



**Economic and Social
Council**

Distr.
GENERAL

ECE/TRADE/C/WP.6/2006/7
12 May 2006

ENGLISH ONLY

ECONOMIC COMMISSION FOR EUROPE

COMMITTEE ON TRADE

Working Party on Regulatory Cooperation and
Standardization Policies

Sixteenth session
Geneva, 19-21 June 2006
Item 7 (c) of the provisional agenda

REGULATORY COOPERATION/HARMONIZATION*
Sectoral projects

Proposal for a new regulatory cooperation activity:
“International legal requirements for explosion protection”

Submitted by Germany

This paper contains a proposal for a new sectoral initiative in the area of explosion protection. It is being submitted by Germany and also contains some clarifications made by the secretariat of the International Electrotechnical Commission (IEC) regarding IECx scheme. The project should be based on the UNECE Recommendation “L” (“International Model for Technical Harmonization”), similar to the Working Party’s current sectoral initiatives in the telecom, earth-moving machinery sectors and on safety of pipelines. See http://www.unece.org/trade/ctied/WP.6/major_doc.htm

* The present document has been submitted after the official documentation deadline by the Trade and Timber Division due to resource constraints.

GE.06-22807

1. General aspects, interest of industry

1. The national third-party certification of products which are specially designed and manufactured to avoid ignition hazards in the chemical and petroleum industry is legally required in many countries. National laws and regulations emphasize the mandatory approval of domestically recognized notified bodies. This situation makes it very difficult to open markets for free trade of explosion protected equipment which is, considering recent developments, against the interest of industry.

(a) Users

2. Users in the chemical and petroleum industry act more and more globally with a single engineering approach for their plants:

- (i) To earn savings in engineering, installation and maintenance costs;
- (ii) To buy the equipment in a larger quantity and to get a better price per piece
- (iii) To benefit from global competition between manufacturers.

3. Barriers against this tendency are domestic rules and regulations that require special engineering for the plants from country to country.

(b) Manufacturers

4. Manufacturers want to sell and manufacture their products without additional national certification if the prototype is tested once. In other fields of products (e.g. medical devices) mutual recognition agreements (MRAs) help to abolish such trade barriers by recognizing the specific national way “all in one” to allow market access for this kind of the products. For explosion protected electrical equipment, this “all in one recognition” needs a very long time without any guarantee of success. Numerous MRAs are necessary to cover the interesting markets in order to satisfy the interests of the manufacturers which require many resources to manage such a global system of MRAs.

(c) Industry (users and manufacturers)

5. Industry (users and manufacturers) complain about the present situation, which requires harmonizing national regulations.

- (i) Assuming the use of the relevant IEC standards as safety specifications (written down by the best recognized experts in the world in the field of technical requirements for explosion protected equipment),
- (ii) Supposing the influence of national legal authorities on the rules for globally harmonized legislation

6. In response to the practical day-to-day difficulties with multiple testing and certification, industry came together in 1996 to begin the development of a single Global Ex Certification Scheme, known as IECEx. Now 10 years on, IECEx is delivering all the necessary conformity assessment tools such as:

- (i) Single assessment process for evaluating competence and capability of Ex Testing and Certification bodies, that utilizes and works with National Accreditation systems, to prevent duplication;
- (ii) Detailed Operational Procedures and Manuals that ensure that all Ex Test and Certification bodies approach this highly specialized field in a Standard way;
- (iii) A centralized Management Structure enabling the balance of representation from manufacturer, user and regulators from each Member Country;
- (iv) A standardized set of Ex Test Reports and Audit Report forms;
- (v) A real-time secure "Internet Based" On-Line Certificate system enabling full Regulatory and industry viewing of Certificates, with unique numbering to identify the Certificate issuing body, for full traceability;
- (vi) All rules and procedures to comply with ISO/IEC Standards and Guide for a System No. 5 Certification Scheme;
- (vii) Inclusion of both Ex products and Ex Services (e.g. Repair and Overhaul) under IECEx;
- (viii) Introduction of an IECEx Mark is underway.

7. While providing industry with real and practical solutions, support from the International Regulatory Sector would further assist industry in ensuring standardized regulatory systems. Therefore it should be considered by WP.6 to step into the discussion for a global approach to keep control on the safety level in this industry area and to improve the conditions for global trade in these products.

(d) Regulators

8. Regulators face the difficulty of ensuring safety on complex sites and locations where Ex installations are used while at the same time not being seen as preventing operation of plant and equipment. Some of the main obstacles facing Regulators, when considering Ex equipment tested and approved from outside their country, are an understanding of:

- (i) Which Standard or Specification has been used
- (ii) The competence and thoroughness of the body conducting the assessment

(iii) The structure and framework of the approval system, e.g. does the approval system include technical assessments of the manufacturer's factory and to what level?

(iv) Traceability of the actual product back to the certificate

(vi) The status of the Certificate, i.e. current, suspended, cancelled

9. These very issues have seen Regulators from some European Countries as well as US, Japan, Australia and others participating directly in the management of the IECEx Scheme as delegates to the IECEx Management Committee or Experts on IECEx Working Groups or both. The single IECEx Certification process, detailed in the IECEx Operations Manual together with the single IECEx "OnLine" Certificate of Conformity have been acknowledged by Regulators as excellent tools to assist their Regulatory Compliance regimes. Regulators in some countries are already amending or preparing to amend their Regulations to include provision for the IECEx Scheme. While encouraging the International Ex, Industries would welcome a uniform approach by Regulators.

2. Existing legal requirements as a starting condition, lack of legal harmonization

10. The existing legal provisions to ensure the safety level in explosion protection consist of:

(a) Specifications and technical requirements for the products, their installation, maintenance and repair;

(b) The third party conformity assessment procedures (certification) with competent bodies which have been accredited or notified within the necessary scope;

(c) A legally traced back obligation of the manufacturers to take over full liability for their products after having placed them in the market.

11. Presently those legal systems are available e.g. in the USA (Code for Regulation-CFR) and the EU (ATEX Directive). More and more the legal frames recognize the IEC standards 60079-0 and its Parts. as the technical specifications to refer to. This is an important advantage compared with other industry areas where technical specifications are home-grown or dependent on the expertise of small expert groups. Lack of harmonization can be detected in the:

(a) Global acceptance of competent bodies by national authorities incl. the certification scheme;

(b) Harmonized structure of the legal framework for explosion protected equipment and its use in plants.

3. Terms of Reference for a group of experts (under WP.6) “International legal requirements for explosion protection”

12. An internationally recognized legal framework is to be developed which embraces as an ideal existing national regulations like the US-CFR and the EU-ATEX without the need of change, consisting of:

(a) An approval procedure for technical specifications, preferring IEC and ISO standards;

(b) An accreditation procedure with notified technical experts for certification bodies and laboratories under the rules of ILAC/IAF (ISO/IEC 17025:1999, ISO Guide 65) and with a final approval step done by the national legal authorities;

(c) A certification scheme with detailed rules controlled by the national legal authorities;

(d) A legally recognized Certificate of Conformity, a test report based on detailed evaluation records of the conformity assessment and a QA report based on a production audit on site (ISO Guide 28:2004, type 5 certification);

(e) An agreement between the legal authorities to ensure market surveillance and the pursuit of liability cases;

(f) In acknowledging regulatory input in the development of IECEx to date, a review of the appropriateness of the IECEx Scheme to meet the above needs and where appropriate recommend changes.

14. The Working Group shall consider the IECEx Scheme as an important structure element for the development of legal requirements.

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