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COMMITTEE FOR TRADE, INDUSTRY AND ENTERPRISE DEVELOPMENT

Working Party on Technical Harmonization and Standardization Policies
Thirteenth session (10-12 November 2003)

REPORT OF THE THIRTEENTH SESSION

International Seminar on Regional Experiences in Good Governance for Regulatory Practices
(with special reference to the Balkan countries)

Highlights

This document contains a summary of the discussions and the programme of the International Seminar on Regional Experiences in Good Governance for Regulatory Practices (with special reference to the Balkan countries) held in Geneva on 10 and 11 November 2003 in conjunction with the thirteenth session of the Working Party on Technical Harmonization and Standardization Policies (Working Party 6):

The report of the session is contained in document TRADE/WP.6/2003/16.

The report of the session and other related documents (including background papers and presentations made at the International Seminar) can be found on the Working Party’s website http://www.unece.org/trade/stdpol

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UNECE International Seminar on Regional Experiences in Good Governance for Regulatory Practices (with Special Reference to the Balkan Countries)

Documentation: TRADE/WP.6/2003/2, Adds 1 and 2; Background papers and presentations

1. The Seminar was opened by the Executive Secretary of the UNECE, Ms. Brigita Schmögnerová. She stressed the importance to member States of regulatory-related technical obstacles to international trade and congratulated the Working Party on its initiative of embarking on this essential but complicated area for both Governments and business.

2. The Executive Secretary expressed her appreciation to the Swedish International Development Cooperation Agency (SIDA) for the financial assistance given to support the participation of Balkan delegates in the Seminar.

3. The Secretary General of the International Organization for Standardization (ISO), Mr. A. Bryden, said that the globalization of trade put emphasis on the issue of international standards and their use in trade. Other issues were the relation between voluntary standards and mandatory requirements, the challenge of new technologies and the necessity in certain cases to regulate them. He believed that the discussions at the current Seminar could contribute to strengthening the dialogue on regulatory matters.

4. As background material for the Seminar, participants had the provisional programme (TRADE/WP.6/2003/2), and written submissions (TRADE/WP.6/2003/2/Adds. 1 and 2) as well as presentations on national and regional regulatory approaches and experiences. These documents and presentations are available on the website.

5. The first session was dedicated to presentations on regional experiences or approaches in different parts of Europe, Asia and North America.

6. It was the view of the European Union (EU) that previous efforts to harmonize safety requirements in major product areas had met with little success. This was why the EU had adopted the “New Approach”, whereby legislative harmonization was confined to essential requirements, with the detailed technical requirements laid down in harmonized European standards.

7. The representative of the EU provided information on the substance of the “New Approach” directives, including the principles of work of the European standards bodies and the role of European standards. He also discussed eight basic conformity assessment modules, the role and work of notified bodies, the CE marking, conditions of the use of suppliers’ declaration of conformity and the organization of market surveillance.

8. The paper from the United States National Institute of Standards and Technology (document TRADE/WP.6/2003/2/Add.1) provided an overview of the legislative process in that country, including the roles of Congress and federal agencies, and a number of legal acts, rule-making requirements for agencies, interagency cooperation, and issues of public access to information and the use of voluntary standards drawn up by the private sector.
9. Some participants saw as a potential basis for good regulatory practices in countries in transition those United States acts that provided for greater accessibility and participation by the general public in the rulemaking process (the Administrative Procedures Act) and requirements for an economic analysis of federal regulations (under Executive Order 12866).

10. A representative from a United States transnational engineering company spoke on how that company successfully coped with different regulatory regimes and approaches in the United States and the EU when similar legitimate government objectives were met through different regulatory tools and means.

11. A representative of the CIS Inter-State Council on Standardization, Certification and Metrology outlined the activities of this grouping in standards, technical regulations, certification and accreditation. He presented the draft CIS agreement on harmonization of technical regulations (text contained in TRADE/WP.6/2003/2), which had been prepared on the basis of the UNECE Recommendation L.

12. The agreement, which is expected to be signed in 2004, would be used as a framework for technical regulations to be jointly drafted by CIS States. Following approval it would be transposed into national legislation in each of the 12 member States.

13. A programme for 2004-2007 was already being implemented for drawing up inter-State models of technical regulations (foreseeing over 50 such models). These future inter-State technical regulations would make use of existing CIS standards and those under preparation.

14. A representative of the Asia-Pacific Economic Cooperation (APEC) introduced the activities of 21 of its member countries under the Sub-committee on Standards and Conformance (SCSC). The Sub-committee dealt mainly with promoting: alignment with international standards; mutual recognition agreements in regulated and industry sectors; and good regulatory practice. In the alignment of national standards with international standards, four priority areas had been agreed in 1996: electrical and electronic appliances, food labelling, rubber products, and machinery. Among the new priority areas were: electrical safety, electro-magnetic compatibility, ISO 9000/1400 and ISO/IEC guides.

15. Mutual recognition agreements had been promoted in the following regulated areas: exchange of information on toy safety and on food recalls; conformity assessment on foods and food products; and electrical and electronic equipment.

16. Since 1998, the issue of good regulatory practice (GRP) had been discussed and, in 2000, countries had agreed on principles and guidelines.

17. As an example of the regulatory activities in the region covered by the Association of South East Asian Nations (ASEAN), participants were provided with the text of the agreement on the ASEAN harmonized cosmetic regulatory scheme (document TRADE/WP.6/2003/2/Add.2), which in September 2003 had been signed by 10 countries. The scheme had two basic elements: a mutual recognition arrangement for product registration approvals for certain products and an ASEAN Cosmetic Directive (which covered requirements relating to labelling, product registration, imports/exports, etc.).
18. The representative of the Organisation for Economic Co-operation and Development (OECD) pointed out that good regulatory practices enhanced market openness and reinforced domestic economic performance. She highlighted six principles of efficient regulation in detail: transparency, non-discrimination, avoidance of unnecessary trade restrictiveness, use of internationally harmonized measures, streamlining conformity assessment procedures, and respect for competition principles.

19. The Working Party’s Chairman, Mr. Arvius, presented UNECE regulatory approaches. He outlined the main provisions and mechanisms of the “International Model”, the history of its preparation, its potential use by countries, and pilot regulatory convergence projects initiated by the Working Party on sectoral (“Telecom Industry” project) and regional levels (CIS).

20. During discussions, a number of questions were raised relating to the Technical Barriers to Trade Agreement of the World Trade Organization, its provisions, the obligations of Governments and the role of the private sector.

21. The issue was also raised of how to protect companies from alleged mistakes made at a political level (UN-balanced decisions on regulatory matters). Participants said that they had found it useful to learn how, for example, regulators in the EU and the United States included industry in consultations on projects for new technical regulations.

22. The second session was devoted to regulatory developments in the Balkan region, and presentations were made by a number of countries. The first was devoted to the challenges faced by Slovenia as an EU candidate country. In this presentation, the necessity for accession work to be well organized was stressed. The issues of transposition and harmonization ought to be treated at three different levels: government, ministerial and expert. At the government level, political commitment should be declared, priorities agreed and the necessary resources allocated. At the ministerial level all stakeholders should be involved, awareness campaigns organized, and a pool of experts created. The roles of the various bodies involved should be clearly differentiated: ministries, market surveillance bodies, and enforcement agencies as well as the interests of conformity assessment bodies, of industry, trade and of consumers.

23. The practical work should be organized in working groups of experts, with contributions from industry (e.g. through chambers of commerce), involving the views of different stakeholders, with a view to explaining the benefits to industry and other users and to solving all outstanding issues, including conflicts of interest. The result of such organization on the political and operational level was the successful harmonization of a regulatory regime with EU requirements without transitional periods.

24. The systems of voluntary standardization of accreditation and of metrology in Bosnia and Herzegovina at the State level had been initiated in November 2000 when a number of related laws were adopted. New organizational changes under way foresaw the separation of the Institute for Standardization, Metrology and Intellectual Properties into three independent agencies.

25. No clear State competence existed in the sphere of technical regulations and no State ministries for economy, science, industry, health or agriculture existed to bear the regulatory responsibilities for the new law on technical requirements for products and conformity assessment which would be adopted in the first quarter of 2004. This law would encourage the acceptance of the EU model in technical legislation and, at the same time, define the distribution of competencies between the State and the other entities. Information was also provided on the national transposition of ISO, IEC and European standards.
26. Bulgaria’s legal and organizational regulatory framework had changed significantly during the 1990s. In the regulatory area the main agency currently was the Ministry of Economy and its executive arm, the State Agency for Metrology and Technical Surveillance. Other ministries involved in the regulatory process are those of health, transport and communications, regional development and public works, labour and social policies.

27. Negotiations for signing the Protocol on European Conformity Assessment (PECA) with the EU had started and a fact-finding meeting had taken place in 2002. The sectors to be covered initially were: safety of machinery, lifts, gas appliances, toys, EMC (electro-magnetic compatibility) and electrical safety.


29. The Bulgarian Accreditation Service has been a full member of the European Co-operation for Accreditation (EA) since 2001. Information was also provided on the status of implementation of EU directives, the number of designated bodies, and the number of accredited laboratories and conformity assessment bodies. All European harmonized standards had already been transposed; the ratio for other European standards, in general, was 62 per cent.

30. In the Republic of Moldova technical regulations were developed within the framework of the Law on technical barriers to trade (which introduces a concept of “technical regulation”) and the Law on standardization (establishing the period for transition to voluntary standardization). The Government decision regarding transition to voluntary standardization designated central authorities to decide on technical regulations in specific areas.

31. The institutional structure in the field of technical regulation comprised ministries (responsible for the development of technical regulations on specific groups of products) and the Department of Standardization and Metrology (governmental body), which coordinated the activities related to technical regulation development on the national and international levels.

32. The country had several technical regulations: for example, the Law on wines and winery, the Law on nuts, the Law on tobacco and tobacco products, the Rules on labelling, the Law on foodstuff (in drafting stage). The Law on wines and winery had been drawn up as a specific model but contains some elements from the classical model (essential requirements, classification, requirements regarding placing goals on the market). Since this Law began to be implemented, the volume of wine exports had increased and there had also been an improvement in the quality.

33. A new Law on the conformity assessment of products was to enter into force in January 2004 to replace the old Law on certification.

34. A representative of Romania provided information on their legal framework (laws) for activities in the areas of standardization, conformity assessment, metrology, accreditation and other activities in relevant laws, as well as on the work of relevant agencies (national accreditation body - RENAR, national authority for consumer protection - ANPC).
35. The governmental institutional structure involved in regulatory activities was outlined with particular emphasis on the work of the Ministry of Economy and Trade, the main body responsible for the country’s regulatory framework.

36. Romanian national standards bodies were full members of ISO and IEC, and affiliate members of CEN, CENELEC and ETSI. In order to become full members of European standards bodies, the national strategy had set itself the task of adopting by the end of 2003 all harmonized European standards and 80 per cent of the remaining European standards. At present, Romania has already adopted about 80 per cent of CEN standards, 57 per cent of CENELEC and 59 per cent of ETSI standards.

37. A representative of Serbia and Montenegro presented the legal framework for regulatory activities, organizational changes in the main ministries and agencies dealing with standardization, regulatory and conformity assessment activities, and the main tasks faced by the Government in these areas.

38. A representative of the OECD presented that organization’s experience of working in the Balkan region; in particular, the results of a study on how government restrictions that were applied to different sectors in those countries influenced prices as well as other economic indicators of national and foreign companies operating on these markets.

39. The study had analysed the types of restrictions that existed (e.g. on barriers to trade; on setting up businesses; special rules, if any, for foreign companies; general restrictions for all suppliers; and discriminatory practices for particular businesses whether domestic or foreign). The study had then calculated the possible role/weight of these restrictions, had drawn up a “trade restrictiveness index” and tried to assess the effect of the restrictions on the performance of a number of sectors.

40. The research attempted to measure the negative role of such restrictions in terms of cost increases in services, quantity impacts and the tax equivalent on investment. The study showed, for example, that the tax equivalent of market access and national treatment regimes in banking varied in the different Balkan countries from 3 to 23 per cent. The findings of the study in the telecom area claimed that for fixed phones lifting the restrictions could lower prices by 20 to 30 per cent, and for mobile phones services by 10 to 20 per cent.

41. In general, the results of the study showed the importance of regulatory regimes and how they can affect business development and investment.

42. As an outcome of the International Seminar, the Working Party agreed on the necessity of continuing the dialogue and exchange of information on regulatory approaches. The objective was to improve mutual understanding and confidence building between regulatory authorities; and to encourage and call upon regulators to, whenever possible, implement the least trade restrictive means of meeting legitimate objectives.

43. The Working Party also noted the usefulness of having an overview of regulatory approaches not only in the UNECE region (in particular in the EU, North America and the CIS) but in other regions as well.

44. In commending this initiative, the Working Party asked the secretariat to compile and publish the presentations and submissions made at the Seminar.
45. With regard to the special funding provided to the UNECE for the participation of Balkan countries in this seminar and follow-up activities in that region, the Working Party thanked the Swedish International Development Cooperation Agency (SIDA) and confirmed its desire to provide technical assistance to the Balkan States\(^1\) to enhance their understanding and use of good regulatory practice in accordance with the regulatory techniques laid out in the “International Model”. It was agreed that the Bureau of the Working Party, the secretariat and a network of appointed representatives from the Balkan States should further define the needs and priorities for this project and thereby pay due attention to other technical assistance programmes in the region and the implementation of the technical barriers to trade chapters in the bilateral free trade agreements that had been concluded between Balkan States.

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\(^1\) Bosnia and Herzegovina, Serbia and Montenegro, the former Yugoslav Republic of Macedonia, Albania, Croatia and the Republic of Moldova, as well as Bulgaria and Romania in an observer capacity.
Annex

UNECE INTERNATIONAL SEMINAR ON REGIONAL EXPERIENCES IN GOOD GOVERNANCE FOR REGULATORY PRACTICES
(with special reference to the Balkan countries)

PROGRAMME

Opening session
Welcome remarks from the UNECE Executive Secretary, Mrs. B. Schmögnerová
Introductory comments from the ISO Secretary General, Mr. A. Bryden

Session I International and regional good regulatory practices
1. Regulatory model of the European Union
   Presentation from the European Commission (Mr. N. Anselmann)
2. Regulatory approaches in North America
   Presentation of a paper from the US National Institute of Standards and Technology
3. Regulatory activities between APEC (Asia-Pacific Economic Cooperation) countries
   Presentation from APEC (Mr. K. Noda, JETRO)
4. Regulatory experiences in the ASEAN region (Association of Southeast Asian Nations)
   Presentation of a paper on the ASEAN Harmonized Cosmetic Regulatory Scheme
5. OECD work on regulatory reform and market openness
   Presentation from the OECD, Division of Trade Liberalization and Review, Trade Directorate
   (Ms. M. Moise)
6. Regulatory cooperation in the CIS region
   Presentation from the CIS (Mr. V. Koreshkov, on behalf of the CIS Interstate Council on
   Standardization, Certification and Metrology)
7. UNECE “International Model for Technical Harmonization”
   Presentation from WP.6 (Mr. C. Arvius, WP.6 Chairman)

Discussions

Session II Balkan experiences with regulatory convergence
1. Experience of a candidate country in adapting to the EU framework
   Presentation from Slovenia (Mr. S. Presern, Ministry of Economy)
2. **Regulatory approaches and challenges in other Balkan countries**
   Presentations from:
   - Bosnia and Herzegovina, Ministry of Foreign Trade and Economic Relations (Mr. Z. Bilbija)
   - Bulgaria, State Agency for Metrology and Technical Surveillance (Ms. V. Panayotova)
   - Moldova, Department of Standardization and Metrology (Ms. M. Bizgu)
   - Romania, Ministry of Economy and Trade (Ms. A. Sandru)
   - Serbia and Montenegro, Federal Ministry of International Economic Relations (Ms. A. Blagojevic)

**Balkan experiences with regulatory convergence**
Presentation from the OECD Division of Trade Liberalization and Review, Trade Directorate (Ms. N. Dihel)

**Discussions**

**Session III  Concluding session: lessons for UNECE Governments and possible follow-up in the Balkans**

1. Identification of needs and related capacity building in the region
2. Identification of sectoral needs
3. Prioritization of regulatory needs in the Balkan region.

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