate of accreditation" gives rise to the presumption that, where the instrument of accreditation is employed at designation, the certificate must be issued by an accreditation body. The association of the evidence of compliance with the standards of the EN 45000 series further gives rise to the assumption that the accreditation bodies satisfy the requirements of EN 45003 or EN 45010[145] and that the assessment and surveillance is to have been performed by them. The Member States are however at liberty to maintain this evidence or have it maintained by other means.

Interim conclusions regarding 6):

The numerous permutations and interpretations which Section I.A.m) grants the Member States have contributed substantially to the practice of assessment of bodies seeking notification and the surveillance of notified bodies still not being uniform throughout the Member States; this represents further grounds for challenging the presumption of conformity.

7) Consequences of different permutations and interpretations granted to the Member States by Section I.A.m)

One consequence is **distortion of competition**[146] between the notified bodies, which impairs free competition between the bodies. These differences in the terms of

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142 Cf. Chapter 3.2.2.1 and Annex B.

143 For a detailed discussion of the consequences, refer to Point 7) of the present chapter.

144 The concept set forth in Item I.A.m) in which the body to be notified (actively) submits a certificate of accreditation and the designating authority is obliged to accept this certification is challenged in Chapters 3.3 and 6; the reverse procedure, in which the designating authority actively requires certification, would appear appropriate.

145 See Chapter 2.2.1

146 The issue of distortion of competition has been limited in this study, owing to its scale, to the area subject to statutory regulation; a detailed analysis of the issues of competition and antitrust legislation in the area not subject to statutory regulation, which are currently the subject of discussion, was beyond the scope of the study.

competition have been brought about only in part by the Commission; they are a **consequence of the corresponding decisions by the Member States**, i.e. by the Member States' competent designating authorities.

It might therefore be concluded that it is also the task of the Member States to align these different requirements - or, as the case may be, not to do so. Attention is drawn once again to the concept of the Single Market, for which comprehensive harmonization of legislation was deliberately rejected.

This argument would not be relevant here, however. The New Approach and the Global Approach were introduced by the Council of Ministers and the Commission for the very purpose of preventing product safety, and consequently the protection of health, occupational health and safety, and consumer protection, from falling to a minimum level. The principle of reciprocal recognition of (disparate national) legislation, which was expected to degrade quality, was countered by the introduction of harmonized standards into secondary legislation (directives), the Modules Decision, etc. Accordingly, the legitimation of divergent safety requirements at the "lowest common denominator" was the very development to be prevented.

The discrepancies described here which exist regarding competition are - in complete contrast to the other areas of the movement of goods - not only undesirable, but **counterproductive and unacceptable**; in the past, the Commission and the Council have assumed the task (and must continue to do so) of creating approximately uniform standards.

The Commission could respond here with the argument that the Member States and their designating authorities should be granted a "certain" degree of freedom in accordance with the **principle of subsidiarity**. According to this principle, the EU may intervene only when an issue is likely to be resolved better at the level of Community law. This principle may also be formulated as follows:the Member States retain responsibility despite the principle competence of the Community in such cases where the consideration of particular national characteristics and interests enables an appropriate solution to be anticipated.

In this instance, the reverse is the case. As already described, the New Approach to standardization, accreditation and certification supports the Single Market project with its underlying philosophy of reciprocal recognition of the rights of Member States. With regard to the rights of relevance to safety, reciprocal recognition is not sufficient. The creation of secondary legislation (directives) should, on the one hand, not jeopardize the Single Market project and should therefore contain only minimum provisions; it should however at the same time be supplemented by standards and a procedure for examination of their observance. It would clearly contravene the system were it to be qualified such that the nature of conformity assessment would lead to divergent national standards in the areas of occupational health and safety and health, environmental and consumer protection.

Interim conclusions regarding 7):

The facilities which currently exist by which certificates may be issued within the Member States on the basis of requirements which vary between the Member States represents discrimination against certification bodies whose Member States have selected stricter requirements.

It cannot be acceptable that a system whose purpose is to create uniform standards should be interpreted such that the instruments employed - standards and decisions rather than regulations and directives - may be used at the discretion of the Member States when the instruments employed have been instigated for the very purpose of safeguarding harmonization of the Single Market.

3.2.2.4 Commission recommendations for notified bodies

The European Commission has drafted a series of documents, in part with the agreement of the Senior Officials Group on Standardisation, which contain criteria for notified bodies and their activities and for their accreditation, designation and notification. The documents have been - and continue to be - published in the form of **Certif documents**. An overview of the Certif documents can be found in Annex 3 IV of the "**Blue Guide**". The terms contained in Certif documents which are relevant to the notified bodies were included in the Blue Guide; the Certif documents are consequently now of only secondary importance for the notified bodies. The criteria for the notified bodies are contained in particular in Section 6, "Notified bodies" of the "Blue Guide". The criteria support the requirements of the directives for notified bodies. They are not, however, legally binding.

The Commission has also drawn up and published sector-specific documents in certain product areas which contain criteria both for notified bodies, and for the designating authorities. For the medical devices sector, for example, criteria of this type can be found in the **MEDDEV document** 2.10/2 "Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices". This guidance document, drawn up by the Member States and published by the Commission[147], arose in particular from the need for a uniform, Europe-wide description of the heterogeneous system of designation, which was the prerogative of the individual Member States, in order to make the European conformity assessment system acceptable to third-country opposite parties[148] such as Canada and the USA.

3.2.2.5 EA recommendations for notified bodies

In response to a European Commission mandate, EA (the European co-operation for Accreditation) has drawn up guidance documents for accreditation and conformity assessment bodies in the use of EN 45000 standards[149] as a basis for requirements concerning the activity, assessment and surveillance of notified bodies. A total of **four guidance documents** were proposed in particular for notified bodies, based upon EN 45004, EN 45011, EN 45012 and EN 17025. These guidance documents contain the text of the corresponding EA guidance document, together with criteria for notified bodies. The criteria are based essentially upon the annexes of the directives containing minimum criteria for notified bodies[150], and the "Blue Guide"[151]. Passages of the EA guidance documents which are not relevant to notified bodies were marked especially as such.

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147 http://europa.eu.int/comm/enterprise/medical_devices/guidelinesmed/2_10_2date04_2001.pdf (9.1.2003)

148 Cf. Chapter 3.4

149 Cf. Chapter 2.3.2

150 See Chapter 3.2.2.1

151 See Chapter 3.2.2.4

The guidance documents proposed by EA for designated bodies are, besides the MEDDEV document 2.10/2 cited above, the only documents produced to date to summarize all requirements and criteria for notified bodies derived from the directives, the standards giving rise to a presumption of conformity, the "Blue Guide", and the EA guidance documents for accreditation and conformity assessment bodies. The Commission has however not yet ruled upon the use of these documents. Nor have they been published, with the result that the documents cannot officially be used owing to the European Commission's rights of ownership.

3.3 Accreditation, designation and notification

As outlined in Chapter 1, the European Commission sets out in its communication "A global approach to certification and testing - Quality measures for industrial products"[152] to the Council that the Global Approach is based upon “the **most modern techniques** (accreditation and quality assurance) already covered in international standards (ISO-IEC)“, and concludes with the recommendation to the Member States “to promote on a wide scale the use of standards EN 29000 and EN 45000 so as to harmonize to the greatest possible extent the criteria for the evaluation of quality systems and of certification, inspection and testing bodies, making use of the **instrument of accreditation**”.[153] This contains the declaration of intent to issue a mandate to CEN/CENELC to complete the standards for assessment of the competence of companies in the area of conformity assessment (EN 29000, EN 45000)[154]. It further requests Member States to support the use of these standards both in the area subject to regulation and within private certification systems, and based upon these standards, to introduce accreditation systems.

It further states that the bodies responsible for the conformity assessment procedure are selected by the Member States in accordance with common evaluation criteria, and their identity communicated to the Commission and the other Member States. Where the accredited bodies comply with the European standards (EN 45000), it is assumed that they also meet these criteria. At the same time, it had to be pointed out “that the EN 45000 series of standards is incomplete since it does not cover all conformity assessment activities. It will be necessary, in particular, to establish criteria for the inspection bodies and for the bodies responsible for accrediting the certification and inspection bodies.”[155]

The following chapter aims to analyse the outline, which at that time was still vague, and to describe its current implementation in the Member States. Particular attention has been paid here to the understanding of accreditation, designation and notification and to their interrelationship, these being the key elements for a functional system in accordance with the New Approach.

3.3.1 Responsibilities and the role of accreditation

152 OJ C 267, 19.10.1989, p. 3
153 OJ C 267, 19.10.1989, IV a), p. 7
154 OJ C 267, 19.10.1989, IV b), p. 7
155 OJ C 267, 19.10.1989, b), p. 17

During analysis of both the New Approach and the ensuing essential documents of the Global Approach, up to and including Council Decision 93/465/EEC and its implementation in the New Approach directives, attention is drawn clearly to the **responsibilities of the Member States for designation** of the bodies within their jurisdiction.

Council Decision 93/465/EEC contains a small number of general guidelines concerning the notified bodies, the clarity, legal relevance and current validity of which have already been considered in more detail in Chapter 3.2.2.3.

The statutory basis as such for the designation of the bodies is however derived from the **EU New Approach directives**.[156] The directives contain legally binding criteria which the Member States are obliged to observe during assessment of the bodies to be notified.[157] The directives do not contain specific provisions governing the mechanisms or practical guides to the implementation of these principles. This fact reflects a political decision according to which the designation of the bodies is to remain an exclusively national prerogative, i.e. the **sovereignty of the Member State** is to be preserved.

As a logical consequence of this statutory framework, each Member State has been able to develop its own system for designation of the bodies, which in recent years, in particular as a result of the lack of transparency, has fuelled **doubts concerning the functionality** of the New Approach system. Owing to the great diversity of product areas governed by the New Approach directives and the different requirements placed upon the technical competence of the bodies, heterogeneous systems also now exist within Member States, a state of affairs which calls into question the principle of the presumption of conformity - originally established and still enshrined in the directives - conditional upon fulfilment of the criteria specified in the EN 45000 series of standards and the creation of central accreditation networks.

3.3.1.1 The role of accreditation

Whereas Council Decision 93/465/EEC continues to embody the principle "notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate [..] are presumed to conform to the requirements of the directives"[158], the Blue Guide[159] published in 1999 by the European Commission already qualifies it: "Conformity to the relevant standard of the EN 45000 series on the part of the notified body constitutes an element of presumption of conformity to the requirements of the directive, but is not always in itself sufficient without demonstration of technical capability within the scope of the directives." The Blue Guide further states that the assessment of competence of a body to be designated must relate specifically to knowledge of the products, the technologies employed, and the specific tasks within the conformity assessment procedure.

The **difference is revealed here between this interpretation and the usual understanding of accreditation** according to EN 45000, i.e. confirmation of competence, performance of certain examinations (conformity assessment activities) in accordance with specified procedures (generally with the objective of establishing "compliance with the standard"), as the notified bodies must without exception establish

156 Cf. Annex B, which contains examples from the EU directives.

157 Cf. Chapter 3.2.2.1

158 Council Decision 93/465/EEC, Annex I.A.m)

159 Blue Guide, p. 40f.

the specific product's compliance, as required in the **directives**, with the safety and performance requirements formulated in general terms.

It is precisely the specific character of the "basic requirements" - in place of detailed technical specifications - which in recent years has drawn attention to the deficiencies of accreditation as normally practised in the area not subject to statutory regulation and has called into question the suitability of the EN 45000 series of standards and of accreditation in accordance with these standards as the sole adequate instrument for the assessment of notified bodies.[160]

These observations and considerations have led to the **role of accreditation** currently being reconsidered within the European Commission and the Member States. Irrespective of the extent to which accreditation bodies have been or continue to be involved in the process of assessment of notified bodies, it is now undisputed that the requirements of specific directives must be given consideration during assessment of the bodies. The competence to assess the compliance of products with the pertinent harmonized standards is not sufficient for designation of a body.

3.3.1.2 Designation, notification and publication

Within the current statutory framework, responsibility for the **designation of bodies** is the exclusive prerogative of the Member States. The Member States are at liberty to determine whether, when, and which (technically competent) bodies are designated by them and notified to the European Commission and to the other Member States.

With this **act of "notification"** the Member State fulfils its obligation to report as embodied in the relevant directive. Article 12 (1) of the Pressure Equipment Directive 97/23/EC states, for example: "Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures [..], together with the specific tasks which those bodies have been appointed to carry out and the identification numbers assigned to them beforehand[161] by the Commission. The Commission shall publish in the Official Journal of the European Communities a list of the notified bodies, with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date".[162]

It follows from this firstly, that designation is a **process separate** from notification, one which is primarily of national significance, namely the confirmation that a body is competent and authorized to perform functions within an area of the directive.

It also follows from this article, however, that this national act is not sufficient: the Member State is obliged, firstly, to notify the body to the other Member States and the Commission; secondly, the notification must also contain the identification number issued beforehand by the Commission. Not until the body is notified "to Europe" does designation take full effect[163], as only by this means does the Community learn of the

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160 Cf. in this regard also the discussion in Chapter 3.2.2. Systems applied to the individual member states and the corresponding significance of accreditation within these systems will be discussed in greater detail in Chapter 3.3.2.2.

161 Note: this sequence has been subject to change; older New Approach directives (e.g. 93/42/EEC concerning medical devices) still state that "Member States shall notify [...]. The Commission shall publish [...] a list of the notified bodies, with their identification numbers."

162 Cf. also Annex B2.

163 For a detailed discussion of the legal force and effect of designation, see Chapter 4.

legal validity of a certificate issued by this notified body or of a CE mark bearing the identification number of this body.

In 1993, the Council and the Commission approved a method which specifically describes the above procedure.[164] This document establishes that the **issuing of an identification number** does not constitute liability on the part of the Commission. Rather, it is a purely technical, automated and administrative, legally non-binding instrument by which coherent listing of the notified bodies is to be assured. By contrast, the official notification of the notified body by the Member State - normally by the Permanent Representation - to the other Member States and to the Secretariat-General of the Commission is legally binding.

Designation is thus followed by two essential steps (cf. Fig. 5): notification - which is exclusively the responsibility of the Member States - and **publication**, which is the responsibility of the Secretariat-General of the Commission. In addition to publication in the Official Journal of the European Communities, the Member States are obliged to publish information in their own countries on all bodies notified either by themselves or by the other Member States.[165]

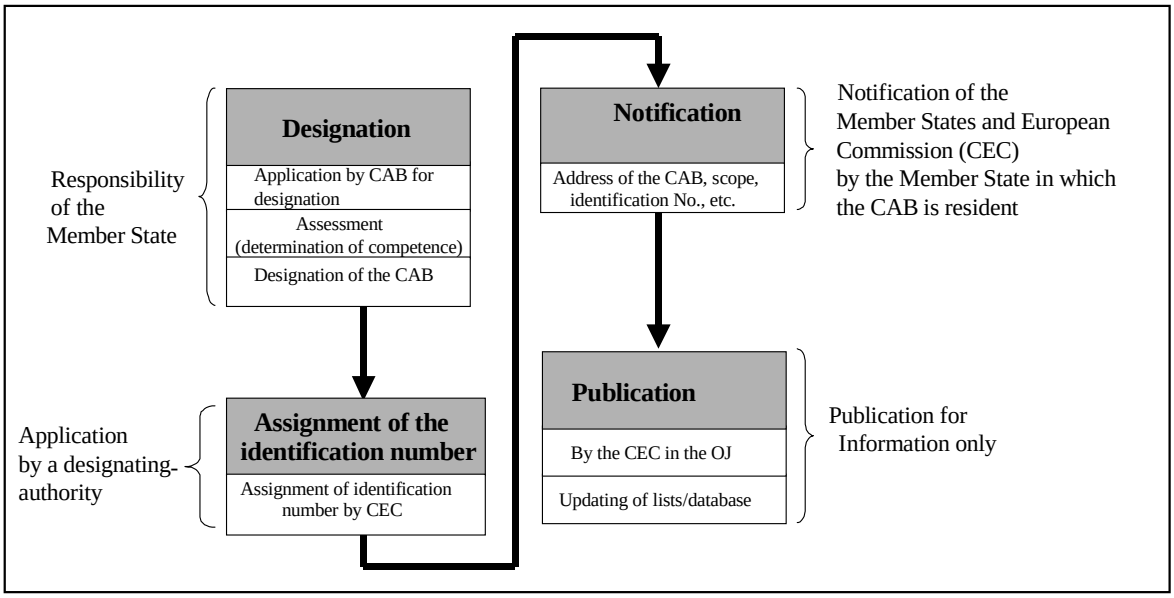

Fig. 5 Designation and notification procedure

164 Cf. in this regard Certif 93/1 Rev. 3 "Method of Coordinating the Procedures Governing the Notification and Management of Notified Bodies" and correspondence III/B/3 –EMP from the European Commission, Industry Directorate-General III, 7.2.1994 on the authorization ....

165 Blue Guide, p. 43. A regulation to this effect can be found neither in the directives (cf. Annex B), in Council Decision 93/465/EEC, nor in the notification procedure described above.

3.3.1.3 Need for surveillance

The activity of the Member State does not, however, end with notification of the body. Council Decision 93/465/EEC itself establishes that notification of the bodies is accompanied by an obligation for the Member State to satisfy itself that the notified bodies **possess at all times** the **technical competence** required by the directives, and to inform the responsible authorities in the individual Member States of performance of their functions.[166] The Council Resolution on the New Approach itself also stated that the Member States were responsible for **monitoring** the work of these bodies.

The New Approach directives have however implemented this philosophy only in part. The directives oblige the Member State to revoke designation (only) should it establish that the body no longer satisfies the specified criteria. Under such circumstances, the Member State is obliged to inform the other Member States and the Commission without delay of revocation of the designation.[167]

These provisions reveal a **weakness of the approach**: the existing statutory framework contains neither a legally binding obligation to conduct regular surveillance, nor a time limit for the validity of designation of the bodies.

The other Member States must thus rely upon the Member State which has designated a body fulfilling the duties placed upon it by the General Guidelines and satisfying itself "permanently" of the observance of the minimum criteria. The present system rules out a right of intervention or examination within the sphere of competence of another Member State, which for that matter would not be compatible with the underlying principles of the Single Market.

Should a Member State take the view that a body designated by another Member State is failing to satisfy the requirements or fulfil its duties, it may lodge a complaint to this effect with the European Commission. The Commission can in turn challenge the responsible designating authority to provide evidence that the body is upholding its competence. Should a Member State fail to meet this request, a procedure may be launched against it in accordance with Article 226 of the EC Treaty.[168]

3.3.2 Designation procedure

The Member States alone are responsible for designation of the bodies. The relevant articles of the New Approach directives indicate[169] that they must apply the minimum criteria set forth in the relevant annexes of the directives for **assessment of the competence**.[170] Furthermore, it is assumed that bodies which satisfy the conditions of the relevant harmonized standards fulfil these criteria.

Binding provisions governing the means by which the Member States must fulfil these provisions or instruments for promotion of transparency **did not exist until recently**.

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166 Council Decision 93/465/EEC, Annex I.A.k)

167 Cf. excerpts from the articles of the directives in Annexes B2 and B9.

168 Cf. Blue Guide, Section 6.2

169 Cf. the articles of the directives in Annexes B2 and B9.

170 Cf. in this regard also Chapter 3.2.2

The European Commission thus states in the Enterprise Directorate-General's draft of the consultation paper for review of the New Approach[171] that until recently, no systematic exchange of information had taken place concerning the criteria and procedures employed at national level for assessment and surveillance of the notified bodies. The Commission concluded that increasing transparency with regard to implementation of the requirements contained in the directives represented "one of the key challenges" for assurance of proper functioning of the directives.

As a result of its conclusions, it created a platform for such an exchange of information in the form of the SOGS "Notified Bodies" working group and challenged the Member States to present the systems followed by them for assessment, designation and surveillance of the notified bodies.

Following initial submission of unstructured system descriptions offering only limited scope for comparison, the Commission drew up, in conjunction with the Member States, a structured questionnaire in which the key elements of the national assessment, designation, surveillance and notification procedures were to be presented in a manner facilitating comparison.[172] Unfortunately, the activities of this working group came to a halt some time ago owing to personnel changes within the responsible Commission service, with the result that structured and therefore directly comparable descriptions have been submitted to date only by Belgium, Germany, the Netherlands, Sweden, and the United Kingdom.

The descriptions available nevertheless provide answers regarding essential issues raised by the study.

3.3.2.1 Designation systems in Germany

In a note for the Senior Officials Group on Standardisation presented in October 2000[173] the German authorities described in detail the procedures and methods of accreditation/recognition, designation and notification, particular attention being paid to the legally binding provisions of the Community and, where such provisions do not exist, the relevant national regulations. The descriptions provided can broadly be confirmed in the light of the above information. The essential principles and particular features of the German systems are summarized briefly below:

Owing to Germany's federal structure, legislative power with regard to the New Approach directives lies with the Federal Government; executive power, conversely, normally lies with the Regional Governments.

Assessment of the competence of the bodies to be notified and notification itself are **federal and regional issues**. The competent designating authorities (DIBt, RegTP, ZLG and ZLS) are also the responsible accreditation bodies. The EU directives are generally compiled by product group for transposition into German legislation in the form of laws and regulations (e.g. the Equipment Safety Act (Gerätesicherheitsgesetz), Medical Devices Act (Medizinproduktegesetz), with the associated regulations), which increasingly stipulate that the competence of the body and observance of the criteria set

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171 SOGS N426 EN of 28.1.2002

172 Cf. for example for Germany: document NQSZ-3 AK 1 N 6, "Übersicht des nationalen Notifizierungssystems Deutschland"; see also Annex E.

173 SOGS N377 EN: German Accreditation, Designation and Notification Procedures under the EC Treaty; Version 1.0 of 20.10.2000, cf. Annex F.

forth in the directives must be established by the responsible authority in an accreditation or recognition process prior to designation. Accreditation in this context is not limited to the criteria and procedures contained in the EN 45000 series of standards; rather, it encompasses all provisions of the relevant laws and regulations. Regular surveillance of the bodies is stated as a further requirement. Notification of the other Member States is the responsibility of the Federal Government.[174]

The designation process begins with submission of an application by the body seeking designation: the application must include the documents specified by the designating authority. This step is followed by assessment in consideration of the statutory requirements and those drawn up by the responsible sector committee, particular importance being attached to the product-specific competence of the body. Following successful completion of assessment, the body is issued an administrative decision to which supplementary conditions are attached concerning for example the duty to report to the designating authority and to participate in the exchange of information.[175] Accreditation/recognition of a notified body is subject to a time limit. During this period, surveillance measures are performed at regular intervals and where particular grounds exist. Following expiry of the accreditation period, which is generally five years, a comprehensive reassessment is performed.

3.3.2.2 Designation systems in other Member States

Descriptions from other Member States comparable in detail to those of the German designation system have not yet been received. In order for a conclusive overview to be obtained from the - in some cases sparse - official data supplied, a number of the essential statements have been compiled in a Table (see Annex D) for the sake of comparison.[176] The **comparison** comprises:

- the bodies responsible for designation,
- the accreditation bodies involved, where applicable, where these differ from the designating authorities,
- the role of accreditation in accordance with EN 45000,
- the existence of harmonized requirements in all sectors (products, directives), and
- the existence of specific sectoral requirements extending beyond EN 45000.

The right-hand column lists particular features of the system concerned and notable information provided by the Member States. Where the descriptions provided contain no information on the point concerned, the cells concerned are empty.

The descriptions reveal that the **terms designation and notification** are not employed uniformly, and in the case of Spain, are used ambiguously.

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174 Cf. in this regard e.g. § 15 (1) and (2) of the Medical Devices Act in Annex C.

175 Cf. in this regard also Certif 97/1 Rev. 3 DE "Deontologischer Kodex über Aufbau und Arbeitsweise des Systems der gemeldeten Stellen" of 17.7.1998

176 The table in Annex D compares the systems of 14 Member States (no description has been received from Italy; it cannot therefore be considered) and Norway (EFTA). The documents containing the data are indicated in the left-hand column.

Common to all system descriptions is the **responsibility of the ministries** or of authorities subordinate to them[177] **for designation**. In the majority of countries (e.g. Germany, Finland, France, Ireland, the Netherlands, Norway, Portugal, Sweden), the responsibility for assessment/evaluation of the bodies to be notified also rests with the designating authorities.

Accreditation bodies exist, with the exception of Luxembourg[178] in all countries. These are for the greater part[179] centralized "national accreditation bodies" with widely differing legal status: public authorities, public law bodies, and even private companies.

Only in a small number of states (Belgium and Greece) is it **mandatory for the designating authority to be accredited** in accordance with EN 45000 – generally without further specification of the standards against which accreditation is to be performed. Some countries, such as the Netherlands, Sweden, or the United Kingdom, regard the existence of accreditation as "useful". Mandatory accreditation is however explicitly rejected by the great majority of Member States. Some countries, in particular Finland, France, and interestingly also Greece, which does require accreditation, state in addition that accreditation in accordance with EN 45000 cannot of itself be regarded as sufficient evidence of competence.

The extent to which **uniform requirements** for the bodies to be notified and for the procedures for assessment and designation exist in all sectors in the individual states often cannot be ascertained clearly from the descriptions. The breadth of requirements extends from "at the discretion of the individual ministries" (Denmark), through "requirements of Certif documents and directives" (France) and the frequent formulation "minimum criteria of the directives and of EN 45000 standards" (Germany, Finland, the Netherlands, Portugal, Sweden). In some countries, "guidelines for designation and surveillance" or similar provisions for performance exist (Luxembourg, Norway, Spain). Portugal is planning to harmonize the procedures for all ministries.

Specific and **sector-specific requirements** exist only in a small number of Member States (Germany, to some extent in the Netherlands, Sweden and the United Kingdom). These will be considered here briefly: the situation in the **United Kingdom will serve as an example**. The system description[180] states:

"1. Accreditation to the relevant EN 45000 standard and for a relevant scope carries an element of presumption of conformity to the minimum criteria of the relevant Directive(s). It is not mandatory."

The Department for Trade and Industry (DTI) and the other government bodies draw up directives for the assessment of a body seeking designation with the support of UKAS, the only accreditation body recognized "in the name of Her Majesty's Government", for specific EU directives. Such a directive was drawn up and adopted for the area of medical devices by the Medical Devices Agency (MDA), which is responsible for this

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177 SWEDAC, being a public body responsible to the Swedish Ministry for Foreign Affairs, is regarded as a public authority in this context.

178 The corresponding description sets out that at the present time, an accreditation body does not exist in Luxembourg, but that such an office, the "Office Luxembourgeois d'Accréditation et de Surveillance (OLAS)", is to be set up. This body has since been set up as part of the Luxembourg finance ministry, cf. http://www.etat.lu/olas.

179 Exception: Germany. Cf. in this regard also Pierre, D.: Accreditation versus Notification, CEOC Workshop "Development in Conformity Assessment", Vienna, 16.10.2002

180 SOGS N326 EN Role of Accreditation and UCAS, 12.09.2000

area, in the form of MDA Bulletin 6 "EC Medical Devices Directive – Requirements for UK Notified Bodies" - without the involvement of UKAS. The introduction to this directive states:

> *"Many of the requirements for a notified body under the regulations are similar to clauses found within the EN 45000 series of standards. Formal accreditation against these standards may establish an applicant's basic competence. However, some aspects of the regulations are not covered by existing standards. Organisations accredited to EN 45000 series of standards will need to establish systems to ensure they comply also with these additional requirements."*

Despite the brevity of the system descriptions in certain cases, it may be concluded that the presumption of conformity **enshrined in the Modules Decision 93/465/EEC cannot be sustained**. Neither the standards in the EN 45000 series, nor the corresponding accreditation are regarded by the majority of Member States as adequate.

The descriptions of the systems further reveal that the terms assessment, evaluation, accreditation, recognition, licensing, designation and notification are interpreted and applied differently throughout Europe.

3.3.3 Requirements placed upon accreditation bodies, designating authorities and notification bodies

Responsibility for designation of the bodies lies solely with the Member States. No provision is made for (regular) inspection of the competence of the notified bodies by the European Commission or other Member States.[181]

This (desired) preservation of the Member States' sovereignty begs the question whether **comparable or harmonized requirements for the bodies responsible for** assessment, accreditation, designation and notification exist. As transparency and mutual confidence are essential pillars of the New Approach, this aspect acquires particular importance.

Specific, legally binding requirements for these bodies are virtually non-existent. Council Decision 93/465/EEC[182] states:

> *"This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks. Where a Member State withdraws its notification of a body, it must take appropriate steps to ensure that the dossiers are processed by another notified body to ensure continuity."*

The relevant articles of the EU directives[183] specify only that the Member States must apply the criteria of the relevant annex when designating bodies. The directives contain no requirements concerning the organization or (technical) competence of the designating bodies. Nor do universal guidance documents exist applicable to all directives for the practical implementation of the principles stated.

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181 Cf. however Council Decision 93/465/EEC, Annex I.A.m)

182 Council Decision 93/465/EEC, Annex I.A.k)

183 Cf. Annex B2 and B9.

The non-binding "Blue Guide"[184] likewise contains **few such provisions**:

> *"In order to build and maintain confidence between the Member States concerning the assessment of notified bodies, it is essential not only to apply the same assessment criteria. It is also important that the bodies performing the assessment of notified bodies have the capability to do so, can demonstrate an equivalent competence and operate according to the same criteria. Such requirements are laid down in EN 45003 and EN 45010. [...]*
>
> *Member states are responsible for ensuring that notified bodies maintain their competence at all times and are capable of carrying out the work for which they are notified. It is up to the Member State to choose the means and methods for this. However, the practice concerning surveillance and re-assessment developed by the accreditation bodies should be followed."*

Emphasis is thus placed upon the standards applicable to the accreditation bodies, namely **EN 45003 and EN 45010**[185]. Application of the standards is, however, voluntary, as is common in the context of the New Approach and elsewhere. The last standard stated in particular was not available at the time of adoption of Council Decision 93/465/EEC (it was not adopted until 1998), with the result that presumptions of conformity of whatever kind can also be challenged in this case.[186]

The standards stated contain general requirements for the operation of accreditation systems. EN 45003, which was revised in 1995, does not address the comprehensive tasks involved in determination of the competence of a body to be notified; the standard merely describes establishment of the competence of a laboratory with regard to the requirements posed by EN 45001.[187] In addition, an explicit requirement is formulated for the accreditation body to restrict its requirements, its assessment, and its decision to accredit, to aspects relating to the scope of accreditation (according to EN 45001).[188]

With EN 45010, adopted only in 1998, consideration was given for the first time to extension of the scope beyond that of accreditation bodies themselves.[189] This standard states that “organizations other than accreditation bodies, concerned with recognition of competence, may also use it [..]”.

EN 45010 also restricts the accreditation criteria upon which the assessment is based to the standards EN 45011/12[190]. New provisions include those governing independence and abstention from activities which are accredited by other bodies; not included however are requirements or provisions concerning designation or notification. EN 45 010 is therefore only of qualified applicability - with regard to the technical procedure of evaluation - for designating authorities.

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184 Blue Guide, Section 6.1

185 Cf. Chapter 2.2.1

186 Cf. Chapter 3.2.2.3

187 Cf. EN 45003 Section 4.1.2

188 Cf. EN 45003 Section 4.1.5

189 Cf. EN 45010, introduction and Section 1.1

190 Cf. EN 45010 Section 2.1.1.3f

This interpretation is in line with the content of various Certif documents of the European Commission.[191] The substance of these Certif documents[192] has largely been incorporated into the "Blue Guide", adopted in 1999, but are still indicated separately in the latter's Annex 3. The status of the individual documents, many of which exist only in draft form, is therefore to a large extent unclear.

In 1998, the "**Code of Conduct** for the Functioning of the System of Notified Bodies"[193] was drafted, the objective of which was/is to lay down clearly the rights and obligations of the notified bodies, and also the rules governing their relationship to the relevant notifying authorities and to the Commission. The intention is for the notifying authorities and notified bodies in the European Union to undertake to follow this code of conduct in order to enhance the credibility of the system as a whole. The modalities of the notification and designation system are to be developed by the Community institutions and applied as a common basis, in particularly by the notifying authorities.

This documents lists **four duties for the notifying bodies**, which are limited essentially to the duty to report to the European Commission and the other Member States, surveillance of the notified bodies and their modalities, and conditions for the bodies designated by them for participation in co-ordination activities and in standardization. This document, too, contains no specific requirements for the organization or the competence of the designating authority.

By contrast, **co-ordination activities launched by the Member States themselves in the area of medical devices** with the document MEDDEV 2.10/2 "Designation and Monitoring of Notified Bodies within the Framework of EC Directives of Medical Devices" led[194] to a document containing requirements which, whilst also not legally binding, was substantially clearer, including for the designating authorities.[195] As the member states were substantially involved in the drafting of this guidance document, it is assumed that they also apply the document, and thus ensure uniform, harmonized application of the requirements of the directives. Besides the requirements for notified bodies, Section III also contains explicit requirements concerning designation and surveillance, such as the scope and nature of assessment and surveillance, or requirements placed upon the assessment personnel.

3.4 EU agreements with third countries

Besides realization of the Single Market within the EU, efforts to assure the free movement of goods are being made **internationally**. The key concern is the elimination of technical barriers to trade. For this purpose, members of the WTO have concluded the

191 Cf. e.g. Certif 97/4 EN Draft: "Accreditation and the Community's Policy in the Field of Conformity Assessment" of 7.4.1997

192 Cf. also Chapter 3.2.2.4

193 Certif 97/1 Rev. 3 EN of 17.7.1998

194 http://europa.eu.int/comm/enterprise/medical_devices/guidelinesmed/2_10_2date04_2001.pdf (9.1.2003)

195 Cf. also Chapter 3.2.2.4

WTO-TBT Agreement[196], which forms the basis of the agreement dealt with in the present chapter.

The elimination of technical barriers to trade is to be assured by two basic principles: that of **most-favoured nation treatment** and that of **national treatment**[197]. In accordance with Article 2.1. of the WTO-TBT Agreement, members of the WTO are "to ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin [principle of national treatment] and to like products originating in any other country [principle of most favoured nation treatment]."

The countries are entitled to examine imported products for compliance with the requirements before or after distribution. Conformity assessments and the associated procedures are among the measures employed in the first case[198]. The conformity assessment procedures are to be drafted, adopted and applied in accordance with Article 5.1.1. of the WTO-TBT Agreement such that the basic principles stated above are observed. In the interests of further facilitation of the movement of goods, the conformity assessments performed by WTO members are to be recognized reciprocally "even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures"[199].

The members are advised to enter into negotiations over the **conclusion of agreements** for reciprocal recognition of the results of conformity assessment procedures[200]. In order for confidence in conformity assessment to be assured by the agreement, the following points must be considered during drafting and implementation: firstly, the conformity assessment bodies involved must possess and maintain appropriate expertise which can be examined for example by means of accreditation; secondly, the results of conformity assessments are to be recognized only of those bodies which are designated by the exporting country and its authorities.

Such agreements are thus concluded only between countries whose **conformity assessment systems satisfy correspondingly high standards**. In addition, Article 6.4 of the WTO-TBT Agreement encourages the members to "permit participation of conformity assessment bodies located in the territories of other Members in their conformity assessment procedures under conditions no less favourable than those accorded to bodies located within their territory or the territory of any other country". Besides the requirement to comply with the basic principles, the agreement clearly states that national bodies should perform conformity assessments in accordance with the procedures of the importing country for goods intended for export, in order to simplify further the traffic in goods.

The EU has concluded **agreements based upon the WTO-TBT Agreement for the reciprocal recognition of conformity assessment** with the USA (MRA-USA), Japan (MRA-Japan), Australia and New Zealand (MRA-Australia), Switzerland (MRA-

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196 OJ L 336, 23.12.1994, p. 86, Agreement on Technical Barriers to Trade (WTO-TBT Agreement), see in this regard also Chapter 1.3.2.1.

197 See Osterheld, B.: Abkommen der EG, p. 91; these principles were developed in the course of GATT, and retained in the WTO-TBT Agreement.

198 See Osterheld, B.: Abkommen der EG, p. 19

199 Article 6.1. of the WTO-TBT Agreement

200 Article 6.3. of the WTO-TBT Agreement

Switzerland), Israel (MRA-Israel) and Canada (MRA-Canada)[201]. In addition, **protocols on conformity assessment** and recognition of commercial products have been adopted with the Czech Republic (PECA-CZ) and with Hungary (PECA-HU) in the context of association agreements.[202]. Both the MRAs and the PECAs are agreements in the context of Article 6.3 of the WTO-TBT Agreement, which forms the subject of the present Chapter.

With the exception of the agreements between the EU and the USA, Canada and Japan, the MRAs and PECAs apply only to **originating products** of the parties to the agreements. The origin of the product is deemed to be the country in which the product was wholly manufactured or, where this is not the case, in which the last substantial manufacturing or processing stage took place. The significance of the origin of products in the context of the agreement is discussed in Chapter 3.4.3.

3.4.1 Mutual Recognition Agreement (MRA)

MRAs all share the same **structure**. They consist of a framework agreement and a number of sectoral annexes. The framework agreement contains general definitions of terminology which are relevant to an understanding of the MRA, and general explanations concerning the scope of the agreement, the institutions involved, and the procedures required for implementation of the system for mutual recognition of the results of conformity assessment. The sectoral annexes refer to product groups, the secondary specific provisions, the applicable laws and regulations, and a list of the responsible bodies and authorities for the product area.

The MRA-USA, the MRA-Canada, the MRA-Australia and the MRA-Switzerland have been analysed in greater depth in the course of the present study. The study particularly addresses the **agreement text**, in order to reveal differences between the European conformity assessment systems. Where corresponding reference is made in the MRAs, the analysis considers the laws and regulations of the parties to the agreement and the relevant international documents such as the EN 45000 series of standards.

The MRAs ensure that the authorities of the importing county recognize the assessment of a product by a conformity assessment body resident in the country of export. However, this applies only to product groups covered by the sectoral annexes of the agreement concerned. The agreements contain the reciprocal acceptance of the conformity assessment procedures; they do not however constitute reciprocal recognition of the laws and regulations. Assessment is consequently based upon the laws and regulations of the importing country.

In order for confidence in mutual recognition to be assured, facility must be provided for the conformity assessment bodies to be designated and examined, and their designation suspended and revoked. The institutions involved, the terminology, the procedures governing inclusion in the sectoral annex, suspension and deletion from the sectoral annex, and the requirements placed within the context of the various MRAs upon conformity assessment bodies, accreditation bodies, and designating authorities, are described below.

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201 MRA-Australia, OJ L 229, 17.8.1998; MRA-USA, OJ L 31, 4.2.1999, MRA-Canada, OJ L 280, 16.10.1998; MRA-Israel, OJ L 263, 9.10.1999; MRA-Japan, OJ L 284, 29.10.2001; MRA-Switzerland, OJ L 114 30.4.2002.

202 PECA-CZ, OJ L 135, 17.5.2001; PECA-HU, OJ L 135, 17.5.2001.

3.4.1.1 Terminology and institutions

For implementation of the system of reciprocal recognition of the results of conformity assessment governed by the relevant MRAs in a manner conducive to reinforcing confidence, the institutions shown in Fig. 6 are involved. In the present chapter, the MRAs considered will be compared with regard to the similarities and differences between the institutions. The relevant terms designation, conformity assessment and accreditation, which are used in this context in the MRAs, will also be considered for this purpose.

	USA	Australia	Canada	Switzerland
Designating authority	Article 1, 6 of the framework agreement	Article 1, 6 of the framework agreement	Article I, VI of the framework agreement	Article. 2, 6 of the framework agreement
Designation	Article 1 of the framework agreement	Article 1 of the framework agreement	Article I of the framework agreement	-
Conformity assessment body	Article 11 of the framework agreement	Article 1, 5 of the framework agreement	Article I, VII of the framework agreement	Article 2, 5 of the framework agreement
Conformity assessment	-	Article 1 of the framework agreement	Article I of the framework agreement	Article 2 of the framework agreement
Accreditation body	-	Annex	Annex V	Annex 2
Accreditation	-	Annex	Annex V	Annex 2
Joint Committee	Article 14 of the framework agreement	Article 12 of the framework agreement	Article XI of the framework agreement	Article 10 of the framework agreement
Joint Sectoral Committee	Article 14 of the framework agreement and in the sectoral annexes	Article 12 of the framework agreement	Article. XII of the framework agreement	-
Sectoral liaison office	Article 13 of the framework agreement	-	Article XIII of the framework agreement and in the sectoral annexes	-
Regulatory authority	Article 1 of the framework agreement	-	Article I of the framework agreement	-

Fig. 6: Terminology and institutions within the context of the MRAs

According to Article 1 (1) of the MRA-USA framework agreement, the **designating authority** is "a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this Agreement." Article 6 of the MRA-USA framework agreement requires the parties to the agreement to ensure that the designating authorities in their respective territories possess the necessary authority and technical competence. With the exception of the MRA-Canada, the

requirements placed upon the designating authorities are the same in all agreements. According to Article VI (1) of the framework of the MRA-Canada, the designating authorities need possess only the authority required in order to assure agreement between of the conformity assessment procedures[203].

By **designation**, the designating authority designates a conformity assessment body to perform conformity assessments within the framework of an agreement[204]. This raises the question as to whether the conformity assessment body is legitimized merely by the act of designation to perform conformity assessments within the framework of the agreement. The answer is no, since in accordance with Article 11 of the MRA-USA framework agreement, the contracting parties recognize only conformity assessment bodies which have been included in the sectoral annexes of the agreement. Inclusion in the sectoral annexes requires the unanimous assent of the Joint Committee[205].

In the MRA-Australia and the MRA-Canada, "designation" refers to the authorization or permission granted by a designating authority to a conformity assessment body to conduct conformity assessments[206]. It could be authorized to perform conformity assessments within the framework of the MRA immediately following designation. In this case too, however, inclusion in the sectoral annex and the associated authority do not take effect until unanimous agreement is reached by the Joint Committee[207].

The significance of designation is summarized as follows "the designation constitutes a formal judgment[208] by the Party that the conformity assessment body has demonstrated an acceptable level of technical competence in providing services identified in the designation and further has agreed to comply with the requirements of the other Party, as set out in a Sectoral Annex[209]. Designation must be followed by the agreement of the opposite party to the agreement and by inclusion in the sectoral annex before the conformity assessment body may commence its activities.

A **conformity assessment body** is a body "engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled"[210]. The conformity assessment body is resident in the country of the party executing the agreement. The conformity assessment is performed by the body in accordance with the requirements of the party to the agreement into whose country the product is imported. The products and companies which the conformity assessment body may examine with respect to the laws and regulations of the importing country are limited to those related to the sectoral annex for which the body has been authorized to conduct conformity assessment.

A **conformity assessment** is "conformity assessment means systematic examination to determine the extent to which a product, process or service fulfils specified

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203 Refer in this regard to 4.4.1.3

204 Article 1 (1) of the MRA-USA framework agreement

205 Article 7, "Designation and Listing Procedures" of the MRA-USA framework agreement

206 Article I of the MRA-Canada framework agreement, Article 1 (1) of the MRA-Australia framework agreement

207 Article XI (4) of the MRA-Canada framework agreement

208 Refer to the discussion in Chapter 4.4.1.3

209 Article VII (3) of the MRA-Canada framework agreement

210 Article I of the MRA-Canada framework agreement

requirements"“[211]. The requirements derive from the laws and regulations in the sectoral annexes. Of note is that the sectoral annex for medical products of the MRA-USA does not refer to the complete EU directives. The conformity assessment bodies in the USA employ only the following annexes of Directive 93/42/EEC and of Directive 90/385/EEC as the basis for their activity:

- Council Directive 93/42/EEC of 14 June 1990 governing medical devices:
  - Annex II: EC declaration of conformity (with the exception of Section 4)
  - Annex III: EU type examination
  - Annex IV: EC verification
  - Annex V: EC declaration of conformity (QA of production)
  - Annex VI: EC declaration of conformity (product quality assurance)
- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
  - ANNEX II: EC declaration of conformity (with the exception of Section 4)
  - Annex IV: EC verification
  - Annex V: EC declaration of conformity (QA of production)

Accreditation bodies act on behalf of the designating authorities. They may be responsible for ascertaining the technical competence of the conformity assessment bodies. In order for **accreditation**[212] of the conformity assessment bodies in relation to the regulations of the opposite party to the agreement to be assured, the accreditation bodies must[213]:

- perform the accreditation procedure (accreditation) in accordance with the relevant international documents (EN 45000 series or ISO/IEC guides) and
- be party to agreements governing reciprocal recognition, within the scope of which they are subject to peer evaluation in which the competence of the accreditation body and the conformity assessment bodies accredited by it are evaluated by recognized experts in the field concerned, or
- be party to comparative programmes in accordance with procedures to be agreed with the purpose of confidence-building and to exchanges of technical experience, in order to sustain confidence in the technical competence of the accreditation bodies and of the conformity assessment bodies. This measure may encompass joint evaluations, special programmes for co-operation, or peer evaluation.

Only in the MRA-USA is the accreditation body not explicitly stated as an institution for examination of the technical competence of the conformity assessment bodies. In this

211 Article I of the MRA-Canada framework agreement

212 Accreditation is stated explicitly in the MRA-Switzerland, MRA-Canada and MRA-Australia as a means of examining the technical competence of a conformity assessment body.

213 See annex of the MRA-Canada

case too, however, accreditation is possible as a measure for examination of the technical competence of the conformity assessment body within the context of the agreement. In accordance with Article 10 Item a) of the MRA-USA framework agreement, the designating authorities may arrange for continuous surveillance of their conformity assessment bodies by means of regular checks or evaluations. In this case too, the accreditation bodies may act on behalf of the designating authority. The parties to the agreement further undertake - as in the agreements in which accreditation is described as a procedure for examination of the conformity assessment bodies - to compare the methods employed in order to determine whether the conformity assessment bodies satisfy the requirements. The parties to the agreement further participate in joint checks and examinations of the conformity assessment activities and other evaluations of the conformity assessment bodies in the context of consultations[214].

The **Joint Committee**[215] is composed of representatives of both parties to the agreement. Decisions must be taken unanimously, each party having one vote. The Joint Committee is responsible for safeguarding the function of the agreement. In this context, it addresses in particular the following issues[216]:

- acceptance, suspension, revocation of designation, and the examination of conformity assessment bodies,
- changes to the transitional arrangements contained in the sectoral annexes,
- decision of all issues relating to the implementation of this agreement and its sectoral annexes which have not been decided by the relevant Joint Sectoral Committee,
- discussion forum for issues arising in relation to the agreement concerned,
- examination of means for improvement of the implementation of the agreement,
- co-ordination of negotiations concerning additional sectoral annexes,
- examination of the issue of whether the agreement and its sectoral annexes should be amended, and
- examination of new or additional conformity assessment procedures.

The Joint Committee may appoint one **Joint Sectoral Committee**[217] for each of the products listed in the sectoral annexes, and charge it with particular tasks. This committee is composed of representatives of the responsible regulatory authority and other competent bodies[218] of the parties to the agreement whose participation is deemed necessary[219]. It concerns itself with specific issues relating to conformity assessment and

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214 Article 10 Items b) and c) of the MRA-USA framework agreement

215 Defined as a "Committee" in the MRA-Switzerland, Article 10 of the MRA-Switzerland framework agreement

216 Article 14 of the MRA-USA framework agreement

217 Defined as a joint sectoral group in the MRA-Canada, Article XI of MRA-Canada framework agreement

218 "Experts" in Article XII (1) of the MRA-Canada framework agreement

219 Article XII (1) of the MRA-Canada framework agreement, Article 14 (2) of the MRA-USA framework agreement

regulation in the sector concerned. It advises the Joint Committee[220]. The Joint Sectoral Committee may also be responsible for resolving sector-specific problems. Decisions taken in the Joint Sectoral Committee must be reached unanimously. Each party to the agreement possesses only one vote. Should agreement not be reached, the Joint Committee may be requested to address the issue [221].

Each party to the agreement appoints **liaison offices** which assume the task of liaison within the context of the relevant sectoral annexes, and informs the other parties to the agreement in writing of their names and addresses[222]. These offices serve as contacts for the other parties to the agreement with regard to procedures, regulations and complaints in the context of the relevant sectoral annex[223].

According to Article 1 (1) of the MRA-USA framework agreement, the **regulatory authority** is "a government agency or entity that exercises a legal right to control the use or sale of products within a Party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements."

It corresponds to the market surveillance authority of the EU Member State concerned, establishment of which was required in the course of implementation of a New Approach directive and which is responsible for the surveillance of products following their distribution[224].

The agreements between the EU on the one hand and Australia and Switzerland for the other do not make provision for a surveillance function by the regulatory authority. From the EU's perspective, a corresponding provision is also unnecessary. Should a Member State identify a product - of whatever origin - which fails to meet the requirements of the relevant directive, it may take measures, for example by removing the product from the market. Naming of the regulatory authorities in the MRA-USA and MRA-Canada is thus intended, in the EU's view, for the purpose of clarification only[225].

3.4.1.2 Procedures for the assessment of conformity assessment bodies

The procedures (Fig. 7) are employed in order to safeguard the quality of the conformity assessment bodies and their activities within the context of the MRA. Common features and differences between the individual procedures in the respective MRAs are to be identified within the analysis.

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220 Article XII of the MRA-Canada framework agreement

221 See e.g. Articles 3.1 and 3.2 of the sectoral annexes concerning telecommunications equipment, MRA-USA

222 Article XIII of the MRA-Canada framework agreement

223 Article 6.4 of the sectoral annexes governing electromagnetic compatibility, MRA-Canada

224 See also in this regard e.g. Article 2 of Directive 90/385/EEC, OJ L 385, 2.8.1993, and http://www.tuev-nord.de/7267_8789.asp (2.11.2002)

225 See Osterheld, B.: Abkommen der EG, p. 268

	USA	Australia	Canada	Switzerland
Inclusion	Article 7 of the framework agreement	Article 12 of the framework agreement Annex	Article XI of the framework agreement Annex V	Article 11 of the framework agreement Annex 2
Contestation, examination, suspension	Article 8 of the framework agreement	Article 8 of the framework agreement	Article VIII of the framework agreement	Article 8 of the framework agreement
Revocation	Article 9 of the framework agreement	Article 12 of the framework agreement	Article XI of the framework agreement	Article 11 of the framework agreement

Fig. 7: Procedures within the context of the MRAs

By virtue of its **inclusion** in the sectoral annex of the MRA, the conformity assessment body is authorized to conduct conformity assessments within the scope of the agreement.

The designating authorities designate only conformity assessment bodies which are able to demonstrate that they understand the requirements and procedures for conformity assessment for which they are designated as set forth in the laws and regulations of the opposite party to the agreement, have experience with such requirements and procedures, and are capable of applying them[226].

The **technical competence** may be established by accreditation or, in the absence of suitable accreditation or under particular circumstances, by other means. Successful accreditation is assumed when the accreditation process has been performed in accordance with the EN 45000 series of standards or the ISO/IEC guides. Other forms of evidence include for example[227]:

- being party to agreements governing mutual recognition or certification systems,
- inspections by inspectors,
- qualifying examinations;
- comparisons between conformity assessment bodies.

Once evidence has been furnished, the designating authorities **inform** the representatives of their own party to the agreement on the Joint Committee of the conformity assessment body to be employed. The following information for the conformity assessment body to be accepted is submitted here in addition to name, address and fax number: range of products, procedures, standards or services, and conformity assessment bodies for which it is licensed, and the procedures for ascertainment of its technical competence.[228] The representatives submit the proposal and all appropriate documents to the representatives of the opposite party to the agreement for their assent[229].

Licensing of the conformity assessment body takes effect by the assent within 60 days of the opposite party to the agreement. Assent may be granted expressly or by

226 Annex A.2, MRA-Australia

227 Annex B.6, MRA-Australia

228 Annex D.10, MRA-Australia

229 Article 12 (6) Item a) of the MRA-Australia framework agreement

conduct[230]. Whereas the MRA-Australia, the MRA-Switzerland and the MRA-Canada permit both express assent and assent by conduct[231], the MRA-USA demands express assent[232]. In contrast to the other agreements, Article 7 Item d) of the MRA-USA framework agreement makes provision for the assenting party to the agreement to apply for an extension of 30 days to permit closer examination of the documents[233].

Should the opposite party to the agreement question, within the time allowed, the technical competence of the conformity assessment body or fulfilment by this body of the requirements, the Joint Committee may rule that the body concerned must be **examined**[234]. The contestation must be supported by objective and relevant arguments made in writing[235]. The MRA-Australia and the MRA-Canada make provision for examination of the conformity assessment body only in exceptional cases, however[236].

Except in the case of the MRA-USA, an examination results in inclusion of the conformity assessment body in the sectoral annex being postponed. The MRA-USA makes provision for the party to the agreement to renew its proposal to include the conformity assessment body in the sectoral annex upon completion of the examination[237].

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230 An implied manifestation of intent constitutes assent by conduct.

231 Article 12 (6) Item c) of the MRA-Australia framework agreement, Article XI (4) Item b) of the MRA-Canada framework agreement, Article 11 Item b) of the MRA-Switzerland framework agreement

232 Article 7 Item c) of the MRA-USA framework agreement

233 This interpretation of the extension appears logical, as such a provision would otherwise be without relevance.

234 Article 12 (6) Item d) of the MRA-Australia framework agreement

235 Article 8 (3) of the MRA-Australia framework agreement

236 Article 8 (2) of the MRA-Australia framework agreement, Article VIII (1) of the MRA-Canada framework agreement

237 Article 7 Item d) of the MRA-USA framework agreement

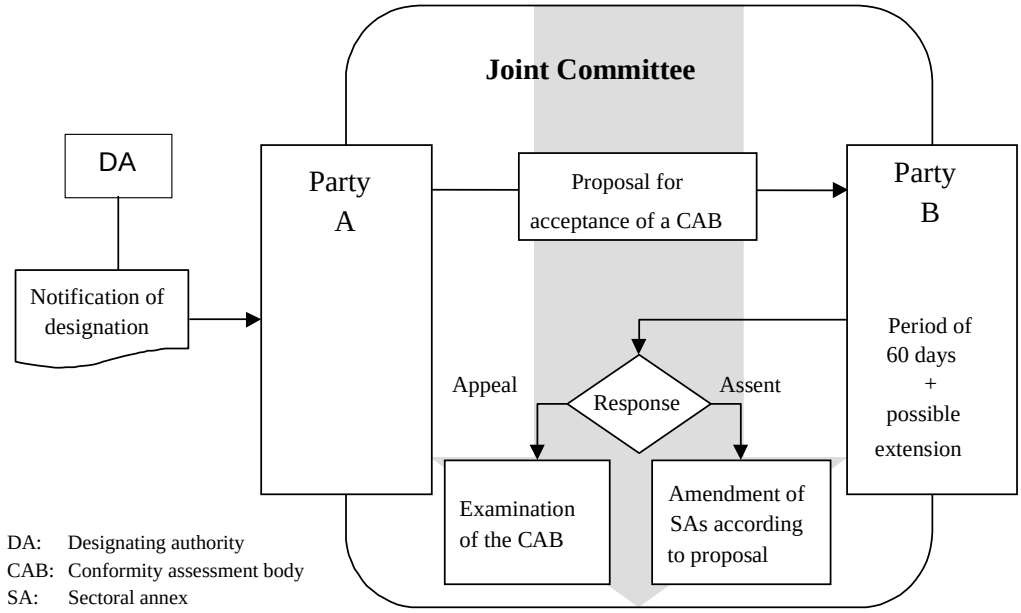

Fig. 8: Acceptance of a conformity assessment body within the context of the MRA

Fig. 8 illustrates once again the **procedure for inclusion of a conformity assessment body** in graphic form. The procedures for inclusion of the conformity assessment body in the sectoral annex are virtually identical in all MRAs. This is further demonstrated by their uniform implementation by the European Union[238].

An **examination** of the conformity assessment body may also be prompted under other circumstances than during the inclusion procedure. Article 8 Item a) of the MRA-USA framework agreement accords a party to the agreement the right at any time to challenge the technical competence of conformity assessment bodies falling within the responsibility of the opposite party to the agreement, and the fulfilment of the requirements by these bodies. A **challenge** must be supported with objective and appropriate arguments in writing and is permitted by certain agreements - as stated above - only under exceptional circumstances.

The MRA-USA is the only one of the agreements discussed here to grant the conformity assessment body the opportunity to eliminate the misgivings by presenting information to repudiate the contestation or by eliminating the deficiencies upon which the contestation was based[239]. Where these measures are taken, further action against the conformity assessment body is not necessary in this case[240].

The parties to the agreement **debate the contestation in the responsible committee**, which may rule that the conformity assessment body be examined[241]. Should the responsible committee call for examination of the technical competence or fulfilment of the requirements, this is performed by the party to the agreement in whose territory the

238 See Certif. 96/3 Rev. 6 EN

239 Article 8 Item b) of the MRA-USA framework agreement

240 This is not formulated explicitly in the MRA-USA. The conclusion appears logical, however, as such a formulation would otherwise be irrelevant.

241 Article 8 Item c) of the MRA-USA framework agreement

conformity assessment body is resident. Should a joint inspection be justified, it may be performed by both parties to the agreement[242]. The parties are supported in their examination by the designating authorities. The MRA-Australia and MRA-Switzerland expressly require that examination be performed jointly[243].

Should **disagreement** arise concerning the status of the conformity assessment body, the body may be suspended. Suspension is not absolutely essential. In accordance with Article 8 Item c) of the MRA-USA framework agreement, a **decision to suspend must be formulated explicitly** by the Joint Sectoral Committee or, where a Joint Sectoral Committee does not exist, by the Joint Committee. According to Article 8 (6) of the MRA-Australia framework agreement, the Joint Committee rule explicitly that the designation be suspended. The phrasing of the agreement permits the interpretation however that the conformity assessment bodies must be suspended in the event of an examination. The suspension remains in force until the parties to the agreement reach agreement concerning the future status of the body concerned[244].

The MRA-USA is the only agreement to regulate the consequences of the Joint Committee not reaching a decision, either at all or **within the time allotted**, which owing to the infrequency of sessions is quite conceivable. In accordance with Article 8 Item e) of the MRA-USA framework agreement, the conformity assessment body may be suspended with immediate effect in response to an application by the contesting body should the Joint Committee fail to reach a decision within ten days. The Joint Committee is charged with reaching a decision should the Joint Sectoral Committee have failed for its part to reach a decision within ten days following notification of the contestation, or should a Joint Sectoral Committee not exist.

The results of conformity assessments performed by the body prior to this point continue to be recognized, in the absence of a ruling the contrary.

Fig. 9 below illustrates the **contestation procedure** with subsequent examination and suspension of a conformity assessment body.

242 Article 8 Item d) of the MRA-USA framework agreement

243 Article 8 (4) of the MRA-Australia framework agreement, Article 8 (2) of the MRA-Switzerland agreement

244 Article 8 Item g) of the MRA-USA framework agreement

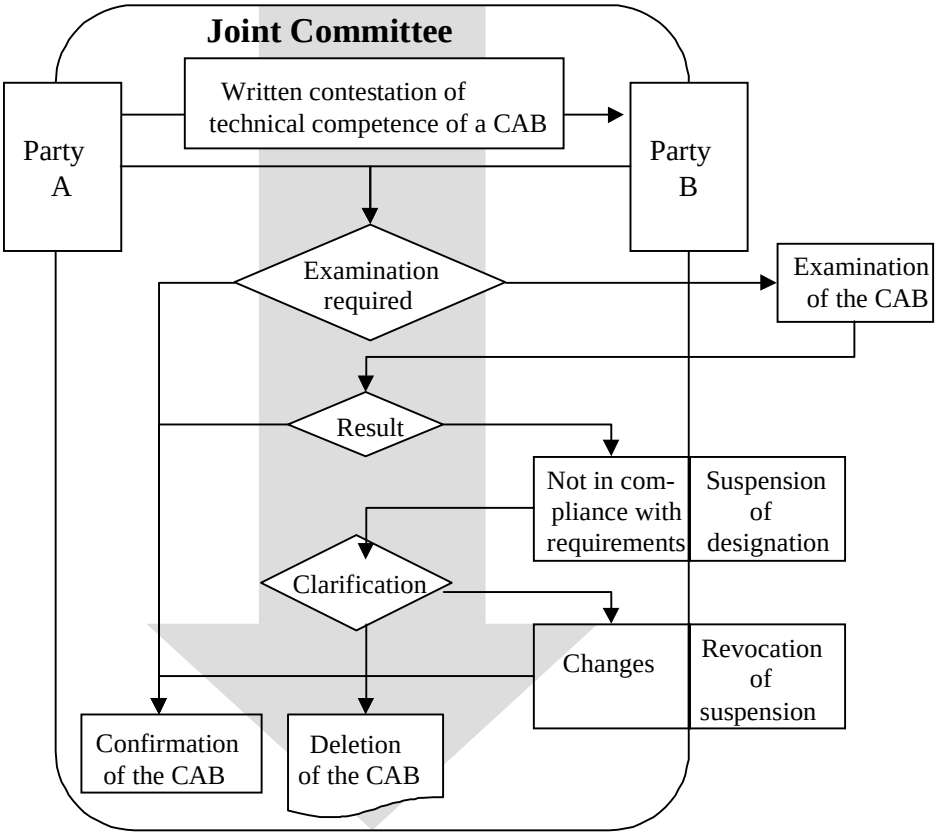

Fig. 9: Contestation, examination, suspension of conformity assessment bodies (CABs) within the framework of the MRAs

Should the conformity assessment body fail to satisfy the requirements to which it is subject, the designation of the included body must be revoked. The MRAs however contain no direct reference to revoking of designation or deletion from the sectoral annex in the course of suspension and examination of the conformity assessment bodies. The question thus arises whether a new application must be submitted by the party to the agreement for deletion from the sectoral annex as a consequence of suspension.

The procedure for the **deletion** of a conformity assessment body from the sectoral annex resembles the procedure first stated for the inclusion of a body. A party to the agreement wishing to delete a conformity assessment body from the sectoral annex informs the opposite party to the agreement in writing of this wish. Only in the MRA-USA is the conformity assessment body first granted leave to provide information refuting the grounds for revocation or to eliminate the deficiencies constituting the grounds for revocation within 30 days of receipt of the communication[245]. Deletion takes effect with the consent of the opposite party to the agreement; consent must be granted within 60 days. Should the revocation be rejected by the opposite party to the agreement, the conformity assessment body is not deleted from the sectoral annex. In this case, the responsible committee may call for an examination[246].

Should the conformity assessment body be deleted from the sectoral annex, the results of conformity assessments performed by the body prior to revocation continue to be

245 Article 9 Item b) of the MRA-USA framework agreement

246 See above: examination procedure.

recognized. The Joint Committee or the regulatory authority of the opposite party to the agreement may however call for annulment of recognition should the requirements placed upon the product within the context of the sectoral annex not be satisfied[247].

3.4.1.3 Requirements for institutions party to the process

The present sub-chapter is intended to draw attention to similarities and differences with regard to the requirements in the respective MRAs to the institutions stated in Fig. 10.

	USA	Australia	Canada	Switzerland
Conformity assessment body	Article 11 of the framework agreement	Article 5 of the framework agreement Annex	Article VII of the framework agreement Annex V	Article 5 of the framework agreement Annex 2
Accreditation body	Article 10 of the framework agreement	Annex	Annex V	Annex 2
Designating authority	Article 6 of the framework agreement	Article 6 of the framework agreement Article 7 of the framework agreement Annex	Article VI of the framework agreement Annex V	Article 6 of the framework agreement Article 7 of the framework agreement Annex 2

Fig. 10: Requirements placed upon bodies within the context of the MRAs

Designation is strictly limited to **conformity assessment bodies** who understand the requirements and procedures for conformity assessment set forth in the laws and regulations of the opposite party to the agreement, have experience with them, and are capable of applying them[248]. They must be **technically competent**. With the exception of the MRA-USA, the criteria according to which the technical competence of the conformity assessment bodies may be demonstrated is stated explicitly in all agreements. Competence is thereby based upon[249]

- technical experience with the products, processes or services concerned,
- an understanding of the technical standards and of the general requirements placed upon protection against risks,
- experience with the applicable laws and regulations,
- material requirements for the performance of the conformity assessment activity concerned,
- appropriate management of the conformity assessment activity concerned, and

247 Article 9 Item e) of the MRA-USA framework agreement

248 Annex A.2, MRA-Australia

249 Annex A.3, MRA-Australia

- any other requirements for the assurance of sustained performance of the conformity assessment activity in an appropriate manner.

The above criteria are based upon internationally recognized documents such as the EN 45000 series of standards or the future ISO 17000 series of standards, and upon specific documents concerning their interpretation, such as MEDDEV document 2.10/2[250]. The MRA-Switzerland is the only agreement to state that these documents are to be interpreted in consideration of the various requirements of the laws and regulations stated in the sectoral annexes[251].

According to Article 11 of the MRA-USA framework agreement, conformity assessment bodies must satisfy the requirement of performing conformity assessments in accordance with the requirements of the relevant sectoral annexes. The technical competence is thus evaluated in accordance with the laws and regulations stated in the sectoral annexes and additionally in accordance with relevant ISO/IEC guides and the EN 45000 series of standards, to which reference is made in some of the annexes.

In the case of the sectoral annex concerning medical products of the MRA-USA, reference is made solely to the laws and regulations. As mentioned in Chapter 3.4.1.1, the corresponding EU directives are not listed in full in the sectoral annex. In particular, Annex XI of Directive 93/42/EEC on medical devices and Annex VIII of Directive 90/385/EEC on active implantable medical devices regarding minimum criteria for the notification of bodies are missing. The responsible party to the agreement (the USA) must of course check nonetheless whether the conformity assessment bodies to be notified understand the requirements and procedures specified in the directives for the conformity assessment for which they are designated. Technical competence is an absolute requirement for this ability.

The parties to the agreement ensure that the **designating authorities** possess the requisite **authority** and the requisite **technical competence** to designate conformity assessment bodies and to monitor them, to delete them from the sectoral annexes and to suspend them[252]. Whether a designating authority is authorized is determined solely by the formal issuing of authority by the relevant party to the agreement. The requirements placed upon the technical competence of the authorities are not defined in the agreements. The references to the relevant laws and regulations and to the relevant international documents also fail to provide any indication of this competence. In practice, the designating authorities examine the technical competence of the conformity assessment bodies on the basis of minimum criteria[253].

The problem described here has been addressed in the MRA-Canada. In accordance with Article VII (3) of the MRA-Canada framework agreement, a designating authority is able, by the act of designation, only to recognize formally that a conformity assessment body has demonstrated adequate technical competence for performance of the services stated in the designation and has further undertaken to observe the laws and regulations

250 Annex A.4, MRA-Australia

251 Annex 2, A.4, MRA-Switzerland; the subordination of these documents and the associated documentation concerning their interpretation to the laws and regulations is however universally applicable owing to the prioritization of the sectoral annexes.

252 Article VI (1) of the MRA-Canada framework agreement

253 See MEDDEV 2.10/2.

stated in the sectoral annexes of the opposite party to the agreement. The designating authorities must therefore possess in particular the requisite authority[254]. As no provision is made for demonstration of the competence of the designating authority, the parties to the agreement are in a position to evaluate only whether their experience with the authorities in the designation of conformity assessment bodies has been positive[255].

The parties to the agreement must therefore guarantee that the systems of designation and surveillance virtually exclude the possibility of products entering the market of the parties to the agreement which do not meet the requirements placed upon them within the scope of the agreement. The designation system of a party to the agreement is examined, once it is in place, by the opposite party to the agreement in consultation with the designating authorities, with regard to whether it provides satisfactory assurance that the designation of the conformity assessment bodies satisfies the requirements placed upon them[256]. In the course of surveillance, the designating authorities consult their partner organizations in order to maintain confidence in the conformity assessment procedures. These consultations also extend to joint participation in examinations of conformity assessments, or other assessments of designated conformity assessment bodies[257]. In accordance with Article 10 Item b) of the MRA-USA framework agreement, the parties to the agreement undertake to compare the methods by which they check whether the conformity assessment bodies satisfy the requirements, and to consult their partner authorities, in order to maintain confidence. The designating authorities may further consult the responsible regulatory authorities of the opposite party to the agreement in order to ensure that all technical requirements are observed and met satisfactorily[258].

The requirements placed upon **accreditation bodies** are not described in the agreements. The requirements through which accreditation gives rise to the presumption that the technical competence of the conformity assessment bodies is assured have already been indicated[259].

As the accreditation process must be performed in observance of the EN 45000 series of standards, the technical competence of the accreditation body follows for example from EN 45010. The accreditation body must thus ensure the availability in particular of sufficiently **well qualified personnel** and have the **necessary resources** at its disposal[260].

The MRA-USA does not make explicit reference to accreditation of the conformity assessment bodies as evidence of their technical competence. The designating authorities may have a check or evaluation performed for the purpose of examination of the technical competence of the conformity assessment bodies[261]. They are thus perfectly able to make use of an accreditation system, provided such a system exists. Should the conformity assessment body be examined by means of accreditation, this must be

254 Articles I and VI (1) of the MRA-Canada framework agreement

255 See Osterheld, B.: Abkommen der EG, p. 229

256 Annex V, C.7, MRA-Canada

257 Annex V, E, MRA-Canada

258 Annex V, E.14, MRA-Canada, Article 10 Item d) of the MRA-USA framework agreement

259 Cf. Chapter 3.4.1.1, "Accreditation"

260 See in this regard Osterheld, B.: Abkommen der EG, p. 225 and Chapter 3.3.1

261 Article 10 Item a) of the MRA-USA framework agreement

performed in accordance with the relevant international documents, in order to maintain the confidence of the opposite party to the agreement in the conformity assessment.

3.4.2 Protocols to the Europe Agreement (PECA)

In accordance with Article 310 of the EC Treaty, the EU "may conclude with one or more States or international organisations agreements establishing an association involving reciprocal rights and obligations, common action and special procedure." The association creates preferential economic relations with third countries and supports the political, economic and social transformation process[262]. Association agreements that have been concluded include those with the EFTA states[263] and with the majority of Central and Eastern European countries.

The **associate membership status of the Central and Eastern European countries** in the Europe Agreement has the purpose of preparing the third countries for future membership. In the course of progressive integration, their legislative and economic structures are brought into line with those of the EU Member States and with Community law[264]. Within the context of economic co-operation between the parties to the agreement, the relevant laws and regulations of the third country are to be aligned with the body of regulations, standards and conformity assessment procedures of the EU[265]. For this purpose, their should firstly be promoted, and secondly, where appropriate, agreements should be concluded regarding reciprocal recognition[266]. To date, the protocols to the Europe Agreement between the European Union and Hungary (PECA-HU) and the Czech Republic (PECA-CZ) governing conformity assessment and the recognition of commercial products have entered into force[267]. The institutions and procedures in the context of PECA will then be described.

3.4.2.1 Institutions

As the main committee, the **Association Council** comprises the members of the EU Council of Ministers and the Commission on the one hand and the representatives designated by the third country on the other[268]. The decisions and recommendations of the Association Council are drafted jointly by the parties to the agreement[269]. Decisions are therefore reached unanimously.

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262 "Der aktuelle Begriff"“, http://www.bundestag.de/aktuell/begriff/2002/03_2002.pdf (20.10.2002)

263 This form of association agreement does not form the subject of the study, as the EFTA states are subject to virtually identical laws and regulations governing the movement of goods within the European Economic Area as those of the EU Member States, and the process of harmonization has been completed.

264 "Der aktuelle Begriff", http://www.bundestag.de/aktuell/begriff/2002/03_2002.pdf v. 20.10.2002; Article 1 of the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Czech Republic, of the other part, OJ L 360 31.12.1994 (EA-CZ).

265 Refer in this context to Article 75 (1) of EA-CZ

266 Refer in this context to Article 75 (2) EA-CZ

267 PECA-HU, OJ L 135, 17.5.2001; PECA-CZ, OJ L 135 v. 17.5.2001; as the two agreements are broadly identical, only the PECA-CZ is cited here.

268 Article 105 of the EA-CZ

269 Article 106 of the EA-CZ

The Council's general **area of competence** is defined by the Europe Agreement between the EU and the third country concerned:

- Its function is to monitor implementation of the Europe Agreement (Article 104 of the EA-CZ).
- For attainment of the objectives of the Europe Agreement and in cases for which provision is made, it is authorized to reach decisions and to issue appropriate recommendations (Article 106 of the EA-CZ).
- Any party to the agreement may refer any dispute relating to the application and interpretation of the Europe Agreement (Article 107 of the EA-CZ) to the Association Council.

The **tasks** of the Association Council in the area of conformity assessment are specified in the context of PECA:

- In the event of revocation of notification[270] it may rule that the conformity assessments performed before this time are invalid (Article 10 of the PECA-CZ).
- During the examination of notified bodies, it may specify suitable measures should the parties to the agreement be unable to resolve the issues and have informed it of them (Article 11 of the PECA-CZ).
- It may formulate rulings on the following points within its responsibility for proper operability (Article 14 of the PECA-CZ, Article 106 of the EA-CZ):
  - amendments to the annexes, addition of new annexes;
  - appointment of teams of experts for examination of the technical competence of notified bodies and the fulfilment of the requirements placed upon them;
  - exchange of information with regard to amendments to the legislation indicated in the annexes;
  - examination of new conformity assessment procedures;
  - resolving of problems relating to the implementation of the PECA.

The **Association Committee** supports the Association Council in the latter's fulfilment of the functions. In accordance with Article 108 (1) of the EA-CZ, it is composed of members of both parties to the agreement and of the Commission, generally high-ranking civil servants. The Association Committee thus has a staff function for all areas of the Europe Agreement. The Association Council may also transfer its authority to the Association Committee in accordance with Article 108 (2) of the EA-CZ. The Committee is thereby authorized to formulate decisions pursuant to Article 106 of the EA-CZ. The Association Committee is thus charged both with consultative and executive functions.

270 With regard to the term "notification" employed in the PECA, see also 97.

The **European Commission**[271], which is also represented on the Association Council and the Association Committee, is responsible not only for the activities ensuing from its membership, but also for the areas below concerning implementation of reciprocal recognition of conformity assessment[272]:

- notification, recognition, suspension and revocation of the designation of bodies;
- appointment of teams of experts;
- consultation, exchange of information, petitions for checks and for participation in checks;
- where necessary, response to petitions for the intervention of the Association Council in accordance with Article 11 of PECA-CZ in the event of unsatisfactory examination of the notified bodies.

These functions serve the purpose of co-ordination, for maintenance of the system for recognition of the conformity assessment procedures. Where bodies are to be notified, for instance, the Commission co-ordinates the flow of information between the parties to the agreement, the Commission departments responsible for the sectors issue comments regarding notification, and finally, the Commission publishes the notified body in the Official Journal and on the web sites provided for the purpose[273]. Publication is solely declaratory in nature. The Association Council/Association Committee is thus involved only in the case of contentious issues, such as the taking of measures concerning examination, suspension, or the withdrawal of commercial products, or for dealing with disputes concerning the application and interpretation of the PECA.

The **designating authorities** in the relevant Member State of the European Community or in the third country are responsible for reciprocal recognition of the results of the conformity assessments for a product area, and are therefore listed in the corresponding specific annex of the PECA[274].

The parties to the agreement must ensure in accordance with Article 9 (1) of the PECA-CZ that the authorities

- continue to apply laws and regulations in force;
- are capable of notifying bodies, of suspending bodies, and of lifting suspension or notification, as and when required;
- are capable of assuring conformity of the commercial products with current law or of requiring their withdrawal from the market.

The requirements placed upon the designating authorities with regard to the authority and technical competence are not governed by the PECA-CZ. The formulation of Article 9

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271 Regarding the structure and *modus operandi* of the Commission, see Oppermann, T.: Europarecht, Paragraph. 330-371

272 Article 3 (1) of Council Decision of 4 April 2001 on the conclusion of the PECA-CZ), OJ L 135, 17.5.2001, p. 1

273 Certif. 96/3 Rev. 6 EN

274 See e.g.: Annex on Mutual Recognition of Results of Conformity Assessment - Machinery - Section II, PECA-CZ

(1) permits the conclusion however that these issues are regulated in a similar way to that in the MRAs[275].

The **notified bodies** are designated by the authority in whose country the conformity assessment body is resident in accordance with the legislation of the country in which the conformity assessment body and the authority are resident[276], and notified by the opposite party to the agreement[277]. Designation documents that the conformity assessment bodies satisfy the requirements. The criteria are minimum criteria which derive from the legal references of the specific annex[278]. The parties to the agreement establish in accordance with Article 9 (2) of the PECA-CZ that the notified bodies in their territory continue to satisfy the requirements of the applicable legislation and that they possess and continue to possess the requisite technical competence.

In accordance with Article 10 (2) Item b) of the PECA-CZ, the conformity assessment body is deemed notified and technically competent for assessment of conformity with the requirements of Community law indicated in the annexes or of national law from the point at which assent is given by the party to the agreement to whose country the product is to be exported. The notified bodies must thus have been included in the annex and may only certify products governed by the annex. No further restrictions are imposed concerning the conformity assessment procedures which may be performed by the notified body.

3.4.2.2 Procedures for the assessment of conformity assessment bodies

In order for a conformity assessment body to be permitted to examine the conformity of products exported to the country of the opposite party to the agreement, it must first have been included in the relevant annex of the PECA. The designating authority must ensure in accordance with Article 9 (2) of the PECA-CZ that the bodies satisfy the requirements of the legislation indicated in the annexes. The minimum criteria for the notification of bodies[279] may be demonstrated by **accreditation**[280]. In the course of the harmonization process, accreditation systems have been set up in the Czech Republic and in Hungary which satisfy the European requirements[281].

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275 Cf. Chapter 3.4.1.1, "Designating authority"

276 The procedure according to which the conformity assessment bodies conduct examinations in accordance with the legislation of the country in which they are resident is a particular characteristic of the PECA which is made possible by the harmonization of legislation.

277 See also e.g.: Annex on Mutual Recognition of Results of Conformity Assessment - Machinery - Section II, PECA-CZ. In contrast to the MRA, the PECA employs the term "notification". This is intended to indicate that communication of assent by the opposite party to the agreement is coupled to legislative consequences. Upon receipt of assent by the opposite party to the agreement, the conformity assessment body is thus authorized to perform conformity assessments. As in the MRA, designation expresses that the conformity assessment body meets the requirements.

278 Refer in this regard e.g. to: Annex VII of Directive 98/37/EC, OJ L 207, 23.7.1998

279 For European bodies, Annex VII of Directive 98/38/EC is to be observed for example for the area of machinery

280 See Certif. 96/3 Rev. 6 EN

281 Refer to the 1999 Regular Report at http://www.europa.eu.int/comm/enlargement/report_10_99/pdf/en/ czech_en.pdf (7.11.2002); http://www.dar.bam.de (7.11.2002)

Provided the result of examination of the body is positive with regard to fulfilment of the minimum criteria stated above, the party to the agreement in the country in which the body is resident informs the opposite party to the agreement of the notification[282]. Upon **assent by the opposite party to the agreement** the body is deemed **notified** and technically competent for assessment of conformity with the requirements indicated in the annexes[283]. No facility is provided for supplementary examination at initial inclusion of the conformity assessment body such as that provided for in the MRA. One reason for this is the harmonization of legislation by the parties to the agreement[284]. Nor does the PECA govern whether assent must be given expressly or by conduct.

The parties to the agreement must **ensure at all times** that the notified bodies resident in their respective countries satisfy the statutory provisions indicated in the annexes and demonstrate the requisite **technical competence**[285].

A party to the agreement may further **challenge** the technical competence of a notified body resident in the country of the opposite party to the agreement and satisfaction of the requirements imposed upon it. The challenge must be substantiated. The opposite party to the agreement is then required to conduct an immediate examination with the assistance of the responsible authority and to report to the petitioning party to the agreement. Examination of the body may also be conducted jointly. The parties to the agreement may employ all necessary available resources for the purpose of examination. These resources are to include the existing accreditation systems. Should the problems not be resolved to the satisfaction of both parties to the agreement, the Association Council may be charged with resolving the issue; reasons for this must be stated. Should the Association Council not rule to the contrary, the conformity assessment body must cease activities from the point at which the Association Council is informed[286].

The PECAs differ from the MRAs in their regulation of **suspension**. Under the PECA, the conformity assessment body may continue to conduct conformity assessments whilst being examined by the parties to the agreement. By contrast, the MRA does not make provision for examination by the parties to the agreement prior to informing of the Joint Committee. The body must thus cease activities during the first examination, which is determined by the Joint Committee.

The extent to which suspension and further-reaching examination by the Association Council is followed by **revocation of notification** is not governed by the PECA. Nor is - in contrast to the provisions of the MRA - a party to the agreement authorized to require the opposite party to the agreement to revoke notification of a conformity assessment body resident within the latter's country. The PECA makes provision solely for revocation of a body in a party's own territory.

Should a party to the agreement decide to withdraw notification of a body within its jurisdiction, it informs the opposite party of this decision in writing. The opposite party need not assent prior to withdrawal of notification. Provided the Association Council

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282 Notification represents confirmation to the opposite party to the agreement that the body satisfies the minimum criteria.

283 Article 10 of the PECA-CZ

284 Refer to the 1999 Regular Report at http://www.europa.eu.int/comm/enlargement/report_10_99/pdf/en/czech_en.pdf (7.11.2002)

285 Article 9 of the PECA-CZ

286 Article 11 of the PECA-CZ

does not decide to the contrary, conformity assessments performed prior to this point in time retain their validity[287].

3.4.3 Rule of origin

Both types of agreement frequently contain a "rule of origin". Where this is the case, they apply only to products which originate in the country of one of the parties to the agreement. The primary purpose of the rule of origin is to prevent **fourth countries** from exploiting the agreement in order to gain easier access to the markets without, in reciprocation, simplifying the import of products from the countries party to the agreement. In other words, agreements which contain no rule of origin govern only the reciprocal recognition of conformity assessment. No distinction is drawn in this case regarding the country of origin of the goods subject to conformity assessment. This country may be a fourth country.

The MRA-USA, MRA-Canada and MRA-Japan do not contain a rule of origin. These agreements permit fourth countries to have products originating in their sovereign territory (e.g. the USA) certified and thus provided with easier access to the market of the opposite party to the agreement (e.g. the EU)[288].

In addition to the aspect of trade policy, that of safety is a further reason for inclusion of the rule of origin in an agreement. Where the agreement contains a rule of origin, goods falling within the scope of the agreement may be certified only if they originate in the countries party to their agreement, and for the safety level of which confidence already exists[289]. For this reason, the EU has concluded agreements governing reciprocal recognition only with selected third countries. In the case of the PECAs, the Eastern European countries of Hungary and the Czech Republic were first required to reach the safety standard of the EU before an agreement could be concluded with them. They obligation to meet the safety level was imposed upon them by the Europe Agreement[290]; progress is reviewed annually and documented by progress reports[291].

Where a rule of origin is agreed upon, the origin of the good is determined in accordance with the **non-preferential rules of origin**[292]. The origin of a good is determined by the country in which it is entirely manufactured, or, where this is not the case, by the country in which the last essential manufacture or processing took place[293].

In accordance with Article 23 (1) of the Customs Tariff[294] goods claimed or manufactured completely in a country are deemed goods of origin of the country

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287 Article 10 of the PECA-CZ

288 See Osterheld, B.: Abkommen der EG, p. 303 f.

289 See Osterheld, B.: Abkommen der EG, p. 248

290 "The aim of this Agreement is to provide an appropriate framework for the Czech Republic's gradual integration into the Community. To this end, the Czech Republic shall work towards fulfilling the necessary conditions," see Article 1 (2) of the EA-CZ.

291 See e.g. footnote 97

292 Article 4 of the MRA-Australia framework agreement

293 Refer in this regard to http://www.zoll-d.de/b0_zoll_und_steuern/e0_praeferenzen/index.html (12.1.2003)

294 Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff of 12.10.1992, OJ L 302, 19.10.1992, corrected with OJ L 79/84, 1.4.1993.

concerned. In this context, "claimed" refers to the creation of products in the areas of agriculture, hunting and fisheries, and the exploitation of raw materials. Entire manufacture refers to the completion of all stages of production, from claiming of the raw product, through to the final product, in a single country. According to Article 24 of the Customs Tariff, a good in whose manufacture two or more countries were involved would be deemed to be a good of origin of the country in which the good was subject to the final significant and economically justifiable process

- performed in a company established for the purpose and
- resulting in the manufacture or a new product or in a significant manufacturing stage.

The criteria stated are formulated in general terms and serve only as a model for the procedure to be followed in individual cases. The requirements placed upon the processing or manufacturing processes for particular goods for the definition of their country of origin in the context of Article 24 should be taken from the CCIP[295]. Within the scope of the Europe Agreement, the requirements placed upon the processing or manufacturing processes are likewise specified in great detail, running to several pages[296]. The origin of the good is clearly defined for the numerous cases here.

295 Commission Regulation 2454/93/EEC laying down provisions for the implementation of Council Regulation 2913/92/EEC, OJ L 253, 11.11.1993.

296 Refer in this regard e.g. to: the list of processes contained in Annex II which must be applied to non-originating materials in order for the manufactured good to acquire the status of originating – EA-CZ

4 Harmonization of terminology and definitions

In this chapter, the key problem areas of conformity assessment (designation, assessment, accreditation) already identified will not only be addressed once more, but clarified from a legal perspective. This discussion - in particular the harmonized definitions of terminology at the end of the chapter - represents the transition point from the analysis phase to the concrete proposals of the study, in particular with regard to the "Common Elements" for bodies to be notified.

4.1 Designation

A conformity assessment body must be designated by the responsible authority in its country of residence before it may be permitted to conduct conformity assessments. The legal consequence of designation differs according to whether the body has applied for permission to conduct conformity assessments within the European Single Market or on the territory of the MRA or the PECA. In addition, the designation procedure is interpreted differently within the EU.

4.1.1 Within the EU

The principle of reciprocal recognition of conformity assessment procedures within the EU is based upon the system of recognition shown in Fig. 11[297].

297 Refer also to the detailed discussion in Chapter 1.2.1

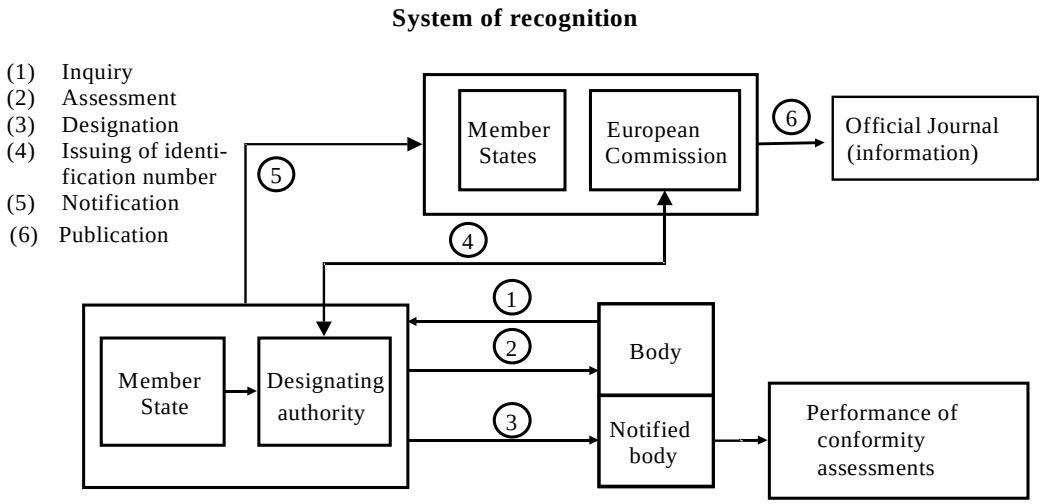

Fig. 11: The system of recognition in the EU

The body seeking designation submits an application for designation in the Member State in which it is resident (1). The Member State, i.e. the responsible authority[298] or a responsible accreditation body, assesses whether the body seeking designation possesses the requisite technical competence and is capable of conducting conformity assessment procedures, and whether it possesses the necessary independence, impartiality and integrity (2). Should the body pass the assessment, it is designated by the responsible authority (3). The other Member States and the European Commission must be informed of the designation. For this purpose, the designating authority applies to the European Commission for an identification number. Issuing of the identification number (4) by the European Commission does not constitute a transfer of rights or an obligation on the part of the European Commission[299]. The notified body is notified to the European Commission and the other Member States with reference to this identification number (5). Notification further includes all information required for the purpose. Finally, the notified body is published in the Official Journal of the European Communities (6). Publication itself is of declaratory significance only[300].

Opinions differ regarding the point in the procedure from which the conformity assessment body may begin conducting its activities. Two views exist in this respect:

- The conformity assessment body may commence its activities as soon as it is designated by the Member State, i.e. prior to notification.

298 This may also be an independent private enterprise vested by decree with specific public authority. Such enterprises may pass administrative decrees; see Obermayer, K.: VwVfG, § 1 Paragraph 81. The transfer of functions to such enterprises is however not the norm within the context of conformity assessment according to the New Approach of the EU.

299 See Blue Guide, p. 43

300 See Blue Guide, p. 43

- The conformity assessment body may commence its activities only once the other Member States and the European Commission have been notified by the responsible ministry[301].

Comment:

Designation is an **act of administration**. It constitutes a sovereign measure which is adopted by an authority for the regulation of an individual case in the field of public law and which is intended for direct external effect[302]. The subject of designation is the conformity assessment body.

The European Commission and the other Member States must likewise be made aware of designation, in order for the "Global Approach" to function. The notification performed on this basis may form part of the act of administration.

Conversely, it may be argued that notification is a **mere administrative procedure** within an authority or between authorities. Administrative procedures in this context are procedures which are neither an administrative acts, nor statutory instruments; they refer, first and foremost, to administrative activities such as those accompanying an act of administration, documenting it, informing other authorities of its claim, or recording it by means of information technology.

Whether notification constitutes part of the act of administration of "designation" or represents a subordinate administrative procedure cannot be established from the terminology alone, for example in accordance with the definitions of act of administration in accordance with the German Administrative Procedures Act (VwVfG). Of importance is whether notification contains primarily **constitutive or declaratory elements**.

Designation is the prerogative of the Member States[303]. **Notification** would be an act of administration or a **necessary component of an act of administration** only if the European Commission were entitled to reject notification of the designation, i.e. if designation were to be open to contestation in the course of notification. Should the European Commission be obliged to accept designation, i.e. should the European Commission's role consist only in ensuring proper publication, it suggests that the action is merely an administrative procedure carried out by the authorities involved in notification.

From Council Decision 93/465/EEC[304] it follows that for a designation based upon successful accreditation, the presumption of conformity applies without restrictions. In the other cases, the European Commission is accorded the right to require the submission

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301 See Blue Guide, p. 43; according to the German Federal Ministry of Economics and Labour (BMWA), the conformity assessment body is informed that it may commence its activities shortly after relaying of the necessary information and the identification number to the European Community and the other Member States.

302 See Paragraph 35 of the Verwaltungsverfahrensgesetz (Administrative Procedures Act, VwVfG); where German Federal authorities are obliged by EU legislation to act, they must apply the VwVfG with the reservation that Community law to the contrary takes precedence, as they act within the context of German public authority in the execution of Community law; Obermayer, K.: VwVfG, § 1 Paragraph 27

303 As already discussed in Chapter 3.3

304 OJ L 220/23, 30.8.1993, Annex I.A.m)

of relevant evidence.[305] It follows that **rejection of the designation** may be anticipated only for the last case stated. In this case, designation remains uncertain; without acceptance by the European Commission, it would be without effect within the European Single Market.

In the event that qualification is not demonstrated in accordance with the EN 45000 series of standards, successful completion of the notification procedure must be awaited before designation is validly declared to the conformity assessment body. An official reply may also be issued conditional upon the European Commission not raising any objections.

In the first case, i.e. where designation is pronounced following successful accreditation, notification is a mere administrative procedure subordinate to the act of administration. The responsible authority should however indicate in the corresponding act of administration that the other Member States may raise questions prior to publication in the Official Journal.

4.1.2 For the territories subject to the MRAs and PECAs

The procedure for recognition of a conformity assessment body for the territory covered by the MRA or PECA is shown in Fig. 12.

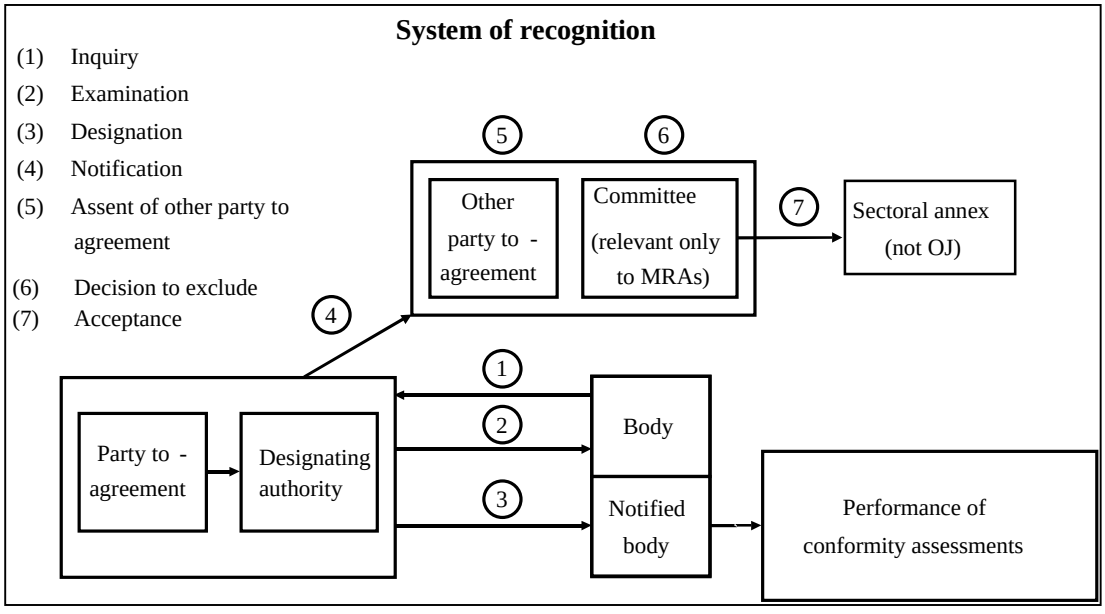

Fig. 12: The system of recognition in the case of agreements with third countries

In contrast to the situation in the European Single Market, the conformity assessment body may not commence its activities within the scope of the MRA until it has been included in the sectoral annex by decision following the **assent of the opposite party to**

[305] In practice, the Commission rarely demands evidence in such cases; rejection of designation is thus unlikely.

the agreement. Publication in the Official Journal is solely of declaratory significance in this instance[306].

Designation by the responsible authority, which also constitutes part of the acceptance procedure, includes recognition by the designating authority that the conformity assessment body has demonstrated a satisfactory technical competence for delivery of the service stated in the designation and has further declared itself willing to observe the laws and regulations of the importing country as stated in a sectoral annex.

The pronouncement of the designation to the conformity assessment body constitutes an **administrative action**, one which is however not valid until the opposite party to the agreement has assented[307]. Assent of the opposite party to the agreement is accompanied by inclusion in the sectoral annex and the conformity assessment body may therefore effectively commence its activities upon the assent of the opposite party to the agreement. The same applies to designation within the context of the PECA; here too, the conformity assessment body may not assume its activities within the scope of the agreement until assent has been granted by the opposite party to the agreement.

4.2 Assessment

EU directives must form the basis for assessment for the **area subject to harmonized statutory regulation**. The directives contain only general criteria, however. Council Decision 93/465/EEC of 22 July 1993[308] makes reference to the harmonized standards of the EN 45000 series. Specification of the provisions of the directive was not, however, fully implemented in these standards[309]. It has become clear[310] that further documents must be exploited for assessment of the technical competence of a conformity assessment body, in addition to the standards in the EN 45000 series and the requirements of the relevant New Approach directives. The ZLG assessment of laboratories and certification bodies in the area of medical devices for example was performed with the aid of[311]:

- the criteria set forth in the German Medical Devices Act (Gesetz über Medizinprodukte, MPG), the regulations issued on the basis of the MPG, and the relevant EU directives;
- the criteria set forth in MEDDEV 2.10/2 and in the standards of the EN 45000 series;
- the supporting requirements (e.g. accreditation rules) specified for the scope for which application was made.

306 See also for example Decision 3/2000 (2001/813/EC) of the 16.1.2001, OJ L 306, 23.11.2001, p. 34

307 See Maurer, H.: Allgemeines Verwaltungsrecht, § 9 Paragraph 25 and § 14 Paragraph. 19

308 OJ L 220, 30.8.1993

309 Cf. Chapter 3.2.2.3

310 Cf. also 3.3.1.1

311 Cf. ZLG accreditation rules; http://www.zlg.de/download/MP/2A03_Akk_Regeln05_2001.pdf

Evidence of successful assessment is provided proactively by the body to be designated in the form of an **accreditation certificate** or other documents.[312] In the prevailing view, accreditation is closely related to assessment in accordance with the EN 45000 series of standards but is not, as described, sufficient.[313]

The reference in the directives and in Council Decision 93/465/EEC, by which evidence may also be furnished by the body to be notified **in the form of other documents**[314] takes account of the fact that no statutory provision is made for an accreditation system. The evidence furnished by other documents is however also based upon the harmonized standards and the additional documents required; these must be comparable in their terms and quality.

Member States who have notified bodies which are not able to **demonstrate their compliance with the harmonized standards** must submit corresponding evidence on the basis of which the bodies were designated[315].

Examples for the last two possibilities stated can be found in the **agreements with third countries**[316]. These possibilities are however to be regarded as secondary with respect to accreditation; they are employed only in the absence of an accreditation system or for other important reasons[317]:

- participation of the conformity assessment bodies in regional or international agreements governing the reciprocal recognition of conformity assessment or of certification systems;
- regular assessments based upon transparent criteria and performed by experts with adequate technical knowledge;
- qualifying examinations;
- comparison of conformity assessment bodies.

In the context of third-country agreements[318] the **technical competence** in relation to the laws and regulations of the opposite party to the agreement is assumed from accreditation **only** if the accreditation bodies

- are subject to agreements for reciprocal recognition of the accreditation systems within the context of which they are subject to peer evaluation in which the competence of the accreditation bodies and of the conformity assessment bodies accredited by them is assessed by recognized experts in the area concerned, or
- in accordance with procedures to be agreed upon, participate in programmes for the comparison and exchange of technical experience, in

312 For criticism of the procedure by which a body seeking designation proactively presents an accreditation certificate which the designating authority must recognize in response, cf. Chapters 3.3 and 6.

313 See also Blue Guide, p. 41

314 The criticism of the procedure expressed above is also valid this case.

315 Council Decision 93/465/EEC, OJ L 220, 30.8.1993, Annex I.A.m)

316 Refer for example to Annex 2 Article 6 Item b) of the MRA-Switzerland

317 Refer for example to Annex 2 Article 6 Item b) of the MRA-Switzerland

318 Annex 2 Article 6 Item a) of the MRA-Switzerland; see also the MRA-Canada and MRA-Australia

order to sustain confidence in the technical competence of the accreditation bodies and the conformity assessment bodies.

In the first case concerning the **MLAs**, in particular, moves are afoot to ensure a harmonized standard of accreditation, which may have an influence upon the area subject to harmonized statutory regulation and the area not subject to statutory regulation within the EU.

Members of the EA have for example concluded an MLA. Accession to the MLA is possible following successful evaluation by a group of selected and trained representatives of the accreditation bodies party to the agreement (peer evaluation). The MLA permits a uniform standard for accreditation by all accreditation bodies. This is also the intention of the international MLA, which has been concluded by the members of the IAF[319]. In order for a uniform standard of accreditation to be sustained, the members of the MLA undertake at accession to co-operate closely with one another[320].

4.3 Definitions

Both between the area subject to statutory regulation[321] and that not subject to statutory regulation, **considerable differences** exist in some cases with regard to the terms accreditation, assessment, designation and notification. These differences have been examined again in Chapters 4.1 and 4.2. The most significant terms relating to conformity assessment are now defined in Chapter 4.3. These definitions have been selected such that they may be widely employed within the area subject to statutory regulation, i.e. such that they may be valid both in the area covered by the New Approach (EU directives) and that governed by the MRAs/PECAs.

In order for reference to be made to the restricted scope of the area subject to statutory regulation where terminology is employed **outside the study** for certain definitions, "(area subject to statutory regulation)" should be appended to the term concerned, as is increasingly becoming the norm in standardization.

In the area subject to statutory regulation, key importance is attached to the act of designation and to the authority performing the act of designation. The act and the authority thus constitute the basic framework of the terminological hierarchy. For the sake of clarity, however, the terms are listed in alphabetical order. Text marked in bold within a definition indicates that the term thus marked is also defined in the present sub-chapter of the study. The definitions have been selected such that the definitions of the terms in bold may be inserted.

The terms for the area subject to statutory regulation have been defined with **close reference** to existing definitions (e.g. MRAs, prEN ISO/IEC 17011 standards); generalizations have in some cases been necessary for the sake of universal validity.

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319 See http://www.dar.bam.de under "MLA" and Chapter 1.3.1

320 See the international MLA of the IAF, IAF-ML-99-001

321 The term "subject to statutory regulation" is understood in this context to mean in particular the area subject to harmonized statutory regulation of the Single Market and the area subject to statutory regulation of third countries within the context of the agreements.

Accreditation

Determination by an impartial third party that a body satisfies the defined requirements and is competent to perform defined conformity assessment activities (without competence to designate).[322]

Accreditation body

Third party conducting **accreditation**.

Assessment (of a CAB)

Procedure by which the **designating authority** assesses whether a body satisfies the requirements set forth in laws and regulations regarding competence for generic (non-product-specific) aspects

2. the specific technical competence

in order to be able to perform conformity assessment activities.

Notified body

Body authorized to perform defined conformity assessment activities within the scope of European directives.[323]

Designating authority

Body established or charged by a Member State which is authorized to designate or to monitor **conformity assessment bodies** falling within its jurisdiction, to suspend designation, to lift suspension, or to withdraw or revoke **designation**.[324]

Designation

Formal decision by a Member State which entitles a body, subsequent to successful **assessment**, to conduct certain conformity assessment activities within the scope of laws and regulations.[325]

Note: authorization is subject to the prior assent of the opposite party to the agreement in the case of agreements between the EU and third countries.

Conformity assessment body (CAB)

Body performing conformity assessment activities (within the scope of laws and regulations).

Note: a variant term, **accreditation body**, is required here in order to distinguish between the body conducting **accreditations**, and the **conformity assessment bodies** which can be accredited/designated.

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322 By analogy to prEN ISO/IEC 17011:2002

323 European Commission: Guide to the Implementation of Directives Based on New Approach and Global Approach, first edition, 1994,

324 Cf. in this regard Article 2 (1) of the MRA-Switzerland framework agreement and Article 1 of the MRA-USA framework agreement.

325 Cf. for example Article 1 (1) of the MRA-Australia framework agreement

Notification

Procedure by which a Member State informs the European Commission and the other Member States of the **designation** of a body.

Third Party

Body independent of the parties directly affected by the conformity assessment activities.

Note: affected parties are suppliers (First Parties) or purchasers/users (Second Parties); affected parties also include **conformity assessment bodies** in relation to **accreditation bodies**.

5 Proposals for harmonization of the requirements placed upon bodies to be notified

A body to be notified must at all times meet the minimum criteria of the relevant EU directives and the principles set forth in the Modules Decision 93/465/EEC. These requirements may be specified in greater detail by the relevant standards in the EN 45000 series. The presumption of conformity warranted by the EN 45000 series established in the Modules Decision 93/465/EEC, by which a body in possession of accreditation in accordance with the EN 45000 series is deemed to satisfy the minimum criteria set forth in the EU New Approach directives, can however not be maintained on the present terms.

The EU directives are of controlling importance for the assessment. The generally formulated minimum criteria governing the notification of bodies in each annex are however not sufficient together with the system of designation placed within the discretion of the Member States to ensure uniform standards throughout Europe.

For this reason, universally valid, common requirements for bodies to be notified ("common elements") are proposed in Chapter 5.2 which in some cases adopt and further specify the minimum criteria set forth in the EU directives. As the wording and in some cases the substance of the minimum criteria set forth in the annexes to the individual directives differ, a proposal for harmonization of the minimum criteria is first elaborated in Chapter 5.1. Finally, the possibilities for effective implementation of the "common elements" are described in Chapter 5.3.

5.1 Harmonization of the minimum criteria for the notification of bodies in EU directives

The wording and in some cases also the substance of the "minimum criteria governing the designation of the bodies to be notified" set forth in the annexes to the individual directives exhibit differences[326]. Substantive reasons for these differences are not evident. A number of bodies are active within the scope of various EU directives and designated for this purpose. In order to prevent multiple interpretations and differences in requirements for identical content in these cases, the minimum criteria should be harmonized.

Such harmonization does not exclude scope being left for additional criteria in order to satisfy the requirements of particular sectors.

The following **proposal for harmonization** of these minimum criteria[327] is based upon the criteria contained in the annexes of the EU directives, which consist of uniformly

326 Cf. Chapter 3.2.2.1 and Annex B.

327 The term "minimum criteria" may imply that the standard attained is very low. This is not the case; for this reason, a term such as "fundamental criteria" would be preferable. The term "minimum criteria" has nevertheless been retained in the present study: firstly, in order to prevent confusion with the "general requirements" of Chapter 5.2, and secondly for historical reasons: these criteria are referred to as "minimum criteria" in the New Approach directives.

used terms. Criteria are added for the exclusion of consultancy activities, differentiation from other activities, and for co-operation between the notified bodies.

1 Independence

1.1 The notified body, its top-level management, and the staff charged with conducting the conformity assessment activities shall not be identical to the designer, manufacturer, supplier, installer, user[328] or operator of the products assessed for conformity by the notified body, nor may they be acting on behalf of any of the persons involved in these activities. They may not be involved either directly or as representatives in the planning, construction, sale, installation or maintenance of these products.

1.2 The notified body and its personnel shall be free of any influence, in particular of a financial nature, upon their evaluation and the results of their conformity assessments, in particular influence by persons or groups of persons with an interest in the results of the activities. They shall not offer or provide any other services which jeopardize the confidence in their competence, objectivity, impartiality or independence. In particular, they may not undertake any consultancy activity in connection with the design, manufacture, marketing or maintenance of the products concerned within the scope of their conformity assessment activities. This does not however preclude the exchange of technical information between the manufacturer of the products and the notified body.

1.3 The notified body and its personnel, whether directly employed or subcontracted, must be independent both of the manufacturers for whom the notified body is performing conformity assessment activities, and of their competitors.

2 Personnel

2.1 The personnel of the notified body shall perform conformity assessments and reach decisions on conformity with the highest degree of professional integrity and the greatest technical expertise. The notified body must have [within the organization] its own personnel for proper completion of the technical and administrative tasks associated with the conducting of conformity assessment activities.

2.2 The personnel charged with conducting conformity assessment activities must meet the following conditions:

- They shall have completed a high standard of technical and vocational training.
- They shall possess adequate knowledge of the laws and regulations concerning the conformity assessment activities which they conduct, and adequate practical experience in the area concerned.

328 In certain cases, it may be necessary to restrict these exclusion criteria. This is the case for example in the area of medical devices, as it may not otherwise be possible to assure the technical competence required during conformity assessment, for example by involving clinicians. Cf. in this regard for example MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices, Section II, 2 a).

- They shall be suitably qualified for the production of certificates, test records and reports in which the conformity assessment activities performed are documented.

2.3 The impartiality of the personnel must be guaranteed. Remuneration of the personnel may not stand in relation to the number of conformity assessments conducted by them, nor to the results of the same.

3 Facilities

The notified body must possess or have access to the equipment (test equipment, calibration equipment, test principles such as regulations, standards, etc.) required for proper completion of the technical and administrative tasks associated with the performance of conformity assessment activities.

4 Liability

The notified body shall take out liability insurance, unless this liability is assumed by the Member State on the basis of national legislation or the conformity assessment activities are conducted by the Member State itself.

5 Confidentiality

The personnel of the notified body shall observe professional secrecy with regard to any information acquired in the course of performance of their tasks within the scope of the directives or any provision of national law giving effect thereto. This requirement shall not apply to the provision of information vis-à-vis the competent administrative authorities of the Member State in which its activities are carried out, or in such cases where a directive makes provision for exemptions.

6 Co-operation

The notified body shall participate in the co-ordination activities organized by the Member States and the European Commission among/between the notified bodies, for example in groups of notified bodies in the context of directives.

5.2 General requirements placed upon bodies to be notified ("common elements")

As shown by the discussion in Chapter 3, the minimum criteria for the notification of bodies formulated in very general terms together with the system of designation at the discretion of the Member States are **not sufficient** to ensure uniformly high standards throughout Europe. For this reason, generally valid, common requirements for bodies to be notified ("common elements") are proposed below which in some cases adopt the minimum criteria (Chapter 5.1) - adapted to the more general formulation "conformity assessment body" and specify their terms in further detail. These requirements are formulated such that they may be employed **comprehensively in the area subject to statutory regulation**, i.e. they may be valid both in the area of the New Approach (EU directives) and in the area governed by the MRAs/PECAs. For this reason, the more

general term "conformity assessment body" is employed below in place of the term "notified body".

The common elements are divided into those placing requirements upon

- the structure,
- the resources,
- the process, and
- the management system

of the body.

5.2.1 Structure

1 Legal responsibility

The conformity assessment body must be a registered legal person or a part of a registered legal person.

Note: owing to their governmental status, state conformity assessment bodies are deemed to be legal persons. Where the conformity assessment body forms part of a larger government body, the government shall be responsible for identification of the conformity assessment bodies in a manner which permits no conflict of interest with the state accreditation bodies or market surveillance authorities. Pursuant to these provisions, the conformity assessment body shall be regarded as a "registered legal person".

2 Organization and responsibilities

2.1 Structure and *modus operandi* of a conformity assessment body[329] shall be such that confidence in their conformity assessment activities is assured.

2.2 The conformity assessment body shall be responsible for its activities and decisions, including the issue, maintenance, extension, restriction, suspension and withdrawal of conformity assessment certificates.

2.3 The conformity assessment body shall possess a description of its legal status which shall include where applicable the names of its owners and, where these are not the same persons, the names of the persons with control over the conformity assessment body.

2.4 The conformity assessment body shall document the functions, responsibilities and authority of top-level management and of further personnel who may have an influence upon the performance and results of the conformity assessment activities.

2.5 The conformity assessment body shall appoint the top-level management (group(s) or person(s)) who shall possess complete authority and bear complete responsibility for

329 Where the conformity assessment body forms part of a legal person, the following requirements shall apply to the legal person in its entirety.

a) the development of arrangements for the *modus operandi* of the conformity assessment body;

b) supervision of implementation of the arrangements and procedures;

c) supervision of the conformity assessment body's finances;

d) decisions taken by the conformity assessment body;

e) contractual agreements;

f) the delegation of authority to committees or individuals, where necessary, for the performance of defined activities in the name of top-level management.

2.6 The conformity assessment body shall document its entire organizational structure by the recording of authority and responsibilities.

3 Independence and impartiality

3.1 The conformity assessment body shall be organized and operated in such a manner as to ensure independence, objectivity and impartiality in its activities, and shall introduce and maintain a documented structure for assurance of its impartiality.

3.2 The arrangements and procedures of the conformity assessment body shall not be discriminatory and shall be carried out in a nondiscriminatory manner. The conformity assessment body shall make its services available to any party seeking conformity assessment which falls within the body's scope of activity.

3.3 The conformity assessment body and its personnel shall not be subject to any influence, in particular of a financial nature, upon their evaluation and the results of their conformity assessments, in particular to influence by persons or groups of persons with an interest in the results of the activities.[330]

3.4 The conformity assessment body shall ensure that each conformity assessment decision is taken by competent persons or committees. These shall not be identical to the parties performing the conformity assessment activities concerned.

3.5 The conformity assessment body and other parts of the legal person to which it belongs shall not offer or provide any activities or supplementary services which call into question their competence, objectivity, impartiality or independence.

3.6 The conformity assessment body, its top-level management, and the staff charged with conducting the conformity assessment activities shall not be identical to the designer, manufacturer, suppler, installer, user[331] or operator of the products assessed by the body for conformity, nor may they be a representative of a person involved in these activities. They must be independent both of the manufacturers for whom the body conducts conformity assessment activities and of their competitors, and shall not be involved either directly or as representatives in the planning, construction, sale, installing or maintenance of these products.

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330 Excerpt from the minimum criteria of the directives; see Chapter 5.1, Section 1.2

331 In certain cases, it may be necessary to restrict these exclusion criteria. This is the case for example in the area of medical devices, as it may not otherwise be possible to assure the technical competence required during conformity assessment, for example by involving clinicians. Cf. in this regard for example MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices, Section II, 2 a).

3.7 The conformity assessment body and its personnel - whether directly employed or subcontracted - shall not offer or perform or have offered or have performed consultancy services to the manufacturer, the representative, a supplier or their competitors, in particular consultancy services concerning the design, manufacture, marketing or maintenance of the products concerned, within the context of its conformity assessment activities. This does not however preclude the exchange of technical information between the manufacturer of the products and the conformity assessment body.

3.8 The conformity assessment body and its personnel shall not bear any responsibility for market surveillance.

Note: should the conformity assessment bodies and market surveillance authorities in a Member State be responsible to the same authority, the areas of competence shall be organized such that no conflict of interest exists between the two bodies.[332]

3.9 The conformity assessment body shall ensure that the activities performed by associated associated bodies (see Section 3.10) do not jeopardize the confidentiality, objectivity and impartiality of its conformity assessment activities. An associated body in the context of Section 3.10 shall not be the designer, manufacturer, supplier, installer or operator of the products the conformity of which is assessed by the conformity assessment body.

3.10 An associated body is a legal person in its own right which is associated with the conformity assessment body in one or more of the following ways:

- common ownership with influence upon the conformity assessment activities of the conformity assessment body;
- common top-level management for the activities described in Section 2.5;
- common personnel for the conformity assessment activities of the conformity assessment body;
- contractual agreements with a bearing upon the conformity assessment activities of the conformity assessment body;
- common names and logo and/or symbols.

Note: in the context of Section 1, a separate part of the public administration outside the governmental conformity assessment body shall be regarded as an associated body.

3.11 The conformity assessment body shall have in place documented procedures for the identification, examination and resolution of all cases in which a conflict of interest is suspected or proven. It shall establish, investigate and document the relationship to the associated bodies in order to identify conflicts of interest, irrespective of whether they have their origin in the conformity assessment body or the activities of the associated body. Should conflicts be identified, suitable measures shall be taken.

4 Confidentiality and secrecy

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332 Based upon Blue Guide, Section 8.1, p. 54

4.1 The conformity assessment body shall take suitable precautions to ensure the confidentiality on all levels, including those of its committees and subcontractors, of the information which comes into its possession during the proper performance of its conformity assessment activities.

4.2 The conformity assessment body shall ensure by legally binding contracts with the personnel employed that professional secrecy and the regulations implementing the provisions of Section 4.1 are observed.

4.3 Confidential information shall not be communicated to other parties without the written consent of the organization or person concerned, except vis-à-vis the competent authorities or in cases where required by legislation.

5 Liability

The conformity assessment body shall have taken precautions to enable it to cover claims for liabilities arising from its conformity assessment activities. It shall take out liability insurance, unless such liability is assumed by the state on the basis of national legislation or the conformity assessment activities are conducted by the Member State itself.[333]

6 Financial stability

The conformity assessment body shall have at its disposal the financial resources required to conduct its business operations and shall document and provide evidence said resources. The conformity assessment body shall be in possession of a description of its source(s) of income.

7 Participation in co-ordination activities

The conformity assessment body shall participate in[334] national and international co-ordination activities by and between the conformity assessment bodies organized by government bodies in order to attain maximum coherence of conformity assessment activities.

Note: participation in international co-ordination activities shall not be mandatory where a principle of delegation is agreed at national level and it is assured that the body remains informed of the decisions and documents drawn up by the relevant group of conformity assessment bodies and applies said decisions and documents.

5.2.2 Resources

5.2.2.1 Personnel

The present chapter contains general requirements concerning the personnel of conformity assessment bodies. Further requirements concerning the personnel employed

333 Excerpt from the minimum criteria of the directives; see Chapter 5.1, Section 4

334 for example in groups of notified bodies organized by Member States or by the European Commission within the context of directives.

for certain conformity assessment tasks may be found in the relevant EN standards[335], in particular

- for the examination and inspection personnel: EN 17025 and EN 45004;
- for auditors: EN 45012;
- for personnel responsible for evaluation and decision-making: EN 45004, EN 45011 and EN 45012.

General requirements are:

1 Availability, competence, independence

1.1 The personnel of the conformity assessment body shall conduct conformity assessments and reach decisions on conformity with the highest degree of professional integrity and the greatest technical expertise. The conformity assessment body shall have at its disposal [within the organization] its own personnel for proper performance of the technical, scientific and administrative tasks associated with the performance of conformity assessment activities.[336]

1.2 The personnel charged with conducting conformity assessment activities must meet the following conditions:

- They shall have completed a high standard of technical and vocational training.
- They shall possess adequate knowledge of the laws and regulations governing the conformity assessment activities to be performed, and shall possess adequate practical experience in the area concerned.
- They shall possess adequate knowledge and experience of the products and technology forming the subject of the conformity assessment.
- They shall be suitably qualified for the production of certificates, test records and reports in which the conformity assessment activities performed are documented.[337]

1.3 The impartiality of the personnel must be guaranteed (see also Chapter 5.2.1, Section 3). Remuneration of the personnel may not stand in relation to the number of conformity assessments conducted by them, nor to the results of the same.[338]

1.4 The conformity assessment body shall record the scope and limits of the duties, responsibilities and authority of each person concerned.

1.5 The conformity assessment body shall require all personnel to undertake formally by signature or equivalent form of confirmation to observe the rules laid down by it. The obligation shall consider aspects concerning confidentiality, economic independence and possible conflicts of interest, and all existing and previous relationships to the clients concerned.

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335 Cf. Chapter 2.2.1

336 Excerpt from the minimum criteria of the directives; see Chapter 5.1, Section 2.1

337 Excerpt from the minimum criteria of the directives; see Chapter 5.1, Section 2.2

338 Excerpt from the minimum criteria of the directives; see Chapter 5.1, Section 2.3

1.6 The conformity assessment body shall establish procedures for the selection (requisite qualifications and vocational experience) and training (requisite initial and ongoing training) of the persons employed for conformity assessment activities.

2 Assessment of performance

2.1 The conformity assessment body shall assure the satisfactory performance of the conformity assessment activities and conformity assessment decisions by the establishment, implementation and maintenance of procedures for monitoring the performance and competence of the personnel involved. In particular, the conformity assessment body shall examine the performance and competence of its personnel in order to establish the need for training.

2.2 The conformity assessment body shall conduct observations, such as on-site observations, or employ other techniques, such as evaluation of the conformity assessment reports or flow of information from its customers, in order to evaluate the performance of each person employed for conformity assessment activities and to recommend corresponding measures for improvement of the performance. Each person shall be assessed on a regular basis, normally at three-yearly intervals.

3 Records

The conformity assessment body shall maintain records of the relevant qualifications, training, vocational experience and competence of each person performing conformity assessment activities. The records shall be kept up-to-date and shall contain at least the following information:

a) Name and address

b) Specified area of competence and responsibility

c) Education and vocational training, skills, knowledge of languages

d) Vocational training (related to the conformity assessment activities to be performed)

e) Training in conformity assessment activities

f) Results of performance assessments

g) Documentation of conflicts of interest (cf. Chapter 5.2.1, Section 3.11)

5.2.2.2 Facilities

The present chapter contains general requirements concerning the facilities which a conformity assessment body must possess. Further details can be found in the relevant EN standards[339].

General requirements

1 The conformity assessment body shall possess or have access to suitable premises and facilities required for proper performance of the scientific, technical and

339 See Chapter 2.2.1

administrative tasks associated with the performance of conformity assessment activities.[340]

Note: facilities may include test equipment and calibration equipment, and also test principles such as laws and regulations, standards, literature, and access to databases etc.

2 The conformity assessment body shall ensure that the test principles and other documents required for conformity assessment activities are completely up-to-date at all times.

3 The conformity assessment body shall possess suitable premises in order to be able to ensure the secure and confidential handling and storage of documents and records including data media and objects under test.

4 The conformity assessment body must ensure the serviceability and accuracy of test equipment at all times. Where conformity assessment activities require the use of technical equipment which is normally under the manufacturer's control and is used by the latter, the conformity assessment body shall be able to demonstrate that it had both access to and complete control of the facilities during its activities.

5.2.3 Process

The process of conformity assessment shall be based upon the conformity assessment procedures established in the relevant directives[341]. In the context of performance of conformity assessment procedures, the conformity assessment body shall fulfil the following generic requirements in the form of **common process elements**:

1 Contractual arrangement with the customer

The conformity assessment body shall require a formal application signed by an authorized representative of the applicant containing the information required by law and necessary for performance of the conformity assessment activities.

2 Subcontracting

2.1 The conformity assessment bodies may, where so permitted by the laws and regulations, transfer certain conformity assessment activities (e.g. tests) to subcontractors. The decision-making process may not however form part of the subcontracting agreement.

Note: a conformity assessment body may subcontract only strictly defined tasks in the form of subcontracting agreements where these are substantial and self-contained parts of the technical activity.[342]

2.2 The conformity assessment body shall ensure that the subcontracted activities are performed in accordance with detailed documented procedures which are

340 Excerpt from the minimum criteria of the directives; see Chapter 5.1, Section 3

341 Refer in this regard to Chapter 3.1

342 Cf. Blue Guide, p. 47

identical or equivalent to those employed in the conformity assessment body itself.

2.3 Should the conformity assessment body subcontract conformity assessment activities, it shall have arrangements in place describing the conditions under which the activities are subcontracted.

2.4 A properly documented, direct, contractual agreement under private law must be in place between the conformity assessment body and its subcontractors (e.g. external auditors, test laboratories[343]) which contains the corresponding provisions, including those governing confidentiality and independence. The subcontractor shall for its part be prohibited from subcontracting work.

2.5 The conformity assessment body shall:

a) assume complete responsibility for the subcontracted conformity assessment activities and shall itself possess the competence in the decision-making process for all subcontracted activities;

b) maintain its responsibility for the granting, maintenance, extension, restriction, suspension, and withdrawal of conformity assessment certificates;

c) establish in advance the conformity assessment activities to be performed, for example in the form of a test plan;

d) ensure that the subcontracted conformity assessment body and its personnel to which the conformity assessment activities are subcontracted are competent and meet the relevant requirements of the directives, in particular those governing independence;

e) obtain the consent of the customer to employ subcontractors prior to concluding the subcontract.

2.6 The conformity assessment body shall maintain a list of its subcontractors. It shall possess means for evaluation or monitoring of the competence of the subcontractors and for recording of the results.

2.7 Subcontractors may be assumed to be competent when they are accredited by the responsible authority or the competent national accreditation body for the performance of conformity assessments within the scope of the applicable laws and regulations.

3 Use of test reports submitted by the manufacturer

Certain conformity assessment modules make provision for the submission of test reports by the manufacturer. Where such test reports are used in the context of conformity assessment decisions, the conformity assessment body shall observe the following:

3.1 The conformity assessment body may, where corresponding provision is made in the laws and regulations, consider test reports presented by the manufacturer in its conformity assessment decision.

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343 Cf. Blue Guide, p. 47

3.2 The conformity assessment body must satisfy itself that the test reports have been issued by conformity assessment bodies which are competent and independent of the manufacturer.

Note: for the EC design-examination certificate (Module H), test reports issued by the manufacturer's test laboratories may also be considered.

3.3 The conformity assessment body shall assume full responsibility for the test results employed.

4 Decision-making process

4.1 Prior to reaching a conformity assessment decision, the conformity assessment body shall ensure that the information and documents required for the decision such as test reports or audit reports are available in full.

4.2 Based upon an assessment of the available information and documents, the conformity assessment body shall decide whether the requirements of the laws and regulations are met.

4.3 Should the requirements be met, the conformity assessment body shall issue the requisite conformity assessment certificates and dispatch them to the customer without delay.

4.4 The conformity assessment certificates must satisfy the provisions set forth in the laws and regulations or agreed in co-ordination groups.

5 Records

5.1 The conformity assessment body shall maintain records in order to be able to demonstrate that the applicable requirements of the laws and regulations are met. The records shall in particular contain:

a) records of conformity assessment activities and of results of conformity assessments;

b) the relevant correspondence;

c) copies of the conformity assessment certificates.

5.2 The conformity assessment body shall hold the records in safe keeping in order to ensure confidentiality. The records shall be managed.

6 Use of the identification number/identification of the conformity assessment body

6.1 The conformity assessment body shall have arrangements in place for the protection and use of the identification number with which it has been issued.

6.2 The conformity assessment body shall ensure, by agreements reached with its customers, that the identification number is not abused.

6.3 Should abuse of the identification number come to the conformity assessment body's attention, it shall take appropriate measures in order to prevent further abuse.

7 Duty to report

7.1 Vis-à-vis customers

The conformity assessment body shall maintain the following information at its customers' disposal which is to be updated at appropriate intervals:

a) information on the conformity assessment programme to be performed;

b) information on the requirements to be met (laws and regulations, basic requirements, harmonized standards, etc.);

c) general information on the fees/prices of conformity assessments;

d) a description of the rights and duties of the conformity assessment bodies and of customers;

e) information on complaints and appeals procedures.

7.2 Vis-à-vis authorities

The conformity assessment body shall inform the competent authority immediately of:

a) essential changes in particular concerning its legal form, organization, *modus operandi*, personnel and subcontractors;

b) any incidents coming to its attention relating to products within the scope of the conformity assessment certificates which it has issued;

c) all conformity assessment certificates issued, suspended, withdrawn or denied, except where regulated to the contrary in the case concerned or by statute.

7.3 Vis-à-vis third parties

The conformity assessment body shall upon request provide public access to the status of the conformity assessment certificates which it has issued, except where otherwise regulated by statute.

5.2.4 Management systems

The conformity assessment body shall introduce, implement and maintain a management system and continually improve its effectiveness in compliance with the requirements laid down for conformity assessment bodies.[344] The following sections define general requirements applicable to the management system of conformity assessment bodies.

1 General requirements

1.1 Top-level management of the conformity assessment body shall define and document arrangements and quality targets, including a quality policy, for its activities and shall demonstrate its obligation regarding the quality and compliance with the requirements laid down for conformity assessment bodies. Management shall ensure that the fundamental arrangements are understood, implemented and maintained at all levels of the conformity assessment body. The objectives shall be measurable and shall conform to the fundamental arrangements applicable to the conformity assessment body.

344 Cf. also SOGS N 426, Table 3

1.2 The conformity assessment body shall operate a management system appropriate to the nature, area and scale of its activities. All applicable requirements shall be addressed either in the manual or in the associated documents. The conformity assessment body shall ensure that the manual and the associated documents are accessible to all personnel. It shall further ensure that the procedures of the system are implemented effectively.

1.3 Top-level management of the conformity assessment body shall designate a member of the managerial staff who - independent of other responsibilities - shall have responsibility and authority to:

a) ensure that the processes required for the management system are introduced, implemented and maintained;

b) report to top-level management on the performance of the management system and any need for improvements.

2 Document control

The conformity assessment body shall lay down procedures for the control of all documents relating to its conformity assessment activities. The procedures shall define the measures required to:

a) confirm the appropriate nature of documents prior to issue;

b) revise and update documents where necessary and to re-attest them;

c) assure that amendments and the current revision status of the documents are identifiable;

d) assure that the relevant versions of the documents concerned are available to the personnel, to subcontractors and to customers where they are needed;

e) assure that the documents remain legible and easily identified;

f) assure that documents of external origin are marked and their distribution controlled;

g) prevent accidental use of outdated documents and to mark such documents appropriately should they be retained for any purpose;

h) assure where relevant the confidentiality of documents.

3 Records

3.1 The conformity assessment body shall lay down procedures for the identification, collection, registration, access, filing, storage, care and disposal of its records.

3.2 The conformity assessment body shall have at its disposal procedures for controlling the storage of records for a period corresponding to its contractual and legal obligations. Access to these records shall be controlled in accordance with the confidentiality agreements.

4 Complaints and appeals procedures[345]

345 A "complaint" constitutes any expression of dissatisfaction by a person or organization vis-à-vis the conformity assessment body to which a response is expected in connection with the activities of the

The conformity assessment body shall establish a procedure for the handling of complaints. The conformity assessment body shall:

a) reach a decision concerning the justification for the complaint;

b) assure that complaints concerning customers of the conformity assessment body are first dealt with by the customers themselves;

c) designate for the investigation of complaints a person or group of persons who are competent and independent of the subject of the complaint;

d) take corresponding measures and assess their effectiveness;

e) inform the customers of the final decision(s) of the conformity assessment body;

f) maintain records concerning all complaints, final decisions and follow-up measures taken.

5 Nonconformances and corrective measures

The conformity assessment body shall establish procedures for the identification and control of nonconformances within its own activities. The conformity assessment body shall further take corrective measures, where necessary, to eliminate the cause of the nonconformances and to prevent their recurrence. The corrective measures must be appropriate to the consequences resulting from the difficulties which have arisen. The procedures shall encompass the following:

a) identification of nonconformances (e.g. from complaints and internal audits);

b) identification of the causes of nonconformances;

c) assessment of the need for measures to ensure that the nonconformances do not recur;

d) establishment and timely implementation of the necessary corrective measures;

e) recording of the results from the corrective measures taken;

f) review of the corrective measures taken and their efficacy.

6 Preventive measures

The conformity assessment body shall establish procedures by which scope for improvement may be identified and preventive measures taken, in order to exclude potential causes of nonconformances. The preventive measures shall be commensurate with the consequences of the potential problems. The procedures for preventive measures shall establish requirements for

a) recognition of possible nonconformances and their causes;

b) establishment and implementation of the requisite preventive measures;

c) recording of the results from the measures taken;

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body or its customers (based upon ISO/IEC DIS 17000); this also includes appeals, for which reason this element has been included under this heading and not, although possible, under "common process elements". An "appeal" is the desire on the part of the customer for renewed examination of a negative decision on the part of the conformity assessment body (based upon prEN ISO/IEC 17011)

d) examination of the efficacy of the preventive measures taken.

7 Internal audits

7.1 The conformity assessment body shall audit its activities in order to demonstrate that they satisfy the requirements established for conformity assessment bodies and that the management system is being implemented and maintained.

Note: ISO 19011 provides guidance documents for the performance of internal audits.

7.2 Internal audits must generally be performed at least annually. The frequency of internal audits may be reduced should the conformity assessment body be able to demonstrate that its management system has been implemented effectively and has proved stable. An audit programme shall be planned which makes allowance for the status and the significance of the areas to be audited and the results of past audits.

7.3 The conformity assessment body shall ensure that:

a) Internal audits are performed by personnel possessing sound expertise in conformity assessment issues, in the performance of audits and in the requirements placed upon conformity assessment bodies;

b) internal audits are performed by persons other than those performing the activity to be audited;

c) the personnel responsible for the area to be audited is informed of the audit results;

d) timely and appropriate measures are taken;

e) all possibilities for improvement are identified.

8 Management assessments

8.1 Top-level management of the conformity assessment body shall establish procedures for regular assessment of its management system in order to assure the latter's sustained suitability and efficacy with regard to fulfilment of the relevant requirements and of the established quality policy and quality targets. These assessments should normally be performed once each year.

8.2 The inputs for the management assessments shall contain, where available, the current performance and the possibilities for improvement with regard to

a) audit results;

b) results of assessments, where applicable;

c) participation in international activities, where applicable;

d) feedback from interested parties;

e) performance of the conformity assessment process;

f) nonconformance trends;

g) follow-up measures from past management assessments;

h) attainment of targets;

i) changes which may influence the management system;

j) analysis of complaints and appeals.

8.3 The results of the management assessment shall contain measures relating to:

a) improvement of the management system and its processes;

b) improvement of services and of the conformity assessment process in compliance with the relevant standards and the expectations of the interested parties;

c) the need for resources;

d) definition or redefinition of fundamental arrangements and objectives.

5.3 Possibilities for implementation

The terms set forth in the Modules Decision 93/465/EEC giving rise to the presumption of conformity created by the EN 45000 series of standards are highly questionable and that it cannot always be assumed at the present time that a body in possession of accreditation in accordance with these standards satisfies the minimum criteria set forth in the EU New Approach directives. Furthermore, the directives contain requirements which in some cases differ, which has resulted in legal uncertainty and differences in approach on the part of the designating authorities. Different means by which the minimum criteria defined in Chapters 5.1 and 5.2 for notification of the body and for the common elements are to be implemented will therefore be presented below. These means have already been discussed in part in recent years within the European Commission's Senior Officials Group.[346]

The following possibilities, which may also be employed in combination, may be considered: firstly, direct establishment in European secondary legislation (directives, regulations); secondly, establishment in the form of harmonized standards. An additional, third possibility is the creation of a European guide, and a fourth possibility, implementation by means of "common technical specifications". The last of these options is a class of documents which is more binding than the harmonized standards but less binding than the EU directives. The relative merits and drawbacks of these possibilities will be discussed below.

Only brief consideration will be given to the implementation of product-specific requirements which must provide technical detail of the implementation, discussed below, of the common elements.

5.3.1 Direct implementation in European law

The experience now gathered with the New Approach in various product areas in the course of over 15 years has also increasingly revealed its weaknesses. Discussions within the Senior Officials Group on Standardisation have shown the concept to be in need of reinforcement, particularly in the area of assessment, designation and monitoring of the

346 Cf. e.g. SOGS N 426 EN of 28.01.2002

notified bodies. The departments of the Commission therefore state in a working paper[347]:

> *"The New Approach and the Global Approach are heavily influenced by the principle of subsidiarity, i.e. the directives set out the obligations of Member States but leave a wide margin of discretion to each Member State on how to implement these obligations. Consequently, each Member State has developed its own systems and procedures in accordance with its legal and administrative traditions. Such a decentralised approach can only function effectively if all stakeholders are confident that the different national systems can deliver a homogeneous degree of safety and a level playing field throughout the Community."*

A possibility which may be derived from these considerations is that of not only embodying the **minimum criteria** placed upon bodies to be notified[348] directly in European secondary legislation by means of directives or regulations, but also of defining the much more comprehensive "**common elements**"[349] and for that matter the criteria for assessment, designation and surveillance[350] at this level. This would however constitute a departure from the philosophy of the New Approach:

A proposal to establish the comprehensive "common elements" as binding provisions in directives or even in regulations would be rejected by many Member States, and also by the European Commission. Such an adoption would not be compatible with the New Approach and the Global Approach; it would **contravene the system**: the New Approach and the Global Approach are based upon a dedicated system according to which the Single Market is to be implemented and its function maintained. This system makes provision for **harmonization of legislation only on a limited scale** by the creation of directives and regulations; indeed, the intention is for "foreign" rights to be recognized to the greatest extent possible.

The feared weakness of this concept, namely that it may result in harmonization at a low standard with negative consequences for occupational health and safety and health and consumer protection is to be prevented by further harmonization, to be achieved in this case by uniform technical standards. As will be discussed in Chapter 5.3.2, these standards do not constitute "legislation", a fact stated by the Council in its Resolution of 7 May 1985[351]. Their observance nevertheless is not optional, as the burden of proof of compliance with the directives is transferred to a manufacturer whose product does not comply with the standards.

On the one hand, this system provides manufacturers and the individual Member States on the one hand with a certain freedom of choice; on the other, it prevents them from deviating excessively from the purpose of the standard. By establishing acceptance of this system, the Commission and the Council have succeeded in implementing the free movement of goods without having to accept tangible differences in standards.

Binding establishment of comprehensive, detailed criteria for notified bodies or designating authorities in a directive or regulation would constitute a return to the system

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347 SOGS N 426 EN of the 28.01.2002

348 These can be found in Chapter 5.1.

349 These are defined in Chapter 5.2.

350 These can be found in Chapter 6.

351 OJ C 136, 4.6.1985

of the greatest possible harmonization of legislation. This system proved unsuccessful in the past; the Commission and Council are unlikely to revert to it.

Under the premise that the underlying concept is to be retained, the solution which suggests itself is for criteria in **directives** to be limited to the **minimum criteria** for bodies to be notified as harmonized and revised in the present study, and for the detailed formulation of these criteria to be left or consigned to the sphere of standardization, in accordance with the system of the New Approach (cf. Chapter 5.3.2).

Such a procedure would be suitable for sustained elimination of existing weaknesses. Council Decision 93/465/EEC sets forth conditions for notified bodies which are not currently addressed in the directives[352]. In addition, the directives often contain requirements which are similar, but for generally unknown or incomprehensible reasons are formulated differently[353]. This leads both to difficulties and to a certain level of legal uncertainty, particularly for the bodies conducting activities in accordance with several directives, and to differences between the procedures followed by different designating authorities.

One possible solution to these deficiencies would be for the minimum criteria for bodies to be notified[354] to be standardized, as has been done in Chapter 5.1 - and either to harmonize them in the form of standard formulations in all New Approach directives (one article each for notified bodies and an annex containing minimum criteria), or - and preferably - [355] to remove the requirements placed upon bodies to be notified from the (individual) directives and to establish them in a horizontal directive which would necessarily replace the minimum requirements formerly set forth in the individual sectoral directives. Such a procedure would represent a significant step towards the original intention of the New Approach, namely that of creating a common legal basis.

The "stricter" requirements demanded by the supporters of individual product areas - and declared opponents of a horizontal directive - could also be enshrined simply and transparently in this way. The supplementary or divergent conditions could, provided the legal permissibility of such an arrangement were enshrined in the horizontal directive, easily be established in the form of "special conditions" in the corresponding sectoral directive.

5.3.2 Implementation by standards

The standards in the EN 45000 series embodied in the Modules Decision 93/465/EEC and drafted in response to a European Commission mandate are neither up-to-date, complete and free of difficulties of interpretation, nor are their terms sufficient, closer examination, for assurance of the intended presumption of conformity. Furthermore, the

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352 For instance, co-operation between notified bodies, or the transfer of documents when a notified body ceases operations.

353 Cf. Chapter 5.1

354 The reader's attention is drawn again at this point to the fact that "minimum criteria" may imply a very low standard, which is in fact not the case in this context; cf. Footnote 110.

355 In accordance with SOGS/WG 1 and NQSZ; cf. Feitenhansl, N.: Entwicklungen von Anforderungsnormen für den Bereich der Akkreditierung (KAN conference held on 11./12.10.2001 in Dresden), p. 85f.

European standards institutions CEN/CENELEC, who originally held overall control, have transferred responsibility for standardization in the area of conformity assessment to ISO/CASCO[356]. A danger therefore exists that the needs deriving from the requirements of the European system may have to be put aside during continued standardization of conformity assessment, in the interests of worldwide acceptance of standards.

It follows that close attention must be paid during the development or updating of standards by ISO/CASCO that the standards concerned are suitable for sustained specification of the **requirements placed by the European system** upon bodies to be notified and their activities within the individual conformity assessment modules. Should this not be the case, their terms would still fail to give rise to a presumption of conformity with regard to the fulfilment of requirements set forth in the directives.

If the developments in ISO/CASCO are now considered and compared to the European requirements, the **following situation** may be observed (cf. Fig. 13).

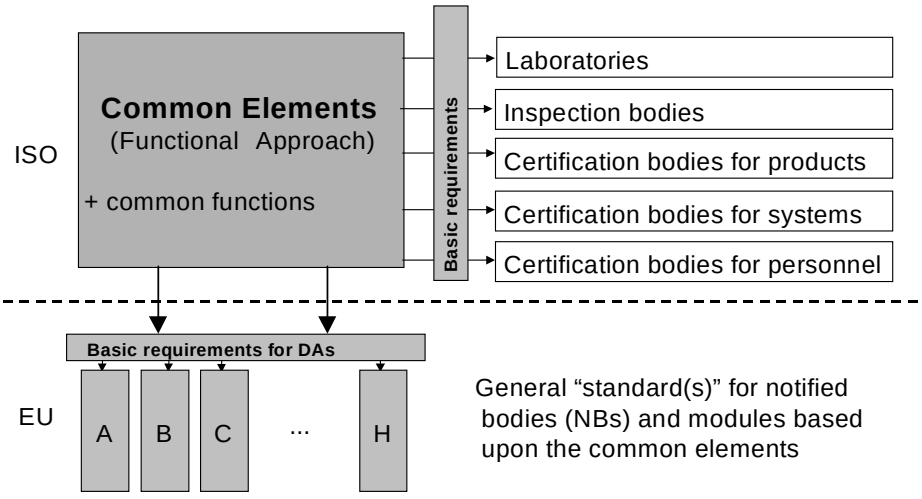

Fig. 13: Possible implementation of the "common elements" in standardization

If these developments and requirements are linked to the "common elements" formulated in Chapter 5.2, **two essential alternatives** to their implementation in the form of standards are conceivable:

1) Exclusively ISO/CASCO solution

In this case, ISO/CASCO adopts the "common elements" drawn up in the present study into its body of standards. These standards thus also become applicable for the area subject to statutory regulation in Europe. The advantage here would be a **body of standards harmonized worldwide** for conformity assessment bodies which would take into account both many needs of the area subject to (harmonized) statutory regulation and those of the area not subject to statutory regulation. Such a concept would have **advantages**

356 Cf. Chapter 2.1

- for the conformity assessment bodies (no overlapping and contradictory requirements),
- for MRAs, PECAs and other reciprocal agreements (national or regional requirements would be superfluous).

Introduction of the "common elements" proposed here into the ISO/CASCO body of standards is certainly possible at the current time, as CASCO WG 23 is in the process of drafting common elements for standards in the 17000 series which are to be updated in the future, whilst at the same time WG 5 is introducing the planned standard governing definitions (ISO 17000) and the functional approach.[357]

ISO/CASCO (upper half of Fig. 13) is currently defining its own "common elements" for all types of conformity assessment bodies[358]. To date, draft texts have existed for a range of structural elements such as requirements concerning the structure, impartiality, confidentiality, and the management system.[359] ISO/CASCO's objective is to define uniformly the requirements elements applicable to all types of conformity assessment body, in order to eliminate, in the ongoing development of standards for conformity assessment bodies, the variations in formulation and to some degree also requirements for factual issues which are essentially identical currently found in the requirements standards for bodies[360].

ISO/CASCO has however also declared its intention to retain the existing form of standards geared to the assessment body, i.e. separate standards for laboratories, inspection bodies, certification bodies for products, systems and personnel, and for accreditation bodies. These standards should contain identical requirements in the form of "common elements". There is no intention to create a vertical standard or standards structure, such as that suggested in the upper half of Fig. 13, which would unite the requirements common to the different bodies in a form of "generic standard".

The adherence of ISO/CASCO to separate standards for the different types of conformity assessment body brings with it a **danger** that these standards may in future **not** be suitable for satisfying the **requirements of the EU New Approach**.

The hope that ISO/CASCO might develop standards fulfilling the specification function within the European system will be difficult to realize, despite the close co-operation of CEN/CENELEC, as ISO/CASCO is interested first and foremost in a system of conformity assessment activities which can be applied worldwide and find wide acceptance. Local peculiarities such as those presented by the European system, even though they enjoy a certain status externally[361], may be taken into account only if they are capable of attracting majority acceptance.

2) Supplementary European standards

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357 Cf. Chapter 2.1.2

358 ISO/CASCO WG 23

359 Cf. for example ISO/CASCO Document WG 23/16 (Rev) June 2002

360 Cf. Chapters 2.1.1 and 2.2.1

361 Cf. for example the third-country agreements (Chapter 3.4), or the Australian medical devices legislation, which is almost identical in its underlying features to the European legislation.

Should the new ISO/CASCO standards fail, in form or substance, to satisfy the needs of the "common elements" for the New Approach developed in the present study, a second alternative would be to consider the drafting of supplementary European standards for notified bodies by way of a corresponding mandate to CEN/CENELEC.

Despite the fact that (formally) uniform standards for conformity assessment bodies worldwide would no longer then exist, this **European solution** may be **beneficial** for the following reasons: unambiguous standards are required for the European system which specify, for all directives, the minimum criteria indicated in Chapter 5.1 and which set forth in a clear and comprehensible manner the requirements placed upon bodies to be notified with regard to both the structural and organizational aspects and the conformity assessment activities to be performed by the body in the context of the individual modules. The relationship required for the European system between the modules and the standards is a particular argument in favour of this European solution.

Supplementary standards of this kind would then have to be drafted by CEN/CENELEC on the basis of a clear **mandate** by the European Commission and, following adoption, be published clearly as **harmonized standards** pursuant to the solution for directives as described above.[362][363]

As the bodies to be notified generally conduct activities not only in the area subject to statutory regulation, but also in the area not subject to such regulation, **no substantial differences** should exist in the **substance** of their requirements should exist between the ISO standards and the European standards to be created. This could be achieved by agreement by the two areas upon a set of "common elements" ("common building blocks") which would form the basis of both the ISO/CASCO and the European standards.

To this end, the individual elements would have to share an identical core. They could, however, according to the differences between the requirements in the areas stated above, permit different alternatives, or differences in the level of depth of requirements. For instance, the criteria for independence contained in requirements could be divided between that for first, second and third parties, and supported by restrictions such as "third parties only within the area subject to statutory regulation" for the New Approach.

Efforts should nevertheless be made internationally to establish harmonized common elements for the areas of resources and, in particular, for the process/functions, in addition to the elements already discussed by ISO/CASCO (which are concerned primarily with requirements placed upon the structure and the management system). This would reinforce consistency of their respective terms and could thus pave the way to greater acceptance of the system.

5.3.3 Implementation in the form of guidance documents

Besides direct implementation of the minimum criteria in European secondary legislation by way of directives and the establishment of the "common elements" in standards, implementation is also conceivable in the form of a guidance document adopted by the European Commission.

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362 Cf. Chapter 5.3.1

363 The existing deficit, that of the questionable harmonization of standards in the EN 45000 series (cf. Chapter 3.2.2.3), could thus be eliminated

Closer inspection quickly reveals the drawbacks, however, which clearly outweigh the **benefits** such as comparatively swift and economic implementation. The most significant **point of criticism** continues to be the **dubious legal force** of such a guidance document, which is substantially inferior to that of standards. Even though standards are always voluntary in nature and their application is not absolutely mandatory, they nevertheless define the "recognized state of the art". In accordance with the New Approach, a party subject to the legislation is at liberty to apply standards, including standards giving rise to a presumption of conformity. Should the party not apply the standard, it is obliged to demonstrate how the requirements set forth in the laws and regulations are satisfied (reversal of the burden of proof).

By contrast, guidance documents may only have a non-binding, recommendatory character which can be presented by the Member States as a voluntary basis for the activity. The declared objective, that of creating a coherent system of designation and surveillance with identical or at least equivalent requirements throughout Europe, will hardly be reached by this means.

Like guidelines and announcements, a guidance document enjoys only **limited** legislative status: a guidance document is not based upon delegated powers and does not therefore constitute secondary Community legislation in any form. In the form of published administrative principles, it reflects the interpretation of the Commission and the Council, in a similar manner to an announcement.[364] Where the guidance document is applied, the Commission reserves the right to conduct a review of individual cases, the results of which may differ whilst at the same time not being arbitrary. The Commission is at liberty to reach a substantiated, different result of assessment of each individual case. In the motion for judgement of the "Miller International" case[365] the Advocate-General Warner draws the corresponding distinction with regard to the legally binding effect: the Commission must adhere to an interpretation expressed in an announcement and may not depart from it at will, but only for compelling reasons.

To this extent, they have a certain **binding effect upon** the Commission itself. In **business practice**, guidance documents (and guidelines) fulfil an orientation function which should not be underestimated. Conversely, the ECJ and the first-instance court are not bound by the guidance documents/guidelines[366]. The same applies to the national authorities and courts.[367] This does not mean, in turn, that national courts and authorities may not consider them in their rulings.[368] The announcement does not however take priority over national law, even where the corresponding agreement falls within the scope of an announcement.

The legally binding effect of announcements and guidelines/guidance documents therefore represents a grey area. Announcements certainly do not constitute a statutory basis; at the same time, they constitute more than merely a comment by third parties, since the Commission, which has a "legislative" function, may not act in contravention of its own policy when acting in its executive capacity.

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364 Lange, K.W.: EWS 2001, p. 19

365 AG Warner, Schlussanträge in der Sache 19/77 "Miller International" Digest 1978, p. 157.

366 Guidelines on Vertical Restraints, OJ C 291, 13.10.2000, No. 3f.

367 Refer in this respect to Geiger, A.: EuZW 2000, p. 325

368 BGH 15.3.1973, WuW/E BGH 1259 "Bremsrollen".

The situation is different, however, in the case of **guidelines** to which **reference is made in the legislative measure**.[369] These guidelines do not constitute a grey area. They supplement rules of law; a guideline is a **binding** reference in support of a rule of law, constituting in that respect (as with the process by which the decision itself is reached) part of a *sui generis* legal instrument of the Union. The guidelines in the Modules Decision 93/465/EEC are closely associated with (technical) standards - to which reference may be made; they govern the organization of these standards (their involvement and the permissible use of alternatives). There is consequently no reason, in legal terms, not to accord these "organizational provisions" legally binding status.

In conclusion, a guidance document is not a suitable instrument for binding establishment of the requirements to be placed on bodies to be notified. Guidance documents may nevertheless be **useful** for **practical specification of the generic principles for specific directives**. An example of this usage is the guidance document MEDDEV 2.10/2, "Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices" drafted by the Member States in the area of medical devices, which describes requirements placed upon bodies to be notified within the scope of the medical devices directives and the process of designation and surveillance, and, together with other documents, makes an important contribution towards mutual alignment of the systems within the Member States. This became particularly apparent during negotiations with representatives of designating authorities of the third countries[370], who had been critical in particular of the differences in procedure in the Member States prior to adoption of this guidance document.

5.3.4 Implementation in the form of "common technical specifications"

With adoption of Directive 98/79/EC on in vitro diagnostic medical devices, a **new class** of normative documents was created by the European Parliament and the European Council in the form of the "common technical specifications" (CTS), which rank above harmonized standards but below the directives in terms of their legally binding force. The CTS are generally adopted by a committee comprising representatives of the Member States and the European Commission[371] and are as a general rule required to comply with them;

> *"if for duly justified reasons manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto"*[372].

Were such a legal instrument also be put in place for the process of designation and surveillance in the framework directive described in Chapter 5.3.1, documents containing provisions could be created - on a level above standardization but still below direct European lawmaking - adapted to the European system and satisfying its requirements, which above all would reflect the **responsibility of the Member States**. Unlike statutory

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369 Cf. Council Decision 93/465/EEC, Article 1 of which makes reference to the guidelines contained in the annex; cf. also Chapter 3.2.2.3, Question 2)

370 In particular with the US Food and Drug Administration (FDA), and Health Canada.

371 Cf. Directive 98/79/EC Articles 5 and 7

372 Directive 98/79/EC Article 5 (3)

provisions, standards are developed by private organizations and are not generally subject to any control by a body representing public authority. This leads, among other things, to standards being developed which specify the safety level prescribed by statute only in part or unsatisfactorily. One reason for this is the lack of participation by the authorities, and thus the frequent imbalance between the interested parties represented on the standards committees.

As CTS are however adopted (jointly) by the Member States, they would be a suitable instrument on the one hand, for recognizing the responsibility for the designation and surveillance of the bodies responsible to a Member State, and on the other, for moving much closer towards the goal of a coherent European system by the creation of a jointly established catalogue of requirements.

6 Proposals for harmonization of the designation and notification procedures for notified bodies

In addition to harmonization of the requirements placed upon bodies seeking notification, a need also exists for the procedures of assessment and designation to be structured uniformly and transparently. Chapter 3 described the designation systems which may currently be found in the individual Member States, and the proposed improvements which have already been put forward. It was shown that the presumption of conformity created in Council Decision 93/465/EEC cannot be maintained by the terms and that the designating authority is responsible for assessment of the body seeking notification. In contrast to the mechanism created in the Modules Decision - according to Annex I.A.m), the body to be notified presents for example (proactively) an accreditation certificate which the designating authority must then (in response) recognize - the initiative must be taken by the Member State. The system of designation must therefore be operated under the responsibility of the body established or charged by the Member State for the purpose; these bodies must themselves express the requirements to the bodies seeking notification.

In Chapter 4.3, this view was defined with general provisions for designating authorities, assessment and designation; at the same time, the principle was established that in the area subject to statutory regulation, key importance is attached to the act of designation and to the authority responsible for conducting designation.

Legally binding provisions governing how designation and in particular the procedures for assessment and surveillance of the notified bodies are to be performed do not exist at the present time.[373]

In order for an **equivalent, transparent system of designation**[374] to be put in place, provisions are required at different levels. These provisions concern[375]

- designation itself (Chapter 6.1), comprising the application submitted by a body seeking designation, assessment for establishment of the competence, and based upon these procedures, designation proper (act between designating authority and body seeking notification);
- the notification phase (Chapter 6.2), beginning with a request by a Member State for issue of the identification number, up to notification proper (with scope, identification number) of the other Member States and the European Commission, and the publication phase, i.e. publication by the European Commission in the Official Journal of the European Communities and maintenance of the lists/databases of notified bodies;
- surveillance (Chapter 6.3) of the notified bodies,

which will be addressed in more detail below. Chapter 6.4 also proposes requirements to be placed upon the designating authorities.

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373 Cf. Chapter 3.3

374 Cf. SOGS N 426 EN of the 28.1.2002

375 Cf. Fig. 5 in Chapter 3.3.1.2

6.1 Designation

6.1.1 Application procedure

The assessment procedure in the context of the EN 45000 standards embodies a requirement for the bodies to be notified to submit a minimum set of documents prior to on-site assessment.[376] This principle is also to be applied to application by a body seeking designation.

The designating authority must request a formal **application** signed by an authorized representative from the body seeking designation. The **documents** to be submitted with the application must be sufficient to permit assessment of whether the minimum criteria (cf. Chapter 5.2) are observed, at least on a theoretical basis. The following information in particular is required for this purpose, which may be structured into four groups as for the common elements in Chapter 5.2:

1 General information on structure and organization

- Name, address, person responsible
- Declaration of the structure and ownership (certificate of registration of the company/organization)
- Purpose of business
- Organization, organization chart(s), description of departments and functions, responsibilities
- List of authorized signatories for conformity assessment certificates
- Basic arrangements/declarations of independence, impartiality, including information on associated bodies
- Basic arrangements for assurance of confidentiality
- Certificate of liability insurance
- Information on financial stability, sources of income
- Existing recognitions, accreditations, designations

2 Information on resources (in particular the body's personnel)

- Director/deputy of the body to be designated
- Quality Manager
- Signature arrangements (sample signatures)
- Qualification criteria and basic regulations governing authorization of the personnel charged with conformity assessment activities; authorization matrix, where applicable detailed up-to-date records of qualifications, vocational experience, training, and performance assessments of the personnel (internal and external) charged with conformity assessment activities, procedures for authorization

376 Cf. EN 45003, Section 6.1.4 and EN 45010 Section 3.1

- Criteria for the personal and vocational independence and impartiality of the personnel charged with conformity assessment activities
- Information on initial and further training
- Information on subcontractors (laboratories, experts) with a description of their qualifications/activities and contractual arrangements

3 Information on the processes, i.e. information on the conformity assessment activities for which application is being made

- Description of the scope for which application is being made (directive, modules, products, technologies)
- General terms of business, rules of procedure for testing and certification, charges/price list
- Quotation (example), forms (application etc.), information for customers
- Contractual arrangements with customers
- Description of the procedure - arrangements concerning conformity assessment activities (including monitoring), in particular description of examination and evaluation with respect to the basic requirements, risk analysis, EC design examination, EC type examination, EC examination (where applicable)
- Check lists
- Reporting (example audit and assessment reports)
- Basic arrangements for the issuing, extension, maintenance, suspension and withdrawal of conformity assessment certificates
- Sample conformity assessment certificates, arrangements for use, etc.
- Arrangements concerning changes in the requirements for conformity assessment

4 Information on the quality management system

- Quality Manual
- List of applicable supporting documents (procedural and work instructions, SOPs, etc.)
- Quality policy
- Basic arrangements governing the control and retention of documents and data
- Basic arrangements governing the handling of complaints and appeals
- Basic arrangements governing internal audits and management assessments

The designating authority should further require that the applicant[377]

377 Cf. in this regard also Certif 97/1 Rev. 3 EN of the 17.07.1998

- fulfil at all times the obligations arising from designation, in particular duty to report, and the regulations set forth by the designating authority
- provide in a timely fashion the information necessary for performance of the tasks of the designating authority and the market surveillance authorities
- inform the manufacturer of relevant information, in particular information obtained through co-ordination activities and interpretations of EU directives
- participate in the co-ordination activities of the notified bodies at national and international level
- clearly separate activities conducted in its capacity as a notified body from other activities, and reasonably inform the manufacturer of the latter.

These obligations may also be combined with designation; the body seeking designation should however be informed of them prior to submission of the application, for reasons of transparency.

6.1.2 Assessment

Assessment must establish whether the body seeking designation possesses the necessary competence for performance of conformity assessment and has introduced a management system. This applies both to initial applications and to subsequent applications for extension of the scope of designation.

In accordance with Chapter 4.3, "assessment" refers to a procedure "by which the designating authority assesses whether a body satisfies the requirements set forth in laws and regulations regarding 1. competence for generic (non-product-specific) aspects, 2. satisfies the specific technical competence [..]".

Whereas the competence for generic aspects (1.) should be described adequately by the common elements defined in Chapter 5.2, additional provisions are required for the second aspect. It is important that the designating authority lay down the clearest criteria possible for the "**specific technical competence**" for the performance of conformity assessment activities covered by a directive, in order to create a transparent standard for all parties involved. For reasons relating to competition, these criteria should preferably be drawn up in European co-ordination committees, as only by this means can the desire be fulfilled for equivalent notified bodies to be created. One example is the Notified Body Operations Group set up by the Member States in the area of medical devices, whose activities include the establishment of specific competence criteria for the personnel of the notified bodies for special conformity assessment activities.[378]

The assessing body must possess suitable, competent personnel and expertise in order to be able to assess not only the generic aspects, but also fulfilment of the criteria for the specific technical competence. These requirements and criteria are addressed in more detail in Chapter 6.4.

Owing to the divergence of practices in the Member States, it would also appear appropriate to establish provisions governing the type, scale and point in time of assessment of a body seeking designation.

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378 Cf. in this regard also Chapter 3.2.2.4

Differences exist to some degree with regard to on-site assessment, which in some cases is not performed until after designation. The background to this procedure is the lack of an opportunity to examine performed conformity assessment activities, and to evaluate the efficacy in practice of the system set up by the body, prior to the body's designation. It has nonetheless been shown to be **good practice** to observe the assessment steps set out in EN 45003 and 45010:

- Preparation
- Document examination
- On-site assessment
- Assessment report
- Evaluation and decision (cf. in this regard Chapter 6.1.3)

A suitable, modern description of these steps in this context can be found in ISO/IEC 17011, currently being drafted, in "General requirements for accreditation bodies accrediting conformity assessment bodies", Sections 7.5 „Preparation for asssessment“ to 7.8 “Analysis of findings and assessment report”. For application to notified bodies, the formulations should however be adapted to the terminology set forth in Chapter 4.3.

6.1.3 Establishment of competence and designation

Assessment entails establishment of whether the body seeking designation satisfies the general **requirements for competence** and the specific requirements for competence applicable to the scope in respect of which application is being made (modules, products, technologies).

The **result of assessment** must be recorded in a **report** which addresses the general and specific requirements relating to the scope for which application has been made. Of essential importance is that the systems implemented by the body and the essential arrangements must be suitable for performance of conformity assessment activities with the highest professional integrity and the utmost technical expertise. The report should also contain a recommendation of whether and if so for what scope[379] the body should be designated.

Establishment of the competence and the decision concerning designation on the basis of the assessment report is to be taken by the designating authority in observance of the "four eyes better than two" principle. Basic arrangements are required for this purpose; these will be considered in greater detail in Chapter 6.4.

Establishment of competence is accompanied by designation in accordance with the arrangements of the Member State concerned.[380] **Designation** – generally in the form of a act of administration in Germany - may be subject to **obligations** by which the duties of the notified body are established in a comprehensible manner. Examples of such obligations include stricter duties to report or the duty to eliminate detected (noncritical) nonconformances within a specified period. Designation must however rule out essential nonconformances from the established requirements.

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379 With regard to the scope, see Chapter 6.2.1

380 Cf. in this regard also Chapter 3.3.1.2; it is the Member State's prerogative whether it designates (all) technically competent bodies.

It is also appropriate for the obligations listed at the end of Chapter 6.1.1 also to be included in the form of obligations or ancillary provisions in order for a comprehensive catalogue of duties of the notified body to be embodied.

6.2 Notification phase

6.2.1 Scope

An important aspect and one closely linked to notification is the scope, as it must describe the range of activities of the notified body clearly and unambiguously with regard both to the modules and to the products/technologies.

For bodies to be notified for the first time, in particular, it is important that the scope is established unambiguously with regard to the **products and technologies covered**. At this point, products for which the body was not able to demonstrate adequate competence must be prevented from being included owing to unclear information. The designating authority has a particular responsibility in this regard which it must meet i.a. by fulfilling suitable obligations.

Closer examination of the list of bodies notified to date in Europe[381] reveals an enormous **need for improvement** can be observed. The practice to date for establishment of the scope has not been co-ordinated between the Member States, and is not questioned by the European Commission. A harmonized practice of designation with regard to statement of the scope has neither been called for, nor has it come about. This area has however already attracted sporadic criticism.[382]

Under many directives, the bodies are designated for virtually all products (cf. e.g. 99/5/EC on radio equipment and telecommunications terminal equipment, 97/23/EC concerning pressure equipment or 90/385/EEC relating to active implantable medical devices) without closer consideration of the different product categories, groups and technologies covered by these directives. Somewhat more detailed designations can be found (only) for directives which contain a direct classification of the products into categories or groups (e.g. 98/79/EC on in vitro diagnostic medical devices, 98/37/EC relating to machinery); even in these cases, however, different manufacturing or product technologies are not addressed, even though the requirements for testing and assessment may vary widely.

It would appear necessary and desirable in this context for the Member States to agree on a nomenclature or on classification of products/technologies falling under a given EU directive prior to designation and notification, in order both to create clarity and transparency at designation, and to contribute towards fair competition among the notified bodies.

6.2.2 Notification

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381 http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies.htm

382 Cf. "Report on the Functioning of the Medical Devices Directive (93/42/EEC of 14 June 1993)" of the Medical Devices Experts Group, Section 7.3.1, in the Internet at: http://europa.eu.int/comm/enterprise/medical_devices/finalreport5-6-02cor1_3-july02.pdf

The act of designation conducted between designating authority and conformity assessment body is followed by notification[383] of the body to the other Member States and to the European Commission.

The **procedure followed in the past**[384] together with the form employed has been shown, upon closer consideration, **not to have been effective**, and should be revised. This form contains only a small number of mandatory items:

- Name, company logo, address, telephone number, fax number of the body
- Identification number of the body
- Period of validity of notification (unlimited, date valid until)
- Technical competence of the body (accreditation or other evidence)[385]
- Tasks of the body (product/product range, procedures/modules, articles/annexes of the directive)

Interestingly, the European Commission[386] was not originally stated officially as the party to which the form is directed, but received only a copy of the notification, which was directed in the first instance at the Member States. Only in the more recent editions does the European Commission appear before the other Member States (which are treated equally).

The Commission must however be accorded the **central role**, not least as intended by the above definition, as a consistent list may be maintained only through centralized administration of both the identification numbers and the bodies notified under the various directives. In the era of electronic communications, it should be considered whether and to what extent an electronic, database-oriented notification procedure can be set up by the Commission, by which a publicly accessible online database can be operated and maintained up-to-date.

The procedure followed to date presents a **danger** that bodies designated under different directives may be assigned **multiple identification numbers**, contrary to the provisions[387], or that an identification number assigned to a body may be assigned to several legal persons when parts of the business are set up as separate units. An online process would also enable changes of address or the relatively frequent changes of names and/or legal form of a notified body to be effected centrally and for all areas of directives, which would result in a substantial enhancement of data integrity in comparison with the present system.

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383 Refer also to the definition in Chapter 4.3

384 Described in: Certif 93/1 Rev. 3 and in Commission document Directorate-General Industry III B/3 EMP of 7.2.1994

385 The form was subject in this regard to interim revision in 1997 by a "Note for the Attention of the Senior Officials Group on Standardisation“ (DG Industry III/B/4/AL D(97)), and now makes provision for statement of the standard(s) in the EN 45000 series or other basis for an accreditation or the assessment. The terms of this revised form are also employed for the MRAs; in this case, it is extended by the item "Designation Procedure used to determine the competence of the proposed CAB to apply conformity assessment requirements and procedures identified in the legislative, regulatory and administrative provision of the EU" (Certif 96/3 Rev. 4.03 EN of 1.3.1999). Cf. however the comments in Chapter 3.3.

386 Cf. Commission document DG Industry III/B/3 EMP of 7.2.1994, annex

387 For example, Prüf- und Forschungsinstitut für die Schuhherstellung e.V. has been assigned the identification numbers 193 and 713, and LGA Bayern the identification numbers 125 and 780.

Here too, issuing of the identification number could be controlled easily, as each body not yet notified could be "automatically" assigned the next "free" identification number.

A procedure would have to be set up for this purpose in conjunction with the Member States by which the designation/notification authority concerned[388] makes recourse to the data already available for the body concerned when notifying. Should discrepancies be noted between the existing and the new notification data, they must be clarified between the institutions involved within the notifying country, as this country alone bears responsibility for the bodies within its jurisdiction. A procedure of this kind would have the benefit that the database would always contain relatively up-to-date data.

Revision of the system should also include discussion of the aspect of the period for which designation is valid. The practice of many Member States of permanent designation leads to a risk that once designated, the standards of bodies may not be maintained. In the interests of alignment with international practice, the practice of permanent designation should be abandoned, as is already the norm for conformity assessments and also for accreditation and recognition procedures.[389]

6.2.3 Publication

As they result in data being much more up-to-date than that available through the traditional mechanism of publication in official organs, publicly accessible **online databases** or at least frequently updatable extracts (reports) from such databases are gaining ground in certain areas[390]. Such a process should be added to the duty of publication in the Official Journal of the European Communities required by the New Approach Directives.

The two modes of publication should exist in parallel. However, since in practice consolidated lists of notified bodies are currently published **only sporadically** in the Official Journal of the European Communities[391], concerted efforts should be made to **revive** this traditional process and to enhance its legal status in order for it to be regarded (once again) as an official announcement and thus as formal conclusion of a legal instrument.

6.3 Monitoring

388 The tasks and responsibilities for designation and notification may be organized separately or combined within the same body in the Member States.

389 Cf. e.g. § 15 Paragraph 1 of the MPG in Annex C.

390 Cf. for example the lists of the responsible authorities in the area of medical devices, the latest status of which is now accessible following creation of an electronic notification procedure at www.dimdi.de

391 Cf. http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/notified-bodies.htm. The most recent publications in OJ C 292, 13.10.2000 and OJ C 129, 30.04.2001 contain notifications only up to 15.03.2001.

The Member States are obliged to satisfy themselves that the notified bodies permanently meet the applicable requirements.[392] This means that designation must be followed by a system of surveillance.

6.3.1 General provisions

The provisions established in standards EN 45003 and 45010[393] provide a sound basis for surveillance in this context. Upon closer inspection, however, they are seen not to be adequate for assurance of a uniform standard of surveillance, owing to differences between conformity assessment activities and products/technologies. This aspect was addressed during **revision** of this standard **in prEN ISO/IEC 17011**, Section 7.11 of which makes conscious provision for "andere Überwachungstätigkeiten" in addition to the regular on-site inspections. Examples stated include questionnaires presented to the conformity assessment body, the examination of declarations made by the conformity assessment body, and the making available of documents and records or the viewing of results of participation in qualification tests.

With regard to the intervals of on-site inspections, too, prEN ISO/IEC 17011 makes provision for an arrangement more suited to practical circumstances than was the case in EN 45010. Whereas previously, a period of over a year was hardly considered suitable[394], the new draft standard includes the provision that the intervals between on-site inspections depend upon the stability demonstrated for the services of the conformity assessment body. A note contains the sensible recommendation that the first on-site inspection should be performed not later than 12 months after establishment of competence.[395]

6.3.2 Dedicated arrangements for specific directives

The above provisions may certainly be regarded as a suitable basis. In the interests of harmonized designation and surveillance practice throughout Europe, however, specific provisions would appear necessary which should be dependent upon the nature of the conformity assessment activities (conformity with the basic requirements or with standards, product inspections or assessments of QA systems) and the hazards presented by the products; alignment extending across all areas of the directives might result in arrangements being harmonized at a low standard.

Based upon the minimum requirements contained in the standards, **dedicated provisions for specific directives** should preferably be drafted **in co-ordination groups**[396] of the designating authorities responsible for the directive concerned. In addition to the specific requirements placed upon the specific technical competence of the bodies, the arrangements for assessment and monitoring should also be established. These should in particular describe

- the nature of the surveillance measures, e.g.

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392 See Chapter 3.3.1.3

393 Cf. e.g. EN 45010 Section 3.5

394 Cf. EN 45010, note to Section 3.5.1

395 Cf. prEN ISO/IEC 17011: 2002 7.11.2

396 Cf. the Notified Body Operations Group in the area of medical devices.

- (regular) on-site
- observed audits (in the case of modules for assessment of QA systems)
- witness tests (in the case of modules for product examination)

- their scope (for example specification of the minimum duration, scale and depth of sampling, inclusion of subsidiaries - including activities in foreign countries - and subcontractors in surveillance), and
- their frequency (e.g. routine surveillance, surveillance under special circumstances).

The performance or initiation of qualification tests is also possible.

6.3.3 Measures in response to surveillance measures

The objective of surveillance is for the Member States to satisfy themselves that the notified bodies meet at all times the requirements applicable to them and that conformity assessment certificates are rightfully being issued by the designated bodies.

Depending upon the result of the surveillance activity, different **measures** to be taken by the designating authority may be necessary in order to assure the desired situation. The scale of these measures ranges from simple corrective action to be taken by the notified body (e.g. the revision of procedural instructions) through rework (repeat of examinations/audits), to partial (restriction of the scope) or complete revocation of designation.

Once again, the objective must be to establish harmonized requirements throughout Europe to the extent possible in order to guarantee a quality standard suitable for the product concerned, and also to create a level playing-field for competing notified bodies. The provisions of prEN ISO/IEC 17011 may serve as a basis, but are hardly adequate on their own for a uniform Europe-wide monitoring system.

It appears once again advisable to draw up **catalogues of criteria** in co-ordinating groups for designating authorities and specific directives. In order to create a collection of examples, these catalogues of criteria should list provisions with comparable consequences and describe the reasonable measures of the designating authority. The "Designating Authorities Handbook" of the Notified Body Operations Group in the area of medical devices, currently being developed, which pursues this philosophy in an exemplary fashion, is cited here as an example.

6.4 Requirements placed upon designating authorities

Chapter 3.3.3 described the requirements placed to date upon designating authorities, and stated that these are not generally binding. As a first step towards improvement of the situation, the term "designating authority" was defined in Chapter 4.3. The term "designation" presupposes that assessment must have been completed successfully prior

to the act of designation. For the purpose of assessment and monitoring, this body may also be an accreditation body[397].

In the interests of a uniform and transparent system of designation and monitoring it appears appropriate to establish minimum requirements for the designating authorities. The **common elements for conformity assessment bodies** described in Chapter 5.2, divided into requirements to be placed upon

- the structure,
- the resources,
- the process and
- the management system

may for the greater part be adopted for the activities of the designating authority. For the most part, these requirements also essentially address the terms of the future EN ISO/IEC 17011, even though the latter have been adapted both in terminology and in certain provisions to the requirements and particular features of the designating authorities within the context of the New Approach.

With the change to "designating authority" in place of "conformity assessment body" and the adaptations under "conformity assessment activities" and the "issuing ... of conformity assessment certificates" to the terminology of the "designation", the formulations in Chapter 5.2 are also largely valid in this case. **Discrepancies or particular features** derive in particular in the case of requirements concerning legal responsibility, independence and impartiality (see Chapter 6.4.1, structure) and in the description of the common process elements (see Chapter 6.4.3). Where changes are required in particular paragraphs only, the remaining requirements listed in Chapter 5.2 have not been repeated, and should therefore be consulted there.

6.4.1 Structure

1 Legal responsibility

The designating authority shall be a legal person established by or representing a Member State or a part of such a legal person. Should the designating authority be part of a larger governmental entity, the Member State shall be responsible for ensuring that no conflicts of interest with the conformity assessment bodies to be notified or with market surveillance authorities may arise during the performance of the designating authority's activities. Pursuant to the following provisions, the designating authority is regarded as a "registered legal person".

Note: should in exceptional cases the designating authority, the conformity assessment bodies to be notified or the market surveillance authorities in a Member State be responsible to the same authority, the areas of competence shall be organized such that no conflict of interest exists between the two bodies.[398]

2 Organization and responsibilities

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397 The statements below applicable to designating authorities may therefore also be applied to accreditation bodies in the case of assessment and monitoring.

398 Based upon Blue Guide, Section 8.1, p. 54

2.2 The designating authority shall possess the authority and responsibility to designate, monitor, suspend designation, lift suspension or withdraw or revoke designation for the conformity assessment bodies falling within its jurisdiction.

3 Independence and impartiality

3.1 The designating authority shall be organized and operated in such a manner that the independence, objectivity and impartiality in its activities are assured, and shall possess a documented structure for assurance of its impartiality.

3.2 The arrangements and procedures of the designating authority shall not be discriminatory and shall be carried out in a nondiscriminatory manner. The designating authority shall make its services available to all applicants whose wish for conformity assessment falls within the body's area of responsibility.

Note: political decisions by the Member State may lead to restrictions regarding the type or number of the bodies to be notified.

3.3 The designating authority, its top-level management, and the personnel charged with performing assessment and surveillance shall be independent of the bodies to be notified.

Note: observe in this regard the note to 1, Legal responsibility.

3.4 The designating authority and its personnel shall perform their tasks independent of any influence, particularly of a financial nature, upon their evaluation and its results, in particular influence by persons or groups of persons with an interest in the results of the activities.

3.5 The designating authority shall ensure that all decisions are reached by competent persons or bodies who are not identical to those who performed the corresponding assessment activities.

3.6 The designating authority and other parts of the legal person of which it forms a part and their personnel shall not perform or offer to perform any activity which jeopardizes their impartiality or calls into question the confidence in their competence, objectivity, impartiality or independence.

Note: observe in this regard the note to 1, Legal responsibility.

3.7 The activities of the designating authority shall not be presented as if they were related to a consultancy function. No statement or implication may be issued which could suggest that designation might be effected more simply, more easily, more quickly or more economically were use to be made of a certain person or certain persons or consultancy.

3.8 The designating authority shall ensure that the activities of associated bodies do not jeopardize the confidentiality, objectivity or impartiality of its activities. An associated body may however offer or deliver conformity assessment services which fall within the competence of the designating authority, provided the associated body has (vis-à-vis the designating authority):

a) a different top-level management for the activities described in Chapter 6.4.4;

b) at its disposal personnel different to those involved in the designation processes;

c) no means of influencing the result of an assessment.

Note: in the context of Section 1, a separate part of the public administration outside the designating authority shall be regarded as an associated body.

4 Confidentiality and secrecy

4.3 Confidential information may be passed on only within the scope of the statutory arrangements.

5 Liability

- to be regulated at Member State level -

6 Financial stability

The designating authority shall have at its disposal the financial resources required for performance of its business operations. The designating authority shall be in possession of a description of its source(s) of income.

7 Participation in co-ordination activities

The designating authority shall participate in co-ordination groups organized by Member States or by the European Commission within the context of directives in order to attain maximum coherence of the designation and surveillance activities.

6.4.2 Resources

requirements contained in Chapter 5.2.2 concerning the resources of the body to be notified correspond largely to those for the designating authorities; the requirements need not therefore be repeated here.

6.4.3 Process

The process of designation is based upon the conformity assessment procedures established in the relevant directives and the criteria applicable to notified bodies. In the performance of the designation procedures the designating authority must satisfy the following generic requirements, which correspond largely to the common process elements listed in Chapter 5.2.3:

1 Contractual arrangement with the customer

The designating authority shall require a formal application signed by an authorized representative of the applicant. This application shall contain the information required by law and necessary for performance of designation.

2 Subcontracting

In the absence of provisions to the contrary in laws and regulations, the designating authority may transfer certain activities - such as assessments - to subcontractors. With the exception of Section 2.7, the requirements set forth in Chapter 5.2.3 are applicable.

3 Use of reports submitted by the applicant

The designating authority may consider reports submitted by the applicant in its assessment procedure. This does not however absolve it of its responsibility for establishing either the competence for generic (non-product-specific) aspects or the technical competence pertaining to the directive concerned (cf. Chapter 6.1.2). The requirements proposed for conformity assessment bodies in Chapter 5.2.3 may thus be applied here accordingly.

4 Decision-making process

The requirements proposed in Chapter 5.2.3, Sections 4.1 and 4.2 for conformity assessment bodies apply accordingly for designating authorities.

4.3 Provided the requirements are met, the conformity assessment body shall be designated by the designating authority, and notified by the Member State to the European Commission and the other Member States in accordance with the established procedure.

4.4 Designation and notification must satisfy the provisions set forth in the laws and regulations or agreed in co-ordination groups in accordance with Chapter 6.4.1 Section 7.

5 Records

The requirements proposed for conformity assessment bodies shall apply accordingly for designating authorities.

6 Reference to designation

6.1 The designating authority shall take effective measures to ensure that the notified bodies

a) satisfy in full the requirements of the designating authority where reference is made to their designation in communication media such as the Internet, documents, brochures or publicity material;

b) make no reference to designation for branches or activities which are not covered by designation;

c) make no statement with regard to their designation which could be regarded by the designating authority as misleading or unjustified;

d) ensure that no report or certificate or part thereof is used in a misleading manner;

e) where their designation is suspended or withdrawn (irrespective of the circumstances of such a decision), thereafter make no further use of any publicity drawing attention to their former status;

f) do not exploit their designation in a manner from which it may be concluded that the designating authority has deemed a product, process, system or person to be compliant with directives.

6.2 The designating authority must take suitable measures to deal with improper references to the designated status or abuse of the use of markings in advertisements, catalogues, etc.

7 Duty to report

The requirements proposed for conformity assessment bodies with regard to information vis-à-vis applicants (Chapter 5.2.3 Section 7.1 vis-à-vis customers) and Third Parties (Section 7.3) apply accordingly to designating authorities. The corresponding requirements vis-à-vis authorities (Section 7.2) are subject to the relevant national statutory arrangements.

6.4.4 Management systems

The designating authority shall introduce, implement and maintain a management system and continually improve the latter's effectiveness in compliance with the requirements laid down for designating authorities.

The general requirements placed upon the management systems of conformity assessment bodies defined in Chapter 5.2.4 apply also and correspondingly to designating authorities. The requirements need not therefore be repeated here.

6.4.5 Detailed provisions in support of individual directives

As already discussed at several points in previous sections, it would appear imperative in the interests of a Europe-wide harmonized and transparent designation and surveillance system to create detailed provisions in support of specific directives for the work of the designating authorities, in addition to the general requirements formulated here.

Such provisions, governing for example specific competence criteria, assessment and monitoring arrangements, scale and interval of sampling[399], should where possible be established in European co-ordination committees of the designating authorities responsible for the directive concerned and, where necessary, with the involvement of the interested parties.

According to the arrangements for the notification system[400], structures must in addition be created in the Member States which ensure that notification can be performed in a timely fashion and in consideration of the data already in existence for the body concerned under individual directives and that clarification between the institutions involved is possible in the event of discrepancies of the data. Details of these structures cannot however be discussed until the procedure has been re-established.

399 Cf. Chapter 6.3.2

400 Cf. Chapter 6.2.2

7 "Common elements" in EU agreements with third countries and in other international agreements

The "common elements" proposed in the present study for conformity assessment bodies describe minimum requirements for their assessment. These requirements may be implemented in the form of EU directives, standards, guidance documents, or "common technical specifications". The benefits and drawbacks of the various alternatives have been discussed in Chapter 5.3.

Should the "common elements" be described in the form of a standard, the provisions of the WTO-TBT Agreement must be observed. A standard should be introduced in line with the standards of the international standards organizations which already exist or are in preparation. As the "common elements" proposed in the present study are aimed at conformity assessment bodies on the European Single Market and their terms may not conform to the international standard in development, Chapter 7.1 is to address the question of whether a European standard may be introduced in competition with an international standard.

The terminology employed was defined in the course of drafting of the "common elements" for conformity assessment bodies[401]. Attention was paid to compatibility between the definitions and the terms of the agreements between the EU and third countries. This is particularly important, as provision is made in the MRAs - e.g. according to Article 1 (2) of the MRA-USA framework agreement - that the terminology in the agreements should take priority should contradictions arise to the terminology used in internationally recognized documents. Should the terminology of the "common elements" and their definitions depart from those of the agreement, a risk consequently exists of their not being implemented in agreements.

Chapter 7.2 examines first and foremost the extent to which "common elements" for conformity assessment bodies[402] and the uniform definitions may contribute towards solution of the essential problems associated with particular agreements.[403] As the "common elements" naturally contribute to the resolving of problems only if they are considered in the agreements and if in the process the structure and substantial framework of the agreements is preserved, these aspects will also be considered in the present chapter.

7.1 WTO-TBT Agreement

Should the "common elements" be implemented in the form of a standard, it must be ensured that this standard **conforms**, where possible, to the relevant international standards already in existence or currently under development. **Local exceptions** are

401 See Chapter 4.3

402 The "common elements" for designating authorities proposed in Chapter 6.4 are also considered (in Chapter 7.2.1.2); the focus is however upon the "common elements" for conformity assessment bodies.

403 Only the most significant problems will be addressed at this stage. Numerous benefits, including for the agreements, can be derived directly from the discussions in Chapters 5 and 6.

however possible for cases in which the international standards do not make allowance for essential local requirements[404].

The standards organization **ISO/CASCO**, which is also active in the area of "common elements", is interested in a system of conformity assessment activities which may be applied worldwide. this could result in the body of standards currently undergoing development not satisfying the requirements of the EU's New Approach.[405] One potential reason for this is that the international standards organization intends to adhere to the former concept by which standards are oriented towards the different bodies, i.e. dedicated standards for accreditation bodies, laboratories, inspection bodies and certification bodies for products, systems and personnel.

Conversely, the **European system** requires solutions which unite the requirements for test and calibration laboratories, inspection bodies, and product, system and personnel certification bodies an a form of basic standard. These solutions should specify in detail the minimum criteria placed by EU directives upon bodies to be notified, and establish in a comprehensible manner the requirements for bodies to be notified with regard both to the structural and organizational aspects, and to the conformity assessments to be performed by the body within the concept of the individual modules. Only by this means can the safety of products distributed within the European Single Market be assured.

The "common elements" as proposed in the present study underpin the New Approach and thus contribute towards the safety of products distributed within the European Single Market. According to Article 2.4. of the WTO-TBT Agreement, a European standard in competition with the international body of standards may be developed should the latter fail to provide adequate means for attainment of the justified objectives of the EU[406].

Where it publishes a European standard which departs from the international standard, the EU must publish its introduction at a suitable point in time in order for the parties to the WTO-TBT Agreement to become aware of the fact[407]. In addition, it must make the standard available to other parties to the WTO-TBT Agreement upon request, and mark the parts which depart from the relevant international standard.[408]

7.2 EU agreements with third countries

Analysis of the agreements has revealed the possibility of **difficulties of interpretation of these agreements**, in particular the MRAs. Chapter 7.2.1 examines the extent to which the "common elements" and the definitions proposed for the terms employed may contribute towards the solution of essential problems. This is possible only if they are given consideration in the agreements - in the form of a standard, an EU directive, a guidance document, or Common Technical Specifications. This possible procedure for implementation is described in Chapter 7.2.2. Attention should be paid to observance of the structure and substantial framework of the agreements. Whether this is possible is discussed in Chapter 7.2.3.

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404 See Article 2.4 of the WTO-TBT Agreement, and also Chapter 1.3.2.1

405 See also Chapter 5.3.2

406 See Chapter 1.3.2.1

407 See Article. 2.9.1. of the WTO-TBT Agreement

408 See Article 2.9.3. of the WTO-TBT Agreement

7.2.1 Solution of existing problems

In the context of analysis of agreements between the EU and third countries, uncertainties have arisen with regard to assessment, the area of activity of the designating authority, and the act of designation. The extent to which the "common elements" and the definitions proposed for the terminology employed may contribute towards resolving the problems is discussed below.

7.2.1.1 Assessment

The designating authorities designate bodies for the performance of conformity assessments within the context of the MRA only when they understand the requirements and procedures for conformity assessment set forth in the laws and regulations of the opposite party to the agreement, have experience with them, and are capable of applying them[409]. They must therefore be **technically competent**. With the exception of the assessment of conformity assessment bodies for the area of medical devices within the territory subject to the MRA-USA, the competence is evaluated[410] on the basis of relevant international documents, the EN 45000 series of standards, and the ISO/IEC guidance documents.

Assessment on the basis of the normative documents stated above results in the possibility of different standards for conformity assessment systems arising within the territory subject to an MRA, as in the European Single Market.

Assessment may be performed by accreditation or by other means, according to the text of the agreements.[411] Successful **accreditation** is assumed in the context of the MRAs[412]

- when the accreditation procedure is performed in accordance with the relevant international documents, and either
- the accreditation bodies are party to an agreement upon reciprocal recognition (MLA), or
- in the absence of an MLA, the accreditation bodies are involved in procedures for comparative programmes and the exchange of technical information in accordance with procedures to be agreed.

The agreements therefore require the accreditation bodies to be party to an MLA or corresponding procedure in order to assure the most uniform standard possible for accreditation systems. This is to permit the presumption that a uniform standard also exists for the conformity assessment systems.

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409 See Article 2 of the annex to the MRA-Australia

410 Cf. Chapter 3.4.1.3

411 The principle proposed in Chapter 6, i.e. that the designating authority itself should formulate the requirements for an assessment, should however also be adopted in the MRA. The concept also followed in the MRA by which the body to be notified proactively submits evidence of accreditation and the designating authority is obliged to accept such evidence would not appear to be conducive to attainment of the objective. No conclusion may however be drawn regarding whether and to what extent this new principle can be implemented in the MRAs.

412 Cf. e.g. Article 6 Item a) of the annex to the MRA-Australia

The **introduction of the "common elements" for conformity assessment bodies** establishes a **uniform standard** for the requirements for bodies to be notified. Should the conformity assessment bodies be examined on the basis of the "common elements", this thereby contributes towards any disparity between the standards of the conformity assessment systems being eliminated.

An MLA could therefore render the "common elements" for conformity assessment bodies superfluous should this represent the sole reason for its legal validity, as the requirements for bodies to be notified would be examined differently according to the party to the agreement. The accreditation bodies are however subject to additional evaluation by recognized experts in the field concerned (peer evaluation) during their in an MLA. The technical competence of the accreditation bodies and the establishment of this competence is necessary in order for the system of reciprocal recognition of the conformity assessment bodies to be able to function. The MLA will thus continue to be an essential component of the system.

Should the accreditation bodies not have acceded to an MLA, they must take part in programmes for comparison of their activity and for the exchange of technical experience. In this case, too, these programmes should be retained. The accreditation bodies aim for close co-operation in the course of these programmes and are also subject here to peer evaluation.

In the absence of an accreditation system[413], the designating authority requires **alternative evidence** from the conformity assessment bodies of their competence. Such evidence may take the form of[414]:

- accession to regional/international agreements governing reciprocal recognition;
- participation in conformity assessment systems;
- regular examination by experts (peer evaluation);
- qualifying examinations;
- comparison of conformity assessment bodies.

In this context, the **"common elements"** may serve the conformity assessment bodies, where they accede to agreements on the reciprocal recognition of their activity or collaborate in international conformity assessment systems, **as a basis for negotiation**. The "common elements" may serve as a standard in examinations or comparisons of conformity assessment bodies. This will lead to a largely harmonized standard for conformity assessment systems.

7.2.1.2 Designating authority

A significant area of difficulty with regard to the designating authorities are the **contradictions** in the MRAs concerning their authority and competence. On the one hand, the parties to the contract ensure – for example in accordance with Article VI (1) of the MRA-Canada framework agreement – that the designating authorities possess the requisite authority and technical competence to designate or monitor conformity

413 Cf. also footnote in this regard 152

414 Cf. in this regard Article 6 Item b) of the annex to the MRA-Australia

assessment bodies, to delete them from the sectoral annexes, or to suspend them. Conversely, the definitions in the respective Article 1 of the MRAs require only that the designating authority[415] be authorized to designate conformity assessment bodies, to monitor them, to suspend them, to lift suspension, or to withdraw or revoke their designation[416]

The "common elements" for designating authorities and the definitions proposed in Chapter 4.3 for the designating authorities **harmonize** the contradicting provisions in the agreements. This enables the ambiguities concerning the area of activity of the designating authority in practice to be eliminated. The designating authority must - as in the European Single Market - satisfy certain requirements in order for a uniform, transparent system of designation and monitoring to be created. These requirements relate to the structure, the resources, the processes and the management system of the designating authority[417]. A further recommendation is that, similar to the proposals for the New Approach in Chapter 6, the existing principle - by which the body to be designated presents evidence of accreditation and the designating authority is obliged to accept it - be reversed. An arrangement in the MRAs by which the designating authority presents its requirements would also be appropriate[418].

7.2.1.3 Act of designation

According to Article 1 of the MRA-Australia framework directive, the conformity assessment body is empowered by the designating authority to perform conformity assessments. Accordingly, it may assume its activities following designation. This interpretation is to be deemed unacceptable, as the body is **authorized to perform assessments** only once the Joint Committee has given its unanimous approval and the conformity assessment body has been included in the sectoral annex[419].

The designating authority thus formally recognizes by the act of designation that the conformity assessment body possesses adequate technical competence to perform its activities[420]. It is not able to authorize the body to perform conformity assessments within the scope of the agreement.

The definition contained in the MRA concerning designation departs from the terms of the agreement. In order to avoid ambiguity regarding the point in time from which the conformity assessment body may commence its activities within the scope of the agreement, the definition must be brought into line with the content. The **definition of designation** proposed during development of the "common elements" should also provide **orientation** in this context[421].

7.2.2 Process of implementation

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415 See for example Article 1 (1) of the MRA-Australia framework agreement

416 For details, see Chapter 3.4.1.3

417 See Chapter 6.4

418 Cf. Also footnote 152

419 See Chapter 3.4.1.2

420 This issue has been addressed only in the MRA-Canada; see Article VII (3) of the MRA-Canada framework agreement.

421 See Chapter 4.3

The "common elements" may serve as a solution to the problems of third-country agreements only if they are addressed within the MRA and PECA agreements, either in the form of an EU directive, standards, a guidance document, or "common technical specifications". This possible implementation differs according to whether it is applied to an MRA or PECA, and according to the implementation of the "common elements".

7.2.2.1 MRAs

The EU has concluded MRAs with selected third countries. The MRAs have been concluded solely in order to formalize the reciprocal acceptance of the conformity assessments. Reciprocal recognition of the laws and regulations is not intended.

In order for the system of reciprocal recognition of conformity assessments to function, the parties to the agreement must observe the laws and regulations of the opposite party to the agreement as listed in the sectoral annexes of the MRA. In addition, reference is made in the sectoral annexes and the supplementary separate annexes of the MRAs to relevant international documents such as the EN 45000 series of standards and the ISO/IEC guidance documents and to documents for their interpretation which are to be observed in equal measure by the two parties to the agreement. These documents are however subordinate to the relevant laws and regulations of the parties to the agreement. In general, the MRAs explicitly identify all laws and regulations and internationally recognized documents which are to be observed by the parties to the agreement. Only the documents concerning interpretation of the internationally recognized documents are not referred to explicitly.

The **consideration of the "common elements" in the MRAs** is thus dependent upon their implementation:

- in the form of EU directives,
- in the form of standards,
- in the form of guidance documents, or
- in the form of "common technical specifications" (CTS)[422].

Where the "common elements" are implemented in the form of an **EU directive**[423], the EU must inform the opposite party to the MRA concerned of the change to the laws and regulations not later than 60 days prior to entry into force of the EU directive[424]. As the changes concerning introduction of the "common elements" do not concern safety or the protection of health or the environment, no urgent measures are necessary which require the party to the agreement to be informed earlier[425].

The question arises as to whether the amended or new laws and regulations relevant within the context of the MRA come into force at the same point in time as on the territory of the party to the agreement which passed them. The framework agreement

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422 CTS may be classified as laws and regulations, as they are subordinate to a specific EU directive; conversely, they may be classified as standards, as they constitute a normative document; cf. Chapter 5.3. Depending upon their classification, the conclusions of the present chapter concerning EU directives or standards respectively should be consulted.

423 Implementation may be effected either by harmonization of the existing directives, or by the creation of a cross-sector framework directive; see Chapter 5.3

424 See for example Article 12 (2) of the MRA-USA framework agreement

425 See for example Article 12 (2) of the MRA-USA framework agreement

contains no corresponding provision in this respect; a specific provision of this kind would have to be made in the sectoral annexes.

This issue has barely been addressed in the arrangements for the sectoral annexes. In accordance with Article 5 (VII) of the sectoral annex of the MRA-USA governing telecommunications equipment, the amended or new laws and regulations which concern the sectoral annexes thus come into force at the same point in time as on the territory of the party to the agreement responsible for issuing them. As they are brought into force the sectoral annex governing telecommunications equipment is adapted by the parties to the agreement.

An arrangement of this kind is testimony to the parties' confidence in the respective safety standards of the opposing party to the agreement, and is comparatively rare. Should such an arrangement not be documented in the sectoral annex, the Joint Committee must rule upon the amendment or introduction of the laws and regulations and the associated change to the sectoral annex[426]. A unanimous decision must be reached in the Joint Committee. Each party to the agreement has one vote[427]. As the EU must inform the opposite party to the agreement of the introduction of the "common elements" in the form of an EU directive 60 days prior to their coming into force, a joint decision may still be reached in the Joint Committee prior to the EU directive coming into force, in order for the directive also to be relevant for the MRA when it takes effect in the EU. This depends, however, upon the Joint Committee convening in time.

The frequency at which the Joint Committee convenes is not governed in all MRAs[428]. As it can be assumed that uniform arrangements exist for all MRAs, however[429], it can be assumed, in accordance with Article 12 (3) of the MRA-Australia framework agreement, that the Joint Committee convenes annually, and that additional sessions may be convened at the request of the parties to the agreement. This being the case, the amendment or introduction of laws and regulations with a bearing upon the conformity assessment procedure of a party to the agreement within the context of the MRA could, in the absence in the sectoral annex of a provision governing simultaneous entry into force, come into force at the same point in time as on the territory of the opposite party, provided assent is given by the Joint Committee.

Provided they are implemented in the form of a **standard**, the "common elements" are included in the MRA when the Joint Committee unanimously assents to the change.[430] The standards listed to date in the agreements are internationally recognized documents. These standards have therefore come into being through standardization activity by ISO/CASCO. Should the "common elements" now be implemented in a European standard, a possibility exists of the request by the EU to have this European standard included in the MRA being rejected by the third country, despite the far-reaching agreement of the "common elements" of the present study with those of ISO/CASCO[431].

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426 See for example Article 21 (2) of the MRA-USA framework agreement.

427 See for example Article 14 (3) of the MRA-USA framework agreement

428 A corresponding provision is not found in the MRA-USA.

429 Harmonized system within the EU; see Certif. 96/3 Rev. 6 EN.

430 See for example Article 21 (2) of the MRA-USA framework agreement.

431 For further reasons, see Chapter 7.2.3.

In contrast to EU directives, standards or CTS, **guidance documents** are not included in the MRA by joint decision of the Joint Committee.

The guidance document is not binding upon the parties to the agreement. As shown by practical experience in the case of the MEDDEV 2.10/2 guidance document drafted by the EU, the guidance document nevertheless constitutes an important document for alignment of the conformity assessment systems. The document was created for the assessment of conformity assessment bodies for the European Single Market, and is an important instrument, even in the absence of legal force and explicit reference, for examination of the requirements placed upon conformity assessment bodies within the scope of the MRA.

The relevance of the guidance document can also be seen from the fact that the criteria provided as examples for demonstration of the technical competence of the conformity assessment bodies are based both upon internationally recognized documents, and upon specific documents concerning their interpretation, which are drawn upon the basis of need[432]. These specific documents are guidance documents, in the sense referred to here. The abstract reference to them indicates that the guidance documents are not binding, but that the responsible bodies and authorities are nevertheless advised to observe them during their activities.

7.2.2.2 PECAs

As third countries with each of which the EU has concluded a PECA in the context of the bilateral Europe Agreement, Hungary and the Czech Republic must bring their relevant regulations into line with the technical regulations of the Community and with the European standards[433]. These countries further undertake to maintain Community law, including in the areas of standardization, conformity assessment, market surveillance, and general product safety[434]. The reason for this is the progressive political and economic integration of these third countries into the EU.

They must therefore **transpose into national law** the **changes in community law** which arise subsequent to conclusion of the PECA. With the implementation of the "common elements" within the EU, Hungary and the Czech Republic must likewise observe them in their national regulations.

7.2.3 Influence upon structure and content

In the implementation of the "common elements" in the MRAs as described above[435] it must be assured that the existing structure and the substantial framework of the MRAs is retained, as both are the expression of negotiations, in some cases protracted, between the parties to the agreement. Should this requirement not be observed, the result may be that

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432 Cf. for example Article 4 of the annex of MRA-Australia

433 Refer for example to Article 75 (1) of the EA-CZ

434 See for example Article 3 of the PECA-CZ

435 The procedures for designation and surveillance of the conformity assessment bodies are not established in the PECAs owing to the particular situation whereby the third countries adopt Community legislation in their national regulations. The requirements placed upon bodies to be notified do not therefore form a direct component of the agreement. The PECA will not therefore be considered further in the study.

the "common elements" are not observed by the third countries in the context of the MRAs.

7.2.3.1 Basic structure

The agreements between the EU and third countries for reciprocal recognition of conformity assessment systems are based upon the **specimen agreement** drawn up on the basis of Council Decision of 21 September 1992[436]. This specimen agreement served as a negotiating directive during drafting of the agreements, and has been adopted largely verbatim. According to the specimen agreement, **two alternatives** exist for the point in the agreement at which the requirements to be placed upon bodies to be notified, which are described in detail by the "common elements", may be defined.

Firstly, the requirements to be placed upon the bodies to be notified may be implemented – as is the case in the MRA-Australia, MRA-Canada and MRA-Switzerland – as follows: in a separate annex to the framework, "procedures for the designation and monitoring of conformity assessment bodies", which draws no distinction between the parties to the agreement; and additionally in a corresponding section in the sectoral annexes concerning the "procedures for designating conformity assessment bodies", which in this case does distinguish between the parties to the agreement.

The advantage here is that the general requirements to be placed upon bodies to be notified can be described in detail in the separate annex. The drawback is that the separate annex refers to "internationally recognized documents" and the facility is thus excluded - owing to the presence of contradictions - for the listing in the sectoral annexes of specific documents, such as European standards, which are relevant only to one of the two parties to the agreement. By virtue of the fact that the separate annex contains all relevant documents and that no additional documents may be listed in the sectoral annex which are to be observed by only one of the parties, many sectoral annexes lack a corresponding section.

Secondly – as implemented in the MRA-USA - the requirements to be placed upon bodies to be notified may be established in each sectoral annex of the agreement only in a section governing designation, inclusion, suspension, revocation of designation and monitoring of conformity assessment bodies. This section draws a distinction between the parties to the agreement. The advantage is that in contrast to the form described above, specific documents may be listed which are to be observed by only one of the parties to the agreement. The drawback is that the requirements to be placed upon bodies to be notified are not defined in the terms; the reason for this is doubtless the scale of such a definition.

7.2.3.2 Examination of the substantial framework

The substantial framework must be examined in order to determine the probability of the terms of the new "common elements" - a part of which has been reformulated within the context of the present study - being implemented in a form generally acceptable to the parties to the agreement; for the sake of expediency, this implementation should be geared towards the existing structure. If the basic terms of the "common elements" are already present in the MRAs, their acceptance appears likely.

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436 Council Decision of 21 September 1992 authorising the Commission to negotiate agreements between the community and certain non-member countries on mutual recognition, Doc. 8300/92, 28.9.92; see also Osterheld, B.: Abkommen der EG, p. 129ff.

As already mentioned, the terms of the **MRA-USA** lack detailed requirements for notified bodies; reference is made only to relevant ISO/IEC guidance documents and to comparable standards in the EN 45000 series, in some cases cited as examples. As the "common elements" developed in the present study are based in large measure upon requirements already defined there, resulting in major overlaps, consideration of the "common elements" in the MRA-USA appears probable.

In contrast to the MRA-USA, the **MRA-Australia, MRA-Canada and MRA-Switzerland** describe the requirements upon the bodies to be notified, in somewhat more detail, in a separate annex governing the procedure for designation of the conformity assessment body. These requirements are general criteria which are to be observed during assessment of the conformity assessment bodies.

These general criteria are based, for example in accordance with Article 4 of the annex "Procedures for the designation and monitoring of conformity assessment bodies" in the MRA-Australia, upon internationally recognized documents and upon specific documents concerning their interpretation. In accordance with Article 4 of Annex 2 of the MRA-Switzerland, internationally recognized documents are deemed in particular to mean the EN 45000 series or equivalent standards. These documents are however to be interpreted in consideration of the applicable laws and regulations listed in the relevant sectoral annexes.

This means that these MRAs, in contrast to the MRA-USA, also refer to internationally recognized documents, but makes explicit reference in the annex to important requirements placed upon bodies to be notified. This simplifies examination of whether the "common elements" are also contained in the terms of the MRAs (in this case, the MRA Australia). This examination (see Fig. 14) takes the form of a comparison as shown in the example.

"Common elements" of the study	General criteria (Article 3 of the annex of the MRA-Australia - example)
• Structure	• Any other requirements for assurance that conformity assessments will continue to be conducted in a proper manner
• Resources ➢ Personnel ➢ Facilities	• Technical expertise in the products, processes or services concerned • Understanding of the technical standards and of the general requirements concerning protection against risks • Experience with the applicable laws and regulations • Material requirements for the conducting of the requisite conformity assessment activity
• Process	• Any other requirements for assurance that conformity assessments will continue to be conducted in a proper manner
• Management systems	• Suitable management for the conformity assessment activities concerned

Fig. 14: Comparison of "common elements" and general criteria, MRA-Australia serving as an example

Examination of the substantial framework shows that the "common elements" are in harmony with the general criteria which must be observed during assessment of the conformity assessment bodies. The effects of their implementation upon the structure of the MRA in question can therefore be discussed below.

7.2.3.3 Effect of implementation upon the structure of the MRA

Case 1: MRA-Australia, MRA-Switzerland and MRA-Canada

As the general criteria are based upon the internationally recognized documents, laws and regulations, and documents dealing with their interpretation, the structure of the agreement can be retained if the implementation of the "common elements" takes the form of an EU directive, an ISO/IEC standard, or a guidance document.

Owing to lack of experience with the "common technical specifications" (CTS), they cannot yet be classified clearly. On the one hand, they can be classified with European standards owing to their normative character; on the other, they may also be classified with the relevant laws and regulations, as they are subordinate to a certain EU directive.[437] Depending upon the classification, the corresponding comments concerning implementation and effects upon the structure should be consulted.

If the "common elements" are to be implemented in the form of a European standard, the separate annex must be amended if the structure of the agreement is to be retained. The separate annex applies to both parties to the agreement. It makes reference to internationally recognized documents which a European standard for "common elements" would not satisfy. If a European standard is nevertheless to be considered, the

437 See Chapters 5.3.4 and 7.2.2.1

phrase "internationally recognized documents" in the annex must be replaced by a reference to a section in the sectoral annexes concerning the documents relevant to the procedures for designation. This would enable a European standard to be[438] listed at the corresponding point in the sectoral annex, and the structure of the agreement to be retained.

In the MRAs in which the procedure for the designation and surveillance of the conformity assessment body is established in a separate annex, however, the relevant sectoral annexes rarely contain an additional section. If the "common elements" cannot be implemented in the form of an international standard or EU directive, a section concerning the procedures for the designation and surveillance of the conformity assessment bodies, to which reference is made in the separate annex governing the procedures for the designation and surveillance of the conformity assessment bodies, must be inserted in each of the sectoral annexes.

Case 2: MRA-USA

In the MRA-USA, the procedures for designation of the conformity assessment body are formulated in one section only, which is assigned to each sectoral annex and to which reference is made in Article 7 of the MRA-USA framework agreement. An assessment in accordance with Article 7 of the MRA-USA framework agreement must be performed in accordance with the procedures and criteria established in the sectoral annexes. The sectoral annexes exhibit two different arrangements in this context:

With the exception of the sectoral annex governing medical devices of the MRA-USA, **all sectoral annexes** require the parties to the agreement to observe the laws and regulations of the opposite party to the agreement on the basis of observance of the relevant ISO/IEC guidance documents or the comparable standards of the EN 45000 series during their assessment of the conformity assessment bodies in the context of the agreement[439].

The structure of the agreement is thus retained when the "common elements" are implemented in the form of an EU directive or an ISO/IEC standard and the latter are inserted at the relevant point[440]. Should it not be possible to define the "common elements" in an internationally recognized standard and should a European standard therefore need to be created, this standard can be indicated at the same point. CTS can, for the reasons already stated, be classified either as laws and regulations or as European standards and can therefore also be listed in the corresponding section[441] of the sectoral annex.

A guidance document such as that considered under the alternatives for implementation of the "common elements"[442] need not be listed, as its observance remains voluntary. As

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438 See e.g. Section IV of the sectoral annexes governing telecommunications equipment, MRA-Australia.

439 See for example Section VI of the sectoral annexes concerning telecommunications equipment, MRA-USA.

440 See for example "U.S access to EC market" in Section VI, Sectoral Annex for Telecommunication Equipment, MRA-USA.

441 See for example "U.S access to EC market" in Section VI, Sectoral Annex for Telecommunication Equipment, MRA-USA.

442 This is not an ISO/IEC guidance document, normative in nature, but a guidance document in the sense of the MEDDEV document, which is not binding and which is provided for assistance.

the "common elements" are based upon the minimum requirements of the EU directives and the corresponding ISO/IEC standards, which they implement and supplement, it can be anticipated that a guidance document which contains the "common elements" will be observed, despite its voluntary nature.

By contrast, where assessments are performed of bodies conducting conformity assessments in the area of **medical devices**, only those laws and regulations of the parties to the agreement are relevant which concern the area of medical devices are relevant. A detailed description of the requirements placed upon bodies to be notified does not exist, however. The criteria are derived from review of the documents stated.

The complete EU directives have not been considered in the development of this sectoral annex. The annexes governing the minimum criteria for the notification of bodies do not constitute part of the agreement. This procedure employed for the development of the sectoral annex gives rise to the assumption that the "common elements" will not be considered in the sectoral annex if they are implemented in the form of an EU directive, in the form of CTS or in the form of a standard.

The "common elements" may initially be considered in the sectoral annex governing medical devices of the MRA-USA only if they are implemented in the form of a guidance document which provides supplementary interpretation of the laws and regulations. This conclusion is justified by standard practice. The MEDDEV 2.10/2 guidance document, for example, is recognized in particular by the parties to the agreement for interpretation of the sector-specific laws and regulations in the area of medical devices.

If the sectoral annex governing medical devices of the MRA-USA is retained in its current form, the "common elements", should they not be implemented in the form of a guidance document, may consequently be considered only in the remaining sectoral annexes of the MRA. This presents no further problem, as the MEDDEV 2.10/2 guidance document is already in existence, which defines the requirements placed upon conformity assessment bodies in the area of medical devices to the satisfaction of both parties.

List of abbreviations

AG	Advocate-General
APLAC	Asia Pacific Accreditation Co-operation
BGH	Bundesgerichtshof, German Federal Supreme Court
BMG	Bundesministerium für Gesundheit, German Federal Ministry of Heatlh
BMWA	Bundesministerium für Wirtschaft und Arbeit, German Federal Ministry of Economics and Labour
CAB	Conformity Assessment Body
CAPM	Conformity Assessment and Product Marking
CASCO	Conformity Assessment Committee
CB	Certification Body
CCA	Cenelec Certification Agreement
CCIP	Customs Codex Implementation Provisions
CEN	Comité Européen de Normalisation
CENELEC	Comité Européen de Normalisation Electrotechnique
CEO	Chief Executive Officer
CTS	Common Technical Sepcifications
CZ	Czech Republic
DAR	Deutscher Akkreditierungsrat (German Accreditation Council)
DIBt	Deutsches Institut für Bautechnik (German Institute for Civil Engineering)
DIN	Deutsches Institut für Normung
DTI	Department for Trade and Industry (UK)
EA	Europe Agreement
EA	European co-operation for Accreditation
EC	European Commission
ECJ	European Court of Justice
ECOSOC	Economic and Social Council
EFTA	European Free Trade Association
EN	European Standard
EU	European Union
EuZW	Europäische Zeitschrift für Wirtschaftsrecht (journal)
EEC	European Economic Community
EWS	Europäisches Wirtschafts- und Steuerrecht (journal)
FDA	Food and Drug Administration (US)
GATS	General Agreement on Tariffs and Services
GATT	General Agreement on Tariffs and Trade
GCP	Good Clinical Practice

DG	Directorate-General
GG	Grundgesetz (German Basic Law)
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HU	Hungary
IAAC	International Accreditation Co-operation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
KAN	Kommission Arbeitsschutz und Normung (Commission for OH&S and Standardization)
MDA	Medical Devices Agency
MLA	Multilateral Agreement
MPG	Medizinproduktegesetz (German Medical Devices Act)
MRA	Mutual Recognition Agreement
MS	Member State
NJW	Neue Juristische Wochenschrift (journal)
NQSZ	Normenausschuß für Qualitätssicherung, Statistik und Zertifizierung (standards committee for quality assurance, statistics and certification in Germany)
NTA	New Translatlantic Agenda
OECD	Organisation for Economic Co-operation and Development
OEEC	Organization for European Economic Cooperation
OJ	Official Journal
OLAS	Office Luxembourgeois d'Accréditation et de Surveillance (Luxembourg Office of Accreditation and Surveillance)
PAC	Pacific Accreditation Co-operation
PECA	Protocols to the Europe Agreements on Conformity Assessment
prEN	Projet EN (draft for an EN standard)
QA	Quality Assurance
RegTP	Regulierungsbehörde für Telekommunikation und Post (telecommunications and postal regulatory authority)
rev.	Revision
p.	Page
SOGS	Senior Officials Group on Standardisation and Conformity Assessment Policy
START	Standardization and Regulatory Techniques
TABD	Transatlantic Business Dialogue
TGA	Trägergemeinschaft für Akkreditierung GmbH
TRIPS	Trade Related Aspects of Intellectual Property Rights
UKAS	United Kingdom Accreditation Service

UN ECE	UN - Economic Commission for Europe
UN	United Nations
VwVfG	Verwaltungsverfahrensgesetz (German Administrative Procedures Act)
WHO	World Health Organisation
WP	Working Party
WTO	World Trade Organisation
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (central body of the German regions for health protection in connection with pharmaceutical products and medical devices)
ZLS	Zentralstelle der Länder für Sicherheitstechnik (central body of the German regions for safety)

Literature

Breulmann, G. (Eds.): Normung und Rechtsvergleichung in der EWG, Berlin 1993

Edelhäuser, R.: Konformitätsbewertungsverfahren und Normung, in: Anhalt, E.; Dieners, P. (Eds.): Handbuch des Medizinproduktesrechts, Munich 2003, to appear in Spring 2003

Ensthaler, J. (Eds.): Europäischer Binnenmarkt, Berlin 1989

Ensthaler, J.: Zertifizierung, Akkreditierung und Normung für den Europäischen Binnenmarkt, Berlin 1995

Ettarp, L.: SWEDAC DOC 97:10 third edition – An Overwiew of International Conformity Assessment Systems, Stockholm, 5.9.1997

European Commission – Industry Directorate-General: Certif 93/1 rev. 3 – Method of Coordinating the Procedures Governing the Notification and Management of Notified Bodies, Brussels, 07.02.1994

European Commission, Industry Directorate-General: Certif 97/1 EN rev. 3 – Code of conduct for the functioning of the system of notified bodies, Brussels, 17.07.1998

European Commission, Industry Directorate-General: Certif 97/4 EN Draft – Accreditation and the Community's Policy in the Field of Conformity Assessment, Brussels, 07.04.1997

European Commission, Enterprise Directorate-General: Certif 96/3 EN rev.6 – Procedure for Designation of Conformity Assessment Bodies (CABs) under Mutual Recognition Agreements (MRAs) with Non-Member Countries, Brussels, 14.6.2001

European Commission, Enterprise Directorate-General: MEDDEV 2.10/2 Rev. 1 – Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices, Brussels, 2001

European Commission, Enterprise Directorate-General: Methods of referencing standards in legislation with an emphasis on European legislation, Brussels, 2002

European Commission, Enterprise Directorate-General: SOGS N326 EN – Role of Accreditation and UKAS, Brussels, 12.9.2000

European Commission, Enterprise Directorate-General: SOGS N332 EN – SWEDECA's role in assessing and notifying notified bodies under various EU-directives, Brussels, 12.9.2000

European Commission, Enterprise Directorate-General: SOGS N356 EN – Procedure for the assessment, inspection and monitoring of notified bodies, Brussels, 12.9.2000

European Commission, Enterprise Directorate-General: SOGS N370 EN – Memorandum from the Dutch delegation on the SOGS N325 EN document, Brussels, 20.10.2000

European Commission, Enterprise Directorate-General: SOGS N374 EN – How notified bodies are designated in Denmark, Brussels, 12.9.2000

European Commission, Enterprise Directorate-General: SOGS N375 EN – Designation and notification of conformity assessment bodies under the New Approach directives in Finland, Brussels, 20.10.2000

European Commission, Enterprise Directorate-General: SOGS N377 EN – German Accreditation, Designation and Notification Procedures under the EC Treaty, Brussels, 20.10.2000

European Commission, Enterprise Directorate-General: SOGS N378 EN – Description of the systems for the designation of notified bodies in Spain, Brussels, 13.11.2000

European Commission, Enterprise Directorate-General: SOGS N389A1 EN – Austria notification system, Brussels, 13.12.2000

European Commission, Enterprise Directorate-General: SOGS N390 DE – Portuguese notification system, Brussels, 14.12.2000

European Commission, Enterprise Directorate-General: SOGS N391 EN Version 2.0 – How notified bodies are designated in Norway, Brussels, 3.5.2001

European Commission, Enterprise Directorate-General: SOGS N393 EN – Evaluation and notification of notified bodies in Belgium, Brussels, 21.12.2000

European Commission, Enterprise Directorate-General: SOGS N402 EN Version 2.0 – Greek notification system, Brussels, 3.4.2001

European Commission, Enterprise Directorate-General: SOGS N426 EN – Draft DG Enterprise Consultation Document on the review of the New Approach, Brussels, 28.01.2001

European Commission - Enterprise Directorate-General: SOGS/WG1/N017 – Summary of national notification system: SWEDEN

European Commission - Enterprise Directorate-General: SOGS/WG1/N018 – Summary of national notification system: THE NETHERLANDS

European Commission - Enterprise Directorate-General: SOGS/WG1/N019 – Summary of national notification system: UNITED KINGDOM

European Commission - Enterprise Directorate-General: SOGS/WG1/N020 – Summary of national notification system: BELGIUM

European Commission: COM (85) 310 final – Completing the Internal Market: White Paper from the Commission to the European Council, Brussels, 14.06.1985

European Commission: Guide to the implementation of Community harmonization directives based on the new approach and the global approach - First Version, Luxembourg 1994

European Commission: Guide to the Implementation of Directives Based on the New Approach and the Global Approach (Blue Guide), Luxembourg 2000

Feitenhansl, N.: Entwicklungen von Anforderungsnormen für den Bereich der Akkreditierung, Europäische Konferenz "Normung, Prüfung, Zertifizierung" der KAN am 11./12.10.2001 in Dresden, pp. 81-86

Geiger, A.: Die neuen Leitlinien der EG-Kommission zur Anwendbarkeit von Art. 81 EG auf Vereinbarungen über horizontale Zusammenarbeit, EuZW 2000, pp. 325-328

Hansen, W. (Eds.): Zertifizierung und Akkreditierung von Produkten und Leistungen in der Wirtschaft, Munich i.a., 1993

Lange, K. W.: Handelsvertretervertrieb nach den neuen Leitlinien der Kommission, EWS 2001, pp. 18-23

Maurer, H.: Allgemeines Verwaltungsrecht, 13th edition, Munich, 2000

Moench, C.: Der Schutz des freien Warenverkehrs im Gemeinsamen Markt, NJW 1982, pp. 2689-2700

NQSZ: NQSZ-3 AK 1 N 6 – Übersicht des nationalen Notifizierungssystems

Obermayer, K.: VwVfG – Kommentar zum Verwaltungsverfahrensgesetz, 3rd edition, Neuwied i.a., 1999

OECD: TD/TC/WP(98)36/FINAL – Regulatory reform an international standardization, Paris 1999

OECD: TD/TC/WP(99)47/FINAL – Standardization and regulatory reform: selected cases, Paris 2000

OECD: TD/TC/WP(99)8/FINAL – An assessment of the costs for international trade in meeting regulatory requirements, Paris 2000

OECD: TD/TC/WP/RD(2000)1/FINAL – Special meeting on technical barriers to trade – summary report by the secretariat, Paris 2000

Oppermann, T. (Eds.): Europarecht, 2nd edition, Munich, 1999

Osterheld, B.: Abkommen der Europäischen Gemeinschaft über die gegenseitige Anerkennung von Konformitätsbewertungen, Hamburg 2002

Schomaker, A.; Detken, D.: Die EU und die USA, in: Röttlinger, M.; Weyringer, C. (Eds.): Handbuch der Europäischen Integration, 2nd edition, Vienna, p. 536-563

UN ECE WP.6: ECE/STAND/20/Rev.5 – ECE Standardization List, New York i.a. 2002

UN ECE WP.6: ECE/TRADE/17/Rev.4 – Recommendation on Standardization Policies, New York i.a. 2002

Volz, G. (Eds.): Die Organisationen der Weltwirtschaft, Munich i.a.. 1998

Annex

Annex A List of ISO/CASCO standards and guidance documents

Annex B Criteria for the designation and assessment of notified bodies (examples from the New Approach Directives)

- B1 – Medical Devices Directive 93/42/EEC
- B2 – Pressure Equipment Directive 97/23/EC
- B3 – Appliances burning gaseous fuels Directive 90/396/EEC
- B4 – Lifts Directive 95/16/EC
- B5 – Personal Protective Equipment Directive 89/686/EEC
- B6 – Directive 98/13/EC on telecommunications terminal equipment
- B7 – Machinery Directive 8/37/EC
- B8 – Simple Pressure Vessels Directive 87/404/EEC
- B9 – Directive 98/79/EC relating to in vitro diagnostic medical devices

Annex C Extract from the MPG

Annex D Table of national designation systems of the Member States

Annex E SOGS N377 EN – German Accreditation, Designation and Notification Procedures under the EC Treaty (extract)