United Nations ECE/TRADE/C/WP.6/2013/4

Economic and Social Council

Distr.: General
9 September 2013

Original: English

Economic Commission for Europe

Committee on Trade

Working Party on Regulatory Cooperation and Standardization Policies

Twenty-third session
Geneva, 18 (pm) - 20 November 2013
Item 5 of the provisional agenda
International Conference on "Standards and Regulations"

Background paper for the discussion on Recommendation D on "Reference to Standards"

Summary

The present note was prepared by the secretariat, following a request by the Bureau, to facilitate the discussion on Recommendation D "Reference to Standards" at the twenty-third session of the Working Party and at the International Conference on "Standards and Regulatory Frameworks".

It is hereby submitted to generate debate, and to highlight potential issues for discussion. Delegations may wish to raise – in writing prior to the session or orally at the session itself – their own positions on the revision of this recommendation and supporting arguments. The secretariat will facilitate the distribution of all information it receives.

I. The current context of Recommendation D

1. Recommendation D was adopted in 1974, last revised in 1995. The context has significantly changed since then.

(a) The relevance and benefits of the method of "reference to standards" are internationally recognised, both within the ECE region and internationally;

(b) Standards are used in support of legislation by the competent authorities in the majority of ECE Governments as well as internationally;

(c) An important development, within the ECE region, since the last revision of Recommendation D, was the Communication to the Council and the European Parliament "on the role of European standardisation in the framework of European policies and legislation" of 2004 (COM(2004) 674 final). The Communication states that:

i) Standardisation is an integral part of the Council's and the Commission's policies to carry out "better regulation"

ii) European standardization, in support of New Approach legislation has proven to be a successful an essential tool for the completion of the Single Market for goods.

iii) The "New Approach" has proven to be a specific model of legislation by which both the public interest (i.e. protecting public health and safety, consumer and environmental protection) and the interest of private business to produce standards according to the relevant "state of the art", could be merged in an adequate way. It allows for more flexible and less stringent forms of legislation in areas where, otherwise, any detail would have to be determined by the legislative act itself.

iv) The extension of making use of standards in areas of Community legislation beyond the Single Market is highly desirable, taking of course into account the specificities of the ares concerned, in accordance with the Commission proposals on governance and better regulation.

2. These statements and recommendations were confirmed by the Council of the EU in its Conclusions on the role of European standardization of December 2004 (14790/204 Rev 2).

3. In its Conclusions on the role of standardization in the framework of European policies and legislation of March 2002, the Council of the EU invited the Commission and the Member States to continue **the promotion of standards-receptive regulatory models**, such as those developed by the UN/ECE, with the Community trading partners, in order to promote international cooperation and facilitate market access. This invitation is recalled in the Council's Conclusion on the same subject of December 2004.

4. In its Circular A-119 0f 1998 on "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" the Office of Management and Budget of the United States of America provides a detailed description of why, when and how US regulatory agencies should make use of voluntary consensus standards in support of their regulatory activity. http://www.whitehouse.gov/omb/circulars_a119

5. Several useful **guides** have been prepared and published on the use of standards in support of legislation, including

(a) European Commission, Enterprise Guides: Methods of referencing standards in legislation with an emphasis on European legislation, 2002

(b) Standards Council of Canada: NSS Guide "Key considerations in the development and use of standards in legislative instruments", December 2006

(c) ISO/IEC: Using and referencing international standards for technical regulations, September 2007

As a subject, "referencing standards in legislation" is increasingly perceived as an element of "Good Regulatory Practice (GRP)" or "Better Regulation" exercises. The START Team which developed the "International Model for Technical Harmonisation" too, placed the

model in a GRP context, as early as 2001. Of course, the International Model relies heavily on the mechanism of reference to standards:

In parallel to the preparation of CROs, countries should explore the existence of relevant international standards to be considered for reference in formulating CROs. In case no relevant standards exist, countries may consult with relevant international standardizing bodies (ISBs), through their official representatives, regarding the initiation of new standards work to support specific CRO provisions. It is assumed that countries collaborating on a CRO would support related standards development activities, within the limits of their available resources. It is also expected that they would refrain from activities that would conflict with or jeopardize this standardization work in preparation. When the relevant international standards are available from international standardizing bodies they should be referred to in the CRO and the conditions for their use specified.

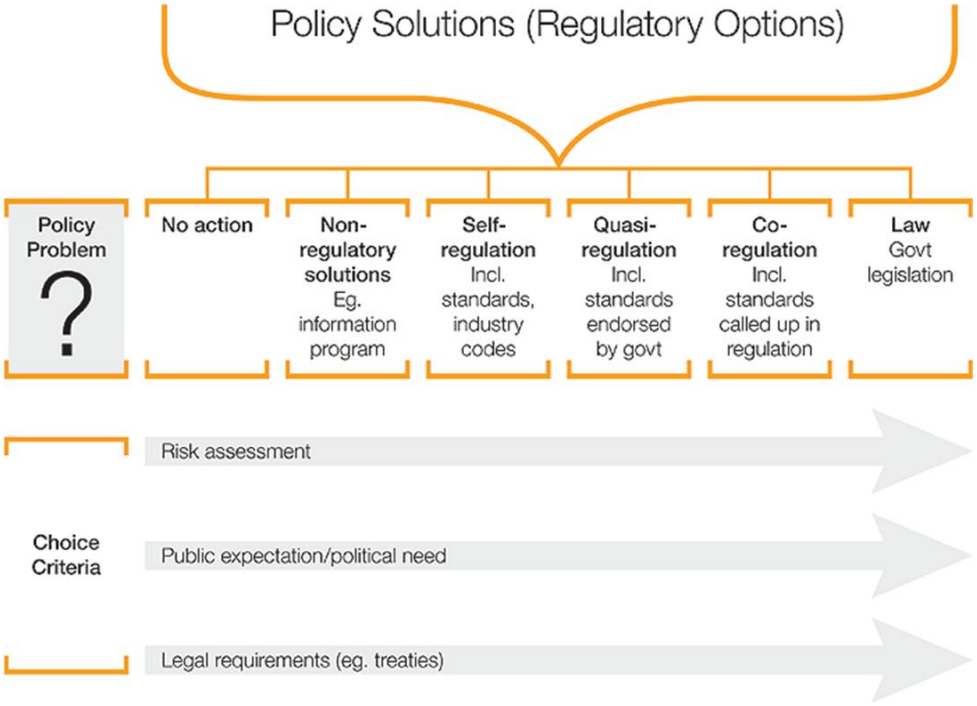
(UNECE Recommendation L)

6. In its Communication on "Implementing the Community Lisbon programme: A strategy for the simplification of the regulatory environment", the European Commission stresses that

Co-regulation *can in certain cases be a more cost efficient and expedient method for addressing certain policy objectives than the classical legislative tools. Standardisation by independent bodies is an example of a well recognised 'co-regulation' instrument. It is actively supported by the Commission as an alternative or complement to legislation".*

7. As a result, the Commission announces that it "will promote a simpler legislative method and will increase its support for standardisation that has proved its worth in the context of the free movement of goods."

8. The following diagram, found on the website of Standards Australia, may serve to illustrate some of the roles standards can play in a policy making context, as a contribution towards better regulation:



II. Additional remarks

9. Although the general method of reference to standards seems to be widely known and accepted, this does not apply in an equal manner to the different techniques for referencing standards, or formulated more broadly, for using standards in support of legislation. All too often, governments and their regulatory authorities only take into consideration the options of either **incorporation** (of the text of the standard into the text of the regulation) or **exclusive reference**. In both cases, the standard becomes part of the legislation and, as such, compulsory. Furthermore, it is rather common for Governments, as in the case of the USA, to oblige their regulatory agencies, when referencing standards in regulations, to only make use of the **dated** (exclusive) reference. Depending on individual practice, this dated reference may even exclude future amendments (after review) of the referenced standard, thus rendering void several of the typical advantages of the reference method.

10. The Federal Law of the Russian Federation "On Technical Regulation", stipulates that "international standards and (or) national standards may be used in full or in part as a basis for development of draft technical regulations". In general practice this means that standards or parts of them are either incorporated into the text of the regulation or referenced in an exclusive manner.

11. The widespread use of the most restrictive method of reference to standards, which transforms voluntary standards into law, has triggered much debate and a number of court cases especially in the USA. The cases focused on issues of payment for, access to and copyright protection of documents that were developed as "voluntary consensus standards" and ended up as "the law". For Standards Developing Organisations (SDOs) the threat from this debate and the ensuing court cases concerned their fundamental business and funding models, which heavily rely on the sales of standards, including standards that are referenced in legislation. If the courts had ruled that exclusively referenced standards are "law", and shall therefore be made available free of charge, this would have dramatically affected the majority of SDOs in the USA and elsewhere. However, most court rulings stated that

- everyone should have the right to access standards referenced in legislation and be able to review them, at a minimum, at government facilities and libraries on a read-only basis AND
- Copyright protection must still be afforded to standards developers for their original works of authorship.

12. As a result of these court rulings, selected referenced standards in the USA are now electronically available for free viewing. The final word however, has definitely not been spoken yet, and whenever standards are rendered compulsory by reference, it is likely that the pressure on regulatory authorities and SDOs to make these standards available without limitations and free of charge will remain or even increase.

13. A potential remedy against this pressure (which may eventually affect the discipline of standardization as such, with the call for free standards spreading even to those voluntary consensus standards that are not referenced in legislation) would be the **indicative reference** to standards. The indicative reference to standards, which allows standards to retain their voluntary status, is an indispensable element of the New Approach and, as such, has significantly contributed to the success of this approach and its reputation, even beyond the borders of the EU. Nevertheless, the actual application of the indicative reference has remained very much a European specialty. One reason for this may perhaps be found in the following chain of arguments:

- The indicative reference to standards is closely linked to the EU's New Approach

- The New Approach relies on the supplier's declaration of conformity (SDoC) as a conformity assessment option deemed adequate for many commodities that are traded in huge quantities
- SDoC requires highly effective market surveillance structures and operations to ensure a high level of product safety
- The necessary investment in market surveillance must for the largest part be made by government as market surveillance is foremost a state responsibility.

14. The conclusion that many countries seem to draw from this is that the application of the indicative reference to standards requires serious investment in infrastructure and human resources for market surveillance that are not deemed feasible under their current economic circumstances.

15. Without expanding on the exact nature of the relationship between market surveillance and the mechanism of reference to standards, it can be confirmed that the establishment of effective market surveillance is a challenge, especially – but not only – for developing countries and newly industrializing economies. Most of the minimum conditions that have to be met indeed require substantial investment, e.g. in the mobilisation and continuous qualification of market inspectors from the state budget. And where investment by private sector parties, for instance in testing facilities, may be an adequate response, there is little guarantee that there will be a satisfactory return on this investment due to insufficient testing demand. Other conditions for effective market monitoring and enforcement of the relevant legislation may require substantial changes to the overall setup of large parts of the quality infrastructure:

- How can we ensure that market surveillance is carried out by a fully independent state body that is free from conflicts of interest?
- Is market surveillance sufficiently and clearly distinct from third party pre-market conformity assessment?
- How do we provide adequate access to independent testing facilities in priority sectors?
- How can we avoid conflicts of interest for bodies involved in both conformity assessment and market surveillance?

16. In summary, the thesis put forward here is that the more attention can be given to effective market surveillance – in addition to third party pre-market conformity assessment – the better the chances for the successful application of the indicative reference to standards.

III. Selected literature

(a) ANSI: "Why Voluntary Consensus Standards Incorporated by Reference into Federal Government Regulations Are Copyright Protected", undated, ANSI website

(b) European Commission, Enterprise Guides: "Methods of referencing standards in legislation with an emphasis on European legislation", 2002

(c) European Commission: "Communication to the European Parliament and the Council on the role of European standardisation in the framework of European policies and legislation" COM(2004) 674 final

(d) ISO/IEC: Using and referencing international standards for technical regulations, September 2007

(e) Office of Management and Budget: Circular A-119 “Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”, 1998

(f) Russian Federation, Federal Law No. 184-ФЗ, dated 27.12.2002"On Technical Regulating“(http://www.gost.ru/wps/portal/pages.en.Activity?WCM_GLOBAL_CONTEXT=gost/GOST/Activity/Standardization)

(g) Standards Council of Canada: NSS Guide “Key considerations in the development and use of standards in legislative instruments”, December 2006

(h) WTO Committee on Technical Barriers to Trade: “Compilation of Sources on Good Regulatory Practice”, G/TBT/W/341, 13 September 2011