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WORKSHOP ON THE IMPLEMENTATION AND USE OF INTERNATIONAL STANDARDS

Application and communications technology products: Need for a harmonized regulatory system

This paper has been submitted by representatives of the Swedish company "Ericsson"/ECTEL.

This document is presented for information to delegates. It contains background information on issues to be discussed at the workshop and also under agenda items 7 and 8(a).

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ECTEL AND EUROBIT GREEN PAPER ON A GLOBAL PRODUCT APPROVAL SYSTEM FOR THE FUTURE

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1 Introduction

ECTEL wishes to make some comments from the Information and Communications Technology (ICT) sector on the issue of product approvals for the future. The aim of this paper is to stimulate the debate on how the regulatory system should be adapted in the future to ensure that products can be placed on a Global marketplace with harmonised administrative procedures. This will benefit all parties - consumers, regulators and suppliers

In the discussion of regulatory changes, it should be noted that the Mutual Recognition Agreements or Arrangements concluded so far do not by themselves require harmonisation of regulatory systems in different regions. They do however point out the differences which exist, and thus help the work for a global harmonisation.

This paper does not question the need for regulation as such. It however strongly asks for deregulation above a basic level. It discusses the future harmonisation of regulatory measures including the method to show compliance.

This paper draws on some conclusions made in previous ECTEL Position papers (for completeness one of them is included in this document as Appendix 1 and 2), and also some papers from other sources, notably the TABD Declarations.

2 The Way Forward (Summary)

The regulatory system must be designed to meet basic needs of the society, leaving issues of performance and functionality of products for the market players to agree upon Furthermore it is important that new innovative products can be placed on the market with maintained level of confidence and at lowest possible cost for administrative procedures. This leads to the need to harmonise regulatory procedures, and as a consequence there is also a strong need for deregulation.

Regulation and Market Surveillance should be such that there is little incentive for suppliers to place non-approved products on the market. This will benefit the serious manufacturers/suppliers and thus also the end-users of products.

It is proposed that

* a global approval system should be based on fair and simple rules;
* a global approval system should be suitable also for developing countries;
* horizontal regulation is applied wherever possible;
* the method used to show compliance to regulation is the Supplier's Declaration of Conformity (SDoC) without mandatory third party intervention;
* countries should deregulate as far as possible in a structured manner;
* the use of additional voluntary systems should only correspond to true market needs.

3 Discussion

3.1 General

Deregulation is starting to take place in many countries, specifically in the telecommunications field, to ensure a fast development of the society. Regulation will more and more concentrate on ensuring that certain public interest objectives are being met, and to ensure fair competition and a level playing field. In this scenario, consumer protection laws will play an increasing role, since quality and performance of products no longer are governed by strict regulation.

It is becoming increasingly clear that current product approval systems need to be evaluated for relevance in the new market scenario. Nowadays the commercial life cycle of ICT products are much

shorter than before and thus it is crucial that the commercial window of opportunity is being utilised to the fullest. This has been addressed in the ECTEL Position Paper on Supplier's Declaration of Conformity (SDoC) and its accompanying paper on Accreditation (attached as Appendix 1 and Appendix 2).

The TransAtlantic Business Dialogue (TABD) has paid much attention to the matter of product approvals. The Declarations from the CAPM[1] and EETIS[2] groups point to the need for a simplified approval system for the global market where the supplier assumes full responsibility for the product.

The European Commission has issued papers on this subject. The position paper from DG III published in 1995[3] points out that "*there are two important aspects to the information revolution:*

* *The final shape information markets are going to take is unknown to regulators or economic operators.*
* *It is driven by innovation. Suppliers will have to respond to the demands of the market place and competitive interaction will determine which services are offered at what prices. There is general recognition that the main players will be private enterprises.*"

In the DG III position paper it is also noted that "*the central issue to be addressed by regulators is, how to assure an appropriate balance between the many rights and competing interests affected by this revolution while keeping enough flexibility to facilitate and accelerate the realisation of the productivity gains and competitive advantages available from the information revolution and in particular from the extensive use of telecommunications equipments and services to support business and social needs.*"

ECTEL's position papers are consistent with this position paper from DG III.

There are several issues that need to be considered when investigating the areas related to product approval. Among these is the global marketplace, which inevitably calls for more liberalisation and use of horizontal measures (where legal initiatives are deemed necessary). Some of these issues are discussed below.

3.2 A Global Marketplace

The marketplace for Information Technology and Telecommunications products is becoming truly global. This is perhaps best seen in the case of mobile satellite telecommunications (Low and Medium Earth Orbit satellites) where by necessity an identical technical solution is employed globally for each system.

A global marketplace inevitably calls for a harmonised approval regime. At present each region (and in some regions each country) has its own sectoral regulation for telecommunications. Although the systems are quite similar in many respects, there are still differences between them. Many of these differences are not directly related to technical matters, but rather to social issues (which however may translate into certain technical features or solutions that differ between regions).

A number of Mutual Recognition Agreements/Arrangements (MRAs) have been concluded, and new ones are being discussed. While it is of great advantage to have MRAs between certain trading parties, at least for the shorter term, it becomes difficult to manage a multitude of MRAs. The MRA between two parties needs updating as soon as the legal system in one country changes. On a global scale a longer term solution for simplified access to each other's markets should be contemplated.

The MRAs do not themselves require harmonisation of regulatory procedures[4], nor harmonisation of

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1 Conformity Assessment and Product marking (CAPM) paper Rome 6-7 November 1997

2 Electrical, Electronic, Telecommunications, Information Technology Sectors (EETIS) paper Rome 6-7 November 1997

3 DG III Industry (Legislation, Standardization and telematic networks): "Telecommunications Terminal Equipment regulatory framework - position paper" (Brussels, 15 June 1995)

4 In some cases regulatory changes are needed in a country to allow for conformity assessment and approvals to be handled outside the country in question. This does not mean that regulation will be

technical standards. As mentioned in Clause 1 they highlight the differences between the regulatory systems of the parties and thus point to areas where harmonisation could be beneficial. MRAs should be gradually revised towards a preferred global solution.

The best way to achieve global harmonisation is to deregulate or at least to minimise regulation. This is noted in the FCC Office of Plans and Policy's (OPP) Working Paper "Digital Tornado: The Internet and Telecommunications Policy"[5]. Where it is deemed necessary to apply legal measures, horizontal regulation should be applied wherever possible, thus leaving only certain sectoral aspects for sectoral regulation(see point 3.4). Global harmonisation of regulation is more easily achieved this way.

NOTE: In order to achieve technical harmonisation on a global level of the standards which support regulation the regulatory systems in the different regions should be equal, i.e. they should be targeting the same matters to the same level of confidence. As an example, at present the EMC standards (save the ones related to emission) created by IEC are written for voluntary, non-regulatory use. However in Europe these standards are being converted to European standards supporting the EMC Directive 89/336/EEC. There is a general concern that these standards exceed what is called for by the protection requirements in Article 4(b) of the EMC Directive, thus adding unnecessary costs to all products.

The success of a change in the regulatory systems is a question of timing. The window of opportunity has come for such a change in the different regions, to achieve a global marketplace thus reducing costs for bringing products on the market. This will in turn benefit the end-users.

There is now a proposal for a Conformity Assessment Agreement (CAA) being discussed in the WTO under the umbrella of Information Technology Agreement (ITA) II, non-tariff barriers to trade. This proposal addresses the IT sector, but following its successful implementation it may be found attractive to widen the scope of application to other sectors, so that the CAA would become horizontal. See Annex A for a proposed CAA.

It is recognised that basic horizontal legal systems related to aspects such as consumer protection and liability need to be in place for a successful transition to a system based on SDoC and Market Surveillance. This is stressed in the UN Economic and Social Council input paper for the "Working Party on Technical Harmonization and Standardization Policies" meeting 18-20 May 1998[6]. See also clause 3.5.5 and Appendices 1 and 2.

3.3 Horizontal regulation

The convergence which is now taking place between different sectors, specifically between telecommunications, media and information technology as discussed in the EU Commission Green Paper on Convergence[7], will make it increasingly difficult to make a regulatory separation of different sectors. Since convergence will benefit the users of products and services, authorities should support

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harmonised between the parties concerned.

5 OPP Working Paper Series, 29 "Digital Tornado: The Internet and Telecommunications Policy", March 1997, page 47: "Government should think not only about the regulatory treatment of new services, but about the implications of those new services for the regulatory treatment of existing services. If a competitive imbalance exists because a new technology is not subject to the same regulatory constraints as a competing older technology, the answer should be reduced regulation of the older technology. Of course, such deregulation should be dependent on the existence of sufficient competition to police the actions of incumbents. The ultimate objective, however, should be less regulation for all, rather than more regulation for some."

6 TRADE/WP.6/1998/8 8 May 1998: UN Economic and Social Council: Working Party on Technical Harmonization and Standardization Policies 18-20 May 1998: "Problems experienced by economies in transition relating to conformity assessment procedures - Supplier's Declaration of Conformity: Adaptation of procedures in terms of constraints on suppliers".

7 COM(97)623, Brussels, 3 December 1997: "Green Paper on the Convergence of the Telecommunications, Media and Information Technology Sectors, and the Implications for Regulation - Towards an Information Society Approach".

this development by adapting (and wherever possible reducing) its regulation in a timely manner. The best way of doing this is to resort to horizontal regulation, and more reliance on competition rules to ensure a level playing field.

NOTE: ECTEL has responded with detailed comments to the Commission Green Paper on Convergence[8].

Also, products are becoming multifunctional, and consequently they may be subject to a number of (at present) sectoral directives. Meeting the legal requirements related to one sector may result in non-compliance with legal requirements of another sector. The best way to ensure that combined products can enjoy easy market access is to use horizontal legislation. Sectoral legislation should be avoided wherever possible. It should be noted that the TABD Chicago Declaration (November 1996) calls for horizontal regulation to enable products to be approved for a global marketplace with minimal delays and costs to the end-user.

A first list of examples of horizontal issues, seen from the EU perspective, is given below. With reference to the TABD recommendations, it is expected that the EU Commission will take appropriate actions with respect to some of these issues.

Issue	Comments
Safety, including electrical safety	Safety has traditionally been subject to horizontal regulation, with appropriate technical standards and guidelines defining the criteria for compliance.
Radio and EMC	Spectrum management issues and the co-existence of products in the electromagnetic environment is a horizontal issue. Due to the intrinsic similarity between radio and EMC, these should be covered by one regulatory framework.
Liability	Consumer protection and liability for defective products is a horizontal issue. There is no rationale to assign different regulatory regimes for different technical sectors.
Privacy	Directive 95/46/EC on the processing of personal data provides a horizontal umbrella for privacy. This is enhanced by directive 97/66/EC on the processing of personal data and protection of privacy in the telecommunications sector. These directives fully cover protection of privacy.
People with special needs	Measures taken in sectoral directives are only targeted towards a limited number of sectoral products. Where legislation is deemed necessary, a high level of well-being and employment for people with disabilities is better achieved through horizontal measures[9].
Environmental issues	Horizontal legislation (where legislation is needed) is preferred because of factors like: - combined products - convergence between sectors - material content

3.4 Sectoral regulation

Sector specific regulation should be used only in special cases, and then related to specific sectoral

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8 ECTEL Position Paper EPP06/98 (04/98).

9 In the Treaty of Amsterdam (2 October 1997), Declaration 22 (Declaration regarding persons with a disability) states that "The Conference agrees that, in drawing up measures under Article 100a of the Treaty establishing the European Community, the institutions of the Community shall take account of the needs of persons with a disability". However it is strongly recommended to ensure horizontal application of Declaration 22 so that optimum solutions for persons with a disability can be found.

aspects. All aspects which can be treated on a horizontal basis should be covered by horizontal measues. The way to minimise sectoral regulation in to deregulate as far as possible. Where sector specific regulation is introduced, the administrative burden to manufacturers should be minimised. Specifically, the Conformity Assessment methods being used should as far as possible be the same as the one(s) used for horizontal regulation to enable one-stop shopping, thus minimising delays and costs (which ultimately will - at least to some extent - be passed on to the end-user). For a Global market, harmonisation of standards supporting regulation is much needed.

3.5 Ways to compliance

One can envisage a number of different approaches to a future global system for product approval. The different approaches need to be scrutinised regarding their merits and drawbacks.

3.5.1 No sectoral regulation at all

A well functioning horizontal regulation could eliminate the need for sectoral regulation. Such horizontal regulation would ensure public interests and fair competition.

3.5.2 National Type Approval

Type approval is associated with costs and delays in product introduction. The delays are often considerable due to the fact that manufacturers need to assist the type approval body with equipment and expertise in the equipment to be tested, which means that type approval will have to be performed country by country rather than testing in all countries at once. This is particularly the case for SMEs, where there is a limited number of expertise available for these tasks.

As a result small markets become unattractive for many suppliers. This will deprive users in these markets of innovative products. The consequences are obvious: large markets will function (longer) but small markets will only see illegal or very old products on their market.

3.5.3 Global Type Approval

A global type approval system needs co-operation between countries. All countries (democratic and non-democratic, developed and less developed) should be members with equal rights and obligations.

All states have to create confidence building authorities to allow for accreditation and notifications that are accepted globally. At a first glance a system like this could look attractive but in reality it will be too slow in supporting the fast development of innovative products. The cost will be enormous and only a few players will afford its implementation.

3.5.4 Alternative approach - safe installation

An alternative approach to "safety of products" as discussed in the subclauses above is the concept of safe installations (safety at workplace). This can be used at a local level, but can hardly be used for a global product approval. This is a kind of indirect product safety regulation that require a supporting local authority assessment system. Such a system cannot be expected to be found in many countries.

3.5.5 Supplier's Declaration of Conformity without mandatory third party involvement

A system based on the use of Supplier's Declaration of Conformity (SDoC) relies on the fact that National Authorities define the regulatory framework for safeguarding the public interests. The

supplier can then decide how to show compliance to such regulation. However, this has to be done in such a way that all players have full confidence in the complete process. Failure in the introduction of the SDoC system will definitely stop these developments for a very long period. Therefore a well functioning Market Surveillance system is a prerequisite.

It is recognised that basic horizontal legal systems related to aspects such as consumer protection and liability need to be in place for a successful transition to the use of SDoC and market surveillance.

See Appendices 1 and 2 for a more detailed discussion on SDoC and alternative compliance mechanism than the mandatory use of accredited laboratories.

Considering all the pros and cons of the alternative solutions mentioned above it is strongly recommended to agree on the alternative with SDoC without mandatory third party intervention as the future system for showing compliance to regulation.

3.6 Placing on the market and right to use

"Placing on the market" and "Right to use" need to be discussed as two issues, not one. This applies specifically where the use of equipment is subject to (user) licensing.

The placing on the market ensures free circulation of goods, and a global marketplace for the sale of goods. The placing on the market should be based on the application of horizontal legal measures like EMC and safety of equipment.

Right to use may in some cases require a license or a contractual agreement between a user and an operator of a service (such as a telecommunications network). The right to use a particular piece of equipment may thus be restricted in certain countries/regions.

3.7 Marking

As stressed by the TABD[10], the use of one single mark indicating the presence of a SDoC where information about compliance issues are given, is strongly preferred. It needs to be stressed that marking of an equipment (as required by regulation) is for administrative control purposes, and is not intended for the user.

3.8 Information to the user

In general, consumer protection laws ensure that users are not being mislead regarding the product they are buying. Horizontal regulation inevitably calls for an increase in the information being given to the end-user regarding the intended use of a product. It is important that users are made aware of certain limitations in the use of a product where this is not obvious. Any limitation regarding installation (e.g. regarding its EMC performance) should also be indicated to the user. The documentation associated with the product will also provide information about performance issues and compliance to relevant standards.

3.9 Market surveillance

[10] Conformity Assessment and Product marking (CAPM) paper Rome 6-7 November 1997, Clause 7.2, Recommended Action 2: "Industry, customers and governments should jointly develop a strategy for reducing the number of national and regional product marks. The approach of ISO/CASCO to create a guide for the use of a single symbol indicating the existence of a Suppliers' Declaration of Conformity should be closely followed to ensure the creation of a global symbol that adds value to all users."

Regardless of conformity assessment system, a country has to maintain a market surveillance system due to two reasons:

* Illegal and unsafe products should not be allowed to be put on and remain on the market.
* Fair market conditions should prevail. Suppliers that follows the rules and bear the administrative costs and delays due to regulations should not be disadvantaged compared to those who do not comply with the rules.

Since market surveillance is needed in all cases regardless of whether there is a third party intervention or not in the approvals process (note that there will always be those who do not follow by the rules), there are no or very little extra costs associated with the use of "SDoC without any third party intervention". It is rather a question of making the results from market surveillance publicly available thus raising the awareness of suppliers and users.

Market forces when allowed to function properly ensure that users get the best value for money.

3.10 Test houses as "Insurance companies"

As long as industry is made responsible for its products they will act in relation to the risks involved. In many situations it can be expected that industry will use third party services to verify its products to be as well positioned as possible if their products are being challenged. This might be good from a quality point as well.

3.11 Complementary non-mandatory verification systems

For systems where several suppliers might be involved there is an obvious need to verify deliveries above the regulated safety level. When telecommunications services were all provided by state monopolies there was no need to distinguish between the two levels of verifications. With increased competition with multiple suppliers and service providers where all players are expected to compete with functionality and quality there is still a need for verifying deliveries according to given specifications.

Criteria for voluntary verification systems:

* It must be cost effective;
* All players should have equal right to influence test specifications for public systems;
* The verification system must be open, meaning that test specifications must be published;
* Manufacturers should be able to declare their products according to the test specifications;
* It should be possible for independent test laboratories to offer test services according to the test specifications;
* In the event of disputes the test specifications are normally referred to when such a dispute is settled.

3.12 Next steps

Different regions are in different stages of liberalisation and deregulation. Consequently the steps that need to be taken to arrive at the goal (as outlined in Clause 2) will differ somewhat between regions.

It is proposed that a discussion is initiated, region by region, regarding how to best adapt the existing regulatory systems so that the future goal is reached in a structured manner within a reasonable time.

Annex A

Proposal for a Conformity Assessment Agreement for the IT Sector

A.1 Introduction

Following the completion of the WTO Information Technology Agreement (ITA) on the abolition of tariffs on Information Technology products, there now comes the time to look for further reduction of non-tariff barriers related to the trade in goods, specifically IT products.

A number of non-tariff measures exist which should be addressed. The TransAtlantic Business Dialogue (TABD) Conformity Assessment and Product Marking document and the sectoral EETIS document approved at the Rome meeting 6-7 November 1997 ask for global agreement on the use of Supplier's Declaration of Conformity (SDoC) as the general means to show compliance to standards, be they regulatory or voluntary. The documents also call for the use of international (global) standards.

This issue was also highlighted by the TABD Rome Communiqué issued 7 November 1997.

In the course of the negotiations of the MRAs between the US and EU it has become apparent that the regions are using similar but not fully identical regulatory systems and standards. The goal appears to be the same, namely to safeguard public interests.

The MRAs themselves do not address simplifications. They will however point to unnecessary costs for suppliers in bringing their products onto the market - costs that eventually will be passed on to the final user. International agreements like the WTO ITA process can be instrumental in bringing down such costs.

There is a proposal to investigate whether an agreement on the general use of SDoC can be achieved through the ITA process in a Conformity Assessment Agreement (CAA) for the EETIS sector[11]. The CAA needs to include Market Surveillance, because this is a necessary complement to the SDoC.

Use of global standards is in most cases subject to the regional and national standardisation bodies accepting such standards for their own needs. The signatories of a "Conformity Assessment Agreement" should be able to influence their respective national standards bodies to adopt international standards wherever possible.

A.2 Definitions of the Conformity Assessment Agreement (CAA)

When making the investigation about the possibility of achieving a CAA, it is important that all parties involved are in agreement on the definitions of CAA, SDoC and Market Surveillance.

In Europe the Council Decision on a Global Approach to Testing and Certification (93/465/EEC) lists a number of ways - modules A to H - to show compliance to New Approach (Council Resolution

[11] Electrical, Electronic, Telecommunications, Information Technology Sectors (EETIS) paper Rome 6-7 November 1997, clause III "Trade Facilitation, Regulatory Reform, and Conformity Assessment".

[12] New Approach Directives are "technical harmonisation directives" where essential requirements are listed in "non-technical ways" and where the use of harmonised standards give presumption of compliance to the directives, although suppliers can use the text of the directive in question to show compliance).

85/C136/EEC) directives[12]. In all of these cases the supplier must prepare a written Declaration of Conformity. This means that even for the case where there is a strong mandatory third party intervention, there will also be an SDoC.

One of the modules, module A, does not require any intervention by a third party. The supplier declares under his sole responsibility that the product meets all the essential requirements that apply to it, prepares the Declaration of Conformity and signs it, thus assuming responsibility for the compliance of the product with the given Directive.

In the New Approach Directives there is always an *a posteriori* Market Surveillance mechanism, complementing the *a priori* conformity assessment procedure.

In the TABD documents the expression "SDoC" has been used in a *de facto* way as meaning Module A of the Global Approach, i.e., no mandatory intervention by a third party. It is therefore proposed that the definition of the CAA includes this element. Definition of Market Surveillance is based on its use in EU Directives. Further guidance and definitions are given in IEC Guide 22.

Supplier's Declaration of Conformity (SDoC): Procedure by which a supplier gives written assurance that a product, process or service conforms to specified requirements. NOTE: The supplier is the party that supplies the product, process or service and may be the manufacturer, distributor, importer, assembler, service organisation etc.

Market Surveillance: Surveillance by a National Authority that products brought onto the marketplace and/or taken into service comply with relevant regulatory requirements. Where it is found that this is not the case, appropriate measures may be taken (such as withdrawal of the product from the market).

Conformity Assessment Agreement (CAA): An agreement on the use of the following conformity assessment procedure:

1. **The Supplier**

a) ensures by way of technical documentation (which may include design calculations, test reports, etc. as appropriate) that the product (or the relevant part thereof) complies with the requirements in one or more legal (or voluntary) measure that are applicable to it, such as a Directive or Rule;

b) prepares a written Declaration of Conformity (SDoC);

c) takes all measures necessary in order that the manufacturing process ensures compliance of the manufactured product with the technical documentation.

2. **The National Authority** operates a Market Surveillance mechanism.

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[12] New Approach Directives are "technical harmonisation directives" where essential requirements are listed in "non-technical ways" and where the use of harmonised standards give presumption of compliance to the directives, although suppliers can use the text of the directive in question to show compliance).

Appendix 1

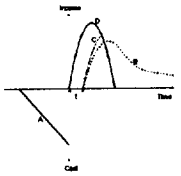
ECTEL position on Supplier's Declaration of Conformity

A conformity assessment system relying on Supplier's Declaration of Conformity (SDoC) is:

* fast;
* fair;
* flexible;
* safe.

Fast and Fair Time to Market

The emerging scenario with a Global Marketplace will lead to more competition, which benefits the customers. As a consequence, the time window during which a product is attractive for the market is becoming shorter and shorter due to more rapid and advanced product development. This time should not be spent waiting for formal approvals, since they do not add any value to the product. Rather, the time delay should be eliminated in order to maximise the potential revenue resulting from product development. In addition, eliminating the time delay for product approval would remove much of the incentive for the grey market (i.e. manufacturers who short-circuit the regulatory approval system).
The following figure illustrates this:



A: Accumulated development cost.

t: Time for type approval. The ideal solution is that this time is reduced to zero. The time is directly dependent upon the number of laboratories available.

B: "Traditional" income curve. Sales start after type approval, with quite extended after-launch sales.

C: Income curve after type approval in today's and tomorrow's business environment.

D: Possible income curve with shorter product life cycles and no delays in product approvals.

Every effort should therefore be put into allowing a product to be legally put on the market as soon as the supplier is prepared to assume legal responsibility for the product.

A flexible system

The approval process should be an integral part of the development process. It is proposed that a three step approach, which takes into account the sensitivity/risk related to the product, be introduced:

* The preferred method is supplier's declaration without any third party involvement, and this should apply to all low-risk products (this method has been in operation in Europe for safety aspects of electrical products since 1973). Further discussion is given in document "Alternative Compliance Mechanism other than the Mandatory Use of accredited laboratories" (attached);
* The manufacturer operates a recognised quality system (e.g. ISO 9001), thus ensuring his competence in the field concerned;
* For high-risk products where there are health and hazardous risks, such as for pharmaceuticals and explosive goods, it might be desirable to have assessment by an accredited third party during the development phase. To make this system efficient, it is important to allow competition between the accredited bodies.

NOTE: In the second step above some manufacturers, particularly SMEs, might not wish to operate a quality system of their own but prefer an intervention by a third party.

This system, including an SDoC, can also be used for areas without regulation, e.g. for environmental issues, functionality and quality aspects.

A safe system relying on Market Surveillance

To make the SDoC trustworthy, a market surveillance operation should be performed by the administrations.
Horizontal measures such as consumer protection and liability (related to safety of products) legislation are always applicable for the products concerned. The surveillance arising from the particular technical legislation should be proportional to the risks. Industry believes that the basis for such surveillance should be customer complaints. Industry also expects that the authorities establish a philosophy (based on proportionality) regarding market surveillance related to each sector.
Product documentation (which can be of a company sensitive nature) supporting the SDoC will be given to the surveillance authorities where there is a justified reason to believe that a product is not in conformity with the relevant regulatory requirements.

NOTE: Industry today uses more and more sub-assemblies from other companies. What information might be needed in a legal situation cannot be predicted at the time the product is brought onto the market. Documentation is stored in different formats in different companies from case to case.

Conclusion

The proposed system with SDoC will enable suppliers to quickly get a market presence, resulting in lower prices which benefit the users.
The grey market cannot be reduced by placing further regulations on those who have been proven to meet all relevant regulatory requirements. On the contrary, a simple regulatory system will

reduce the commercial advantages that the grey market may have.
Regulatory authorities as well as test houses should only play the role of supporting users' and industry's needs in a safe, coherent and transparent environment.

Appendix 2

Alternative Compliance Mechanism other than the Mandatory Use of Accredited Laboratories

1 Introduction

Testing of a product is generally performed in order to gain information about its compliance with stated requirements. The manufacturer's product design specification includes requirements emanating from mandatory standards in different countries/regions as well as from customer requirements.

The regulatory requirements can be imposed either

- in the form of direct requirements in the applicable rules, or
- in the form of essential requirements in the applicable directives.. In this case suitable standards or specifications can be used to provide presumption of conformity with the directive.

Customer requirements are applied on a voluntary basis, however, from a business point of view meeting such requirements may be the difference between success and failure. The manufacturer therefore regards customer requirements as very important.

2 Issues related to legislation

2.1 The issue of confidence

A product shall be in conformance with all relevant regulatory rules and directives when placed on the market and used for its intended purpose. Authorities need a certain degree of confidence that this is the case for products on the market.

NOTE: The issue of confidence is also relevant in a supplier/customer relation; this, however, is in respect of performance aspects of the equipment.

Depending on the nature of the regulation, different measures can be taken to ensure that the confidence level is obtained. In order to reach the same confidence level one may have to use different measures due to the nature of the product (e.g. intervention by third party may be needed for the assessment of a high risk product, such as pharmaceuticals where there are health risks and explosive goods where hazardous situations may arise). Furthermore the measures can differ depending on the way the supplier has chosen to show compliance with the rule/directive. For example, in Europe proof of compliance with the EMC directive can be obtained either by application of relevant (identified) standards giving presumption of conformity with the essential requirements of the directive, or by examination of the product in direct relation to the essential requirements of the directive through the use of a "technical construction file". In the first case, the supplier does not involve any third party, but issues a Supplier's Declaration of Conformity (SDoC). In the second case a Competent Body is involved at certain stages, after which the

supplier issues the SDoC. In both cases the supplier assumes full responsibility for the product.

2.2 The issue of proportionality

The principle of proportionality should apply in deciding the most appropriate measures. The measures put in place should be appropriate to the desired objective.

NOTE: In Europe, proportionality is the guiding principle for all legal measures, to ensure that measures are appropriate for their purposes, and that the measures do not go beyond what is necessary to achieve the objectives. This is stated in the Treaty of Rome, Article 3b, last paragraph: "Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty".

When applying the proportionality principle it appears that the required level of confidence can be obtained through a simple SDoC for most rules and directives, without the need for mandatory third party involvement or accreditation of a manufacturer's own laboratory. In all cases, the SDoC places the responsibility for a product firmly with the manufacturer/supplier. Apart from rules/directives related to technical aspects, product liability legislation is also applicable (but only related to safety).
For some products where there are health or hazard risks, such as pharmaceuticals and explosive goods, a tighter system of proof of conformity may be applied to achieve the desired level of confidence.

2.3 Market surveillance

A market surveillance operation should be performed to make the SDoC trustworthy.
Horizontal measures such as consumer protection and liability aspects are always applicable for the products concerned. The surveillance arising from the particular technical legislation should be proportional to the risks, i.e., different "levels of surveillance" should be used as appropriate.
Product documentation (which can be of a company sensitive nature) supporting the SDoC will be given to the surveillance authorities where there is a justified reason to believe that a product is not in conformity with the relevant regulatory requirements.

NOTE: Industry today uses more and more sub-assemblies from other companies. What information might be needed in a legal situation cannot be predicted at the time the product is brought onto the market. Documentation is stored in different formats in different companies from case to case. It is in the interest of the industry to support administrations with the best information possible but only when there is a justified need.

3 Issues related to supplier/customer relation

In a supplier/customer relationship, compliance with voluntary standards is a matter of negotiation between the parties involved. In this case the issues of confidence and proportionality are also relevant. However, in these cases commercial aspects (price, delivery time, maintenance etc.) play an important role.
For commercial reasons, when dealing with particular customers, a manufacturer may involve a third party, or agree the accreditation of his testing facilities, or operate a quality system e.g. ISO 9000, as the case may be. In each of the cases the cost aspects affecting price and delivery

would be for discussion with these customers.

4 When is there a need for accreditation of laboratory facilities?

4.1 Functions implemented through software

The behaviour of products, and specifically Information Technology and Telecommunications products, is largely dependent upon the software which controls the product. For the testing of software, special instruments are used to determine the compliance of a product with certain standards. It is the test instrument rather than the test engineer that will determine whether the product passes or fails the test. Therefore, as long as the manufacturer uses validated test instruments for his tests, no added value is gained by using a similar instrument at a third party (accredited) laboratory.
It is the manufacturer who has the knowledge about the behaviour of the product, and it is he who prepares the product for testing. This includes the setting of software parameters, provision of suitable external stimuli etc. The manufacturer assumes responsibility for the proper setting of such parameters. Thus it is the manufacturer rather than the test house engineer that will determine whether the product is correctly stimulated and operated during the test.
In practice there is no increase in the confidence level by accreditation of testing facilities when verifying functions implemented through software. The SDoC provides for the necessary responsibilities involved.
One should also note the fact that nowadays the user can control many functions by using his own software which runs on top of the original software. Sometimes the user can control the lower layer functions by parameter settings (e.g., X.25) without any identified problems.

4.2 Functions implemented through hardware

The proper functioning of hardware is nowadays checked with intelligent test equipment, especially in the case of new technologies such as ISDN and digital mobile telephony. The product to be tested is simply connected to the test instrument in a manner agreed by the manufacturer and the test engineer. This is similar to the discussion in point 4.1, and results in the same conclusion.
For horizontal rules/directives such as EMC and safety, compliance standards and guidelines are quite often general to cover a broad range of products. The manufacturer has the detailed knowledge about the product which is needed to enable it to be assessed against the requirements. He may use internal technical expertise to perform the required product inspections and testing, or he may buy such expertise externally as discussed in point 5.
Therefore, for most products the desired confidence level is obtained by using a simple SDoC. This procedure should apply to all products save for high-risk products where there are health or hazardous risks.

NOTE: In Europe, this method has been in operation for safety aspects of electrical products since 1973, and for EMC aspects of non-radio transmitting products since 1989.

For some products, it is still necessary to require that the manufacturer operates a recognised quality system (normally ISO 9000), or to require him to use an accredited testing facility. The trend now is to move towards SDoC.
For high-risk products where there are health or hazardous risks (such as pharmaceuticals and

explosive goods) there is often a rationale for the involvement of an accredited third party for the assessment function in order to achieve the desired level of confidence.

5 Use of independent (accredited) laboratories in the voluntary field

The testing laboratories will probably see a change in the services requested by their customers (manufacturers and suppliers). Due to simplifications and harmonisation of legislative procedures regionally and globally, there will be a decline in the requests for "regulatory" testing.
However, certain areas (e.g., EMC and safety) require a very detailed technical knowledge, so much so that a manufacturer may find it more profitable to buy this knowledge from external experts. The experts may perform inspections of the products as well as some tests.
An independent laboratory with proven competence can sell its services to a manufacturer in various phases of a product's development cycle:

* as a competence centre during the development phase;
* as a verification centre for the final product check.

A manufacturer may wish that an independent laboratory is accredited for its task in order to give the manufacturer enough confidence of the skill of its personnel and its ability to separate "design support" activities from "final verification" activities. The manufacturer is still fully responsible to his customer for the activities related to testing and verification of the product.

6 Conclusions

Accreditation of laboratories is not the only solution for obtaining the desired confidence that products are in conformity with relevant rules/directives. In the spirit of proportionality it is time to place the responsibility for their products firmly on the manufacturers by use of a Supplier's Declaration of Conformity regime. Where needed, this is complemented by a surveillance performed by the authorities.
The increasing demand by customers that manufacturers operate quality assurance systems will ensure that manufacturers use skilled personnel and appropriate test facilities when performing tests.
Regarding high-risk products where there are health and hazardous risks (such as pharmaceuticals and explosive goods) there is probably a need for the involvement of an accredited third party for the assessment function.

Reference list

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APPENDIX 3

Industry proposal for a procedure to ensure interoperability between telecommunications (including radio) systems

1 Purpose and Scope

Although interoperability (i.e. that a specific product can be made to interwork effectively with another product implementing the same profiles of specifications) between products in many cases is ensured to a sufficient degree through normal market competition, there are cases where the players involved wish to further increase the users' acceptance by visibly indicating to users that interoperability is assured for their technologies or systems.

The purpose of this initial discussion paper is to propose a procedure, a Voluntary Verification System (VVS), to ensure interoperability between telecommunications (including radio) systems from different suppliers. It builds upon the full responsibility of the supplier for ensuring compliance to the relevant standard or specification. This is complemented by a mechanism (agreed by the organisations responsible for the system) to resolve interoperability problems between suppliers in case the parties themselves cannot resolve these.

The VVS does not cover issues related to regulatory requirements for the placing on the market and putting into service of the products concerned. It is presumed that the supplier meets all such requirements and conformity assessment procedures. See figure 1.

Figure 1

2 Suggested Voluntary Verification System

2.1 General concept

The regulatory conformity assessment systems are increasingly using the principle of Supplier's Declaration of Conformity (SDoC) without mandatory involvement of third party. The procedure used for showing compliance to the interoperability requirements should not create additional administrative burdens related to the conformity assessment.

Particularly for mass market products it is not reasonable to build up centralised administrative systems for managing information related to the interoperability verifications of single products. The benefit of such administrative systems can never be justified due to reasons of costs, time

delays and reliability of information. Instead information as defined by the organisations responsible for the VVS should be directly available from the suppliers, e.g. via the Internet as already is the case with the IT industry today. As a consequence the suppliers should be qualified instead of products by the organisations responsible for the VVS. In order to meet the qualification program many suppliers will most likely involve independent testing organisations for the technical verification.

It is proposed that the organisations responsible for the VVS in question set up a qualification program for the participating companies. The participation in the program will be regulated by a contractual agreement which state the procedures that must be carried through in order to gain approval of their products and to be allowed to use the brand name (where a brand name is associated with the specifications, e.g. Bluetooth). The agreement will also have to cover how the companies may loose their right to use the specifications and the product brand associated with the specification. These companies should then be trusted to verify and administrate the approval of their products.

2.2 Core standards and test specifications

This proposal assumes that there is always an organisation that owns the standards/specifications used as a basis for the VVS in question. This organisation is responsible for developing the standards/specifications and test suites, maintaining standards and test specifications, correcting errors and improving the clarity as the need arises. Distribution of standards is also handled by this organisation.

This organisation may also be the owner of a VVS as described in this paper.

2.2 Showing compliance with interoperability requirements

The method used to show compliance of a specific product type with interoperability requirements should be the Declaration of Conformity to the standard or specification, prepared by the supplier participating in the VVS. The supplier assumes full responsibility for the compliance with relevant standards or specifications, and decides how compliance is demonstrated, within the boundaries set by the organisations responsible for the VVS. Such freedom will allow for the use of a combination of own and external resources (for e.g. design and testing) in the development of products.

The organisations responsible for a VVS need to agree on relevant qualification program as a prerequisite for participation in the system. In formulating criteria for the program a number of aspects should be considered, such as

- what core standards and test standards are associated with the VVS;
- the use of specific test instruments or test software;
- the test suites that has to be performed in order to gain a compliance with the appropriate specification;
- the need to allow for launching of products before such test devices are available. A commonly used method is to perform practical interoperability tests between systems from different manufacturers (might be time-limited).

The market structure is undergoing rapid changes in the IT and telecommunications sector, and companies are restructuring as needed to stay competitive. The qualification program should not impose restrictions on how companies organise themselves.

2.3 Resolution of interoperability problems

Voluntary systems need a procedure to resolve problems, similar to the Market Surveillance function in the regulatory field. It will build upon agreement between the parties participating in the VVS.

The basis for judgement in case of interoperability problems should be the relevant Core Standard. The test part should match the core standard, not the other way around.

It can be presumed that in most cases of interoperability problems occurring in practice, the parties involved will solve them without delay and without the need of a formal procedure to resolve the dispute. This has shown to be the case for e.g. GSM, where pragmatic and cost optimised solutions have been found to solve the problems that have occurred. Still the contractual agreements on how to solve problems are applicable if the parties involved cannot agree.

In a dispute between a manufacturer and the organisations responsible for the VVS the manufacturer is required to show relevant information (test report, used test instrument etc) according to the agreed principles in the qualification program.

Where there is a need for dispute settlement, the matter should be presented to a "Management/Arbitration Team" (procedure **1** in figure 2).
The recognised owners of the specification or standard should choose members of the Team (preferably uneven number of delegates). The members should be acceptable to the parties involved in the dispute.

The Management/Arbitration Team should judge in the matter, consulting experts on the core standards as appropriate (procedures **2** and **3** in figure 2) and taking into account technical and economical aspects. It is of utmost importance that independence and confidentiality is maintained throughout the process.

The parties concerned (and the Management/Arbitration Team where it is involved) may find that there is a need to suggest clarifications to the core standard or test standard to avoid the issue from occurring again (dotted arrows in figure 2).

Figure 2

1 Conclusion

A Voluntary Verification System (VVS) is proposed, describing a procedure to ensure interoperability between telecommunications and radio systems from different suppliers. Elements of this proposal are:

1. Development, maintenance and distribution of standards and test specifications. The organisation responsible for the specifications may also be the one responsible for the VVS in question.

2. Issues related to VVS, to be handled by the organisation responsible for the VVS in question:
   - Identification of appropriate qualification program for suppliers wishing to participate in the VVS. Appropriate elements of the VVS should be defined by the organisation itself and should include aspects such as identification of specifications, mandatory test suites, use of specific test instruments or test software, etc;
   - Definition of a procedure to resolve interoperability problems occurring in practice;
   - Legal issues such as right to any brand name associated with the specification.

3. Use of Supplier's Declaration of Conformity without mandatory third party involvement to show compliance with the interoperability requirements as given in the specification.