



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on
Regulatory Cooperation and
Standardization Policies

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A.

Further Developments in International Cooperation on Technical Harmonization and Standardization Policies

The Working Party on Technical Harmonization and Standardization Policies,

Noting the special importance of international standardization at the present stage in the development of commercial, economic, scientific and technical cooperation between countries;

Expressing satisfaction with the role accorded to international standardization in the Final Act of the Conference on Security and Cooperation in Europe and at follow-up CSCE Conferences;

Underlining the importance of coordinated standardization and conformity assessment activities in order to further the objectives of the World Trade Organization's Agreement on Technical Barriers to Trade;

Recognizing the importance of the part played by the United Nations Economic Commission for Europe in the coordination of work on the preparation of international standards and on the implementation and application of international conformity assessment procedures and arrangements, and in the encouragement of the work of the competent international standardizing bodies;

Considers it desirable that:

- A.1** United Nations Economic Commission for Europe Governments activate the work on the further development of international cooperation on technical harmonization and standardization policies, in the light of the Agreement on Technical Barriers to Trade of the World Trade Organization and the provisions concerning standardization and certification of the Final Act of the Conference on Security and Cooperation in Europe.



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B. ■ Coordination of Technical Regulations and Standardization¹

The Working Party on Technical Harmonization and Standardization Policies,

Considering that the marked increase in the number of agreements on standards reached internationally and the considerable number of organizations involved in technical regulations and standardization activities suggest a need for coordination which in some cases, especially in respect of intergovernmental organizations, may be acute;

Noting that the purpose of the present recommendations is not to create any additional coordination mechanism but rather to draw the attention of all those concerned with these matters to problems which can arise from insufficient coordination of international or regional technical regulations and standardization activities or from the lack of such coordination, and to define specific measurements to attain more effective coordination;

Noting further that the mere fact that certain problems relating to the lack of satisfactory coordination have been raised and discussed in the Working Party or by experts nominated by it, draws attention to those problems and promotes their solution;

Bearing in mind the objectives of coordination of technical regulations and standardization activities conducted internationally, which should be carried out in order:

- (a) to ensure that international and regional standards take into account the interests of all concerned;

¹ Recommendation adopted in 1970, revised in 1988 and 1996.

- (b) to promote the implementation of relevant international basic standards;
- (c) to attain a uniform use of terms;
- (d) to achieve compatibility with other relevant international standards adopted or in course of preparation;
- (e) to prevent further divergence between national standards and technical regulations resulting from a lack of internationally or regionally agreed standards in areas where they are needed;

Affirming that to this end coordination of all technical regulations and standardization activities conducted internationally should aim at:

- (a) avoiding the creation of technical barriers to trade in accordance with the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) including its "Code of Good Practice on the Preparation, Adoption and Application of Standards";
- (b) concentrating activity, wherever possible, in a given sector or sphere of policy in a single international or regional organization and determining, whenever necessary, concordant target dates so that delays in the completion of one organization's work on a given matter do not affect the work already accomplished by another organization on different aspects of the same matter;
- (c) establishing close contacts between organizations dealing with different aspects of the same product or service or, in cases of acknowledged need, with the same aspect of that product or service;
- (d) facilitating the implementation of international and regional standards by unifying their presentation as a whole or in respect of some elements such as title, index number and year of publication;

Has agreed to recommend the following means to promote cooperation:

At the national level

- B.1** ECE Governments should give consideration to the possibility of extending the practice of designating a single agency or official to be responsible for coordinating governmental technical harmonization and standardization policies. The coordination at the national level of standardization work in international, regional, governmental and non-governmental organizations is of primary importance and should be achieved.

- B.2** ECE Governments are invited to make the necessary arrangements for effective implementation of the work programme embodied in the "ECE Standardization List", a list of sectors which are of interest to UNECE member Governments with a view to providing regular guidance for a programme of work for international standardization and published and kept up to date by the Working Party.
- B.3** ECE Governments should ensure that their representatives at meetings of international or regional organizations are briefed about the advantages to be obtained by implementing the principles enumerated below (B.8.1-4). In pursuance of coordination at the national level, it is also desirable that a participant follows a specific project from the beginning to the end, and for a country to be represented, whenever possible, by the same expert in two or more organizations dealing with related matters.
- B.4** ECE Governments should, in formulating and applying their policies for public purchasing, whenever possible and when permitted by national legislation and legislative processes, make the fullest use of internationally or regionally recommended standards or of national standards based on such standards.
- B.5** ECE Governments should ensure that information on national standards, technical regulations, certification systems and conformity assessment procedures adopted or proposed within their territories be available at an authorized enquiry point, an agency or an office.
- B.6** ECE Governments should ensure that standards organizations act in accordance with the WTO/TBT "Code of Good Practice on the Preparation, Adoption and Application of Standards".
- B.7** ECE Governments should ensure that, at the request of other countries, technical assistance in the field of technical regulations and standardization activities is provided.

At the international level

- B.8** ECE Governments are invited to ensure, to the extent possible, that the following principles are observed when international standardizing activities are initiated or pursued:
- B.8.1** Before an international or regional organization starts standardization work in a particular field, information should be sought at the outset on relevant international or regional standards already adopted, and on any such work under way or suspended, in order to diminish the risk of duplication of work.

- B.8.2** Whenever feasible and unless there are persuasive reasons to the contrary, the work on new standards should normally be initiated through the competent international standards organization. In cases, where there are clearly defined regional needs which are unlikely to be met by the corresponding international organization, a new standardization project could be carried out by the relevant regional organization. In this case it would be advantageous that the international and regional organizations concerned jointly agree on the concrete provisions to apply for the implementation of this principle.
- B.8.3** When work on a specific standard or standards is undertaken by an international or regional organization, close contacts with relevant organizations should also be established or maintained. In this respect, methods already adopted by the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC) are recommended for use by other organizations. These methods include:
- B.8.3.1** inter-secretariat meetings;
 - B.8.3.2** supply of documents from one organization on a selective basis;
 - B.8.3.3** exchange of documents for mutual information;
 - B.8.3.4** attendance from time to time of an observer at a meeting to deal with non-recurrent questions;²
 - B.8.3.5** regular attendance of an observer at meetings of both organizations;
 - B.8.3.6** case B.8.3.5, but always in one direction only;
 - B.8.3.7** convening of coordination meetings on an ad hoc basis;
 - B.8.3.8** a standing coordinating (or steering) committee.
- B.8.4** In order to facilitate their implementation, international and regional standards should be aligned as far as possible to the common layout normally used by the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC), particularly with regard to titles of standards, their index numbers and years of publication.

² Always accompanied by exchange of documents on a regular basis.



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C

International Harmonization of Standards and Technical Regulations³

The Working Party on Technical Harmonization and Standardization Policies,

Noting that the recommendation, which follows, represents a direct contribution by UNECE to the implementation of the relevant provisions of the Final Act of the Conference on Security and Cooperation in Europe;

Recognizing that the harmonization of standards and technical regulations is an important factor in the development of international trade and industrial, scientific and technical cooperation;

Noting that differences in standards and technical regulations applied to international trade in some cases give rise to technical barriers;

Considering that complete and effective harmonization of standards and technical regulations is possible only if carried out in a purpose-oriented manner at the international, regional and national levels;

Seeking to further the objectives of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade;

Considering that the harmonization of standards and technical regulations should be directed towards:

³ Recommendation adopted in 1970, revised in 1980 and 1995.

- (a) expanding the mutually-advantageous exchange of goods and services and facilitating the conclusions of mutual recognition agreements;
- (b) developing and deepening industrial cooperation;
- (c) jointly solving technological and scientific problems;
- (d) improving and assuring product quality;
- (e) reducing the consumption of materials and energy resources;
- (f) improving labour protection, health protection and safety;
- (g) improving environmental protection;

Considering that the recommendation applies particularly to international and regional standards relevant for sectors included in the ECE Standardization List:

Has agreed to recommend the following general principles of harmonization and standards and technical regulations:

- C.1** Work on harmonization of standards and technical regulations should as far as possible be linked with international cooperation in the economic field, in science, technology, and environmental protection.
- C.2** Harmonization of standards and technical regulations should preferably begin with the preparation of a list of standards and technical regulations to be harmonized, taking into account existing or planned economic and scientific and technological arrangements or agreements between countries.
- C.3** The standards and technical regulations selected for harmonization should be those which:
 - (a) Ensure technologically and economically optimal product interchangeability and compatibility;
 - (b) Promote mutual understanding and influence other standards and technical regulations;
 - (c) Play an important part in mutual recognition of conformity assessment procedures;
 - (d) Influence health protection, labour protection, environmental protection and improvements in fire safety;
 - (e) Govern requirements concerning preservation, packaging, marking, labelling, transport and storage of goods;

- (f) Influence the economical use of raw materials and energy;
 - (g) Create or threaten to create technical barriers to international trade.
- C.4 When developing an international standard, other international standards or existing national and regional standards, where appropriate, should be taken into consideration.
- C.5 When developing national standards and technical regulations, first of all international standards and then regional standards should whenever possible be taken as the basis, and national standards and technical regulations in other countries should be borne in mind as far as possible.
- C.6 The timing of any revision of regional and national standards should, if possible, be coordinated with that of the adoption of revision of the relevant international standards.
- C.7 Where national technical regulations or standards are being prepared and relevant international standards exist or their completion is imminent, these or the relevant parts of them should be used as a basis for national technical regulations or standards except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.
- C.8 With a view to more extensive harmonization of standards and technical regulations, representatives of UNECE member countries should, as far as they are able, participate in the work of the appropriate international organizations engaged in the preparation of international standards, concerning products in respect of which technical regulations and standards are adopted or are being prepared at the national level.
- C.9 The texts of national standards and technical regulations of importance to international trade and industrial cooperation should indicate whether they are in conformity with corresponding international or regional standards. Where deviations occur they should be specified in the text and, if possible, the reason should be indicated. Furthermore, deviations should be so described and accompanied by such information as to facilitate the conclusion of contracts referring to such standards or regulations.
- C.10 When developing and harmonizing standards and technical regulations, account should be taken of the relevant principles of the WTO Agreement on Technical Barriers to Trade.



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D. ■ Reference to Standards¹

The Working Party on Technical Harmonization and Standardization Policies,

Recognizing the important advantages offered by the use of the method of "reference to standards", inter alia, that:

- (a) the elimination and prevention of barriers to trade is facilitated when reference is made to regional or preferably to international standards or to national standards transposing international or regional standards;
- (b) the legislative work is simplified and accelerated;
- (c) technical regulations can be changed more easily and at less cost to take account of technological advance;
- (d) the results of the work of international standards organizations can be more easily taken into account;

Noting, however, that to successfully implement the method of "reference to standards", due consideration should be given to different national legislative frameworks.

Has agreed to recommend that:

- D.1** ECE Governments should in legislation whenever possible use reference to national standards, to regional standards or preferably to international standards when they exist, and should promote the wider application of the method of "reference to standards" by drawing the attention of their competent authorities to the advantages of the method and to the alternative techniques of using it.

¹ Recommendation adopted in 1974, revised in 1980, 1984, 1988 and 1995.

- D.2** ECE Governments should endorse principles 1-5 of ISO/IEC Guide 15 on "Reference to Standards" in order to facilitate the preparation of standards for use in regulations, and should actively seek to promote the application of those principles both at the national level and in international organizations concerned with the preparation of standards.
- D.3** ECE Governments should ensure efficient interaction of regulatory authorities and standards bodies. The following guidelines should be observed:
- D.3.1** when regulatory authorities make requests to a relevant body for a standard to be referred to in legislation, an understanding should be obtained at the start on the scope of the standardization work requested, and interested national authorities and intergovernmental organizations should consider whether it is possible to abstain during a certain period from regulatory action which could hamper the work of developing the standard;
 - D.3.2** regulatory authorities should be instructed to play a full part in the development of those standards which are likely to be used as reference in legislation. Authorities should be entitled to participate in standardization work and, where financial constraints and administrative practices render participation impracticable, means should be sought to overcome these difficulties;
 - D.3.3** in the event of a standards body's failure to obtain acceptance of points considered vital to government interest, it should be made clear that the standard concerned is not acceptable for government purposes; authorities may judge whether a standard is appropriate for their purposes, independently of any procedure chosen for the preparation of such standard;
 - D.3.4** when choosing among the various techniques of "reference to standards", it is desirable that authorities adopt a technique which will take advantage of the revision of standards in the light of experience and technical progress with the least delay and by that make optimal use of the standardization work;
 - D.3.5** bodies preparing standards should bear in mind that the presentation of standards should be such as to facilitate their use as reference in legislation. Where legislative interest is restricted to certain aspects of a standard, it is helpful that these aspects be contained in a section which may be separately identified in the regulation concerned;
 - D.3.6** procedures should be established for ensuring that documents to which reference is made are published or are made easily available free of charge or at an equitable price for foreign and domestic parties;

D.3.7 governments should, in cooperation with national standards bodies, prepare guidelines for regulatory authorities for correct and practicable use of the method of "reference of standards" and its different options as well as guidelines for national standardizing bodies on drafting standards.



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E.

Treatment of Imported Products, Processes and Services¹

The Working Party on Technical Harmonization and Standardization Policies,

Recalling that the Economic Commission for Europe in Decision G (XXX) (1975) expressed the hope that their work would result in accelerated progress in international standardization, especially with a view to removing technical barriers to international trade arising out of different standards and technical regulations or their application;

Recognizing the value of prior information by Governments about technical regulations, i.e. during their preparation or prior to the date when they are issued, in cases where there is no adequate international harmonization of such regulations and where the lack of harmonization might constitute a technical barrier to international trade;

Noting that the mutual recognition of conformity assessment procedures through international agreements is the ultimate goal to be achieved with regard to international cooperation in this field;

Has agreed to recommend that:

- E.1** ECE Governments should ensure that imported products, processes and services are treated no less advantageously than national products, processes and services in relation to standards and technical regulations and that the latter should not constitute obstacles to international trade when the products to be imported are in conformity with the standards and technical regulations of the importing country or meet the requirements of standards and technical regulations that are more stringent than those set by the importing country.

¹ Recommendation adopted in 1970, revised in 1976.



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F

Creation and Promotion of International Agreements on Conformity Assessment¹

The Working Party on Technical Harmonization and Standardization Policies,

Noting that the Final Act of the Conference on Security and Cooperation in Europe (CSCE) recognizes international cooperation in the field of certification as an important means of eliminating technical obstacles to international trade and industrial cooperation;

Recalling that the Economic Commission for Europe in Decision D (XXXI) (1976) reminded its competent Principal Subsidiary Bodies that, in addition to the topics specifically referred to in the CSCE Final Act for multilateral implementation by the Commission, they should devote special attention to the multilateral implementation of other provisions set out in the section of the Final Act entitled "Cooperation in the field of economics, of science and technology and of the environment", such as: "2. The promotion of international agreements and other appropriate arrangements on acceptance of certificates of conformity with standards and technical regulations";

Taking into account that even if regulations and standards are harmonized there is still a risk that technical barriers to trade could arise if different conformity assessment procedures exist;

Bearing in mind that national and regional conformity assessment systems, notably those which are mandatory, may constitute barriers to international trade;

Has agreed to recommend that:

¹ Recommendation adopted in 1980, revised in 1988.

- F.1** ECE Governments should promote the establishment of agreements on conformity assessment when justified by the over-all economic benefits to international trade;
- F.2** ECE Governments should, when considering conformity assessment, include any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled;
- F.3** ECE Governments should, with regard to such agreements on conformity assessment, take into account the relevant provisions of Articles 5, 6 and 9 of the World Trade Organization Agreement on Technical Barriers to Trade;
- F.4** ECE Governments should encourage national bodies to apply appropriate ISO/IEC Guides and standards;
- F.5** ECE Governments should encourage the establishment and strengthening of contacts between national bodies in different member countries responsible for agreements on conformity assessment relevant to international trade;
- F.6** ECE Governments should apply and encourage application of the following guidelines in promoting agreements on conformity assessment.

Purpose

1. The main purpose of agreements on conformity assessment should be the creation of mutually favourable conditions for economic cooperation between countries.

Participation

2. Parties to an agreement on conformity assessment may be States, groups of States, Governments or national organizations. In the latter case, these may be governmental or non-governmental.

3. In the case of governmental bodies, participation should be available to any party. In the case of both governmental and non-governmental agreements, parties must be willing to accept and able to conform with the existing rules and obligations. Prior consultations concerning the technical and administrative competence of the conformity assessment bodies of a party seeking participation may be necessary before entry of this party into an agreement on conformity assessment.

Equality of rights, obligations and treatment

4. The principles of equality of rights and obligations and of equal treatment of all products and services covered by the agreement, whether imported or domestic, should be reflected in the agreement (see also Recommendation E).

Availability of information

5. Agreements on conformity assessment should be published in full. Names and addresses of participating bodies, as well as other relevant information about their activities, should be made readily available.

Mutual recognition

6. The first goal of a mutual recognition agreement on assessment of conformity should be the mutual recognition of conformity assessment results carried out in the exporting country in accordance with the requirements of the importing country, for determining conformity with standards or technical regulations. Such agreements can constitute a first step towards a harmonized conformity assessment system for the parties to the agreement.

7. In agreements on conformity assessment, parties should be aware of liability concerns, and may be required to be insured against possible liability arising from their operations.

Harmonization of standards and technical regulations

8. Agreements on conformity assessment should preferably be based on international standards where they exist or as an alternative on harmonized national standards, technical regulations or regional standards.

Consultations and complaints procedure

9. Provisions should be made for informal consultations in the first place between the interested parties and, in cases where these do not resolve difficulties, for a formal complaint procedure. The latter procedure should, when applicable, be initiated within the international organization or other body agreed upon by the parties to the agreement.

Mutual confidence

10. Mutual confidence in the technical competence, reliability and impartiality of the relevant national bodies and systems is a prerequisite for the effective functioning of an agreement on conformity assessment. Mutual confidence may be promoted by implementing the procedures presented in the appropriate ISO/IEC Guides and Standards.



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G

Acceptance of Conformity Assessment Results¹

The Working Party on Technical Harmonization and Standardization Policies,

Bearing in mind that activities for the assessment of conformity of products and services are complementary to standardization activities;

Bearing in mind that it is desirable to facilitate international trade by avoiding the duplication of conformity assessment procedures which are not justified on grounds of safety and public health;

Has agreed to recommend that:

- G.1** Governments should contribute to the development of multilateral agreements for the acceptance of the results of conformity assessment procedures (e.g. calibration, testing, inspection, certification, accreditation) or, in their absence, promote the conclusion of bilateral agreements or other agreements.
- G.2** Governments should take into consideration article 6 of the World Trade Organization Agreement on Technical Barriers to Trade in the acceptance of conformity assessment results.
- G.3** Governments should draft, or contribute to the drafting of, clauses on acceptance of conformity assessment results in more general agreements concerning the harmonization or equivalence of technical regulations, or on mutual recognition of conformity assessment systems.

¹ Recommendation adopted in 1988.

- G.4** National accreditation systems for conformity assessment bodies already existing or in the process of being established, should be based, as far as the requirements for the technical competence of conformity assessment bodies are concerned, on the application of the relevant ISO/IEC Guides and Standards.

- G.5** Governments should promote the conclusion of multilateral agreements or, in their absence, bilateral agreements for the mutual recognition of national accreditation systems.



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H.

Presentation of UNECE Recommended Standards and Harmonized Technical Regulations¹

The Working Party on Technical Harmonization and Standardization Policies,

Recalling that the Working of technical regulation Party on Technical Harmonization and Standardization Policies in Recommendation B on coordination and standardization activities expressed the opinion that international and regional standards should be aligned as far as possible to the Directives used by the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC) in order to facilitate their implementation;

Recognizing the value to interested parties of being acquainted with international, regional and national standards and that this would be facilitated if such standards (and technical reports, etc.) are presented in as uniform a manner as possible irrespective of the technical content;

Has agreed to recommend that:

- H.1** The standards organizations entrusted with the standardization projects contained in the UNECE List of Sectors Requiring Standardization, including especially the UNECE Subsidiary Bodies concerned, are encouraged to use ISO and IEC rules for the drafting and presentation of International Standards.

¹ Recommendation adopted in 1988.



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■ Methodological Studies and Education¹

The Working Party on Technical Harmonization and Standardization Policies has agreed to recommend that:

- I.1** ECE Governments should, in collaboration with appropriate intergovernmental and other organizations and taking into account the activities of the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC), consider the possibility of encouraging:
- (a)** the introduction of the subject of standardization into the scientific and technological curricula of educational establishments;
 - (b)** the education and training of specialists in standardization;
 - (c)** the further study in depth of the methodology of standardization supported by international collaboration.

¹ Recommendation adopted in 1970.



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J.

Definitions¹

The Working Party on Technical Harmonization and Standardization Policies,

Recognizing that internationally agreed general terms and their definitions are indispensable for developing international cooperation in standardization and related activities;

Recalling that the international work on definitions has been initiated at the UNECE²;

Noting that the latest ISO/IEC guides/standards on definitions, namely ISO/IEC Guide 2:2004 "Standardization and related activities -- General vocabulary" and ISO/IEC international standard 17000:2004 "Conformity assessment -- Vocabulary and general principles" meet requests presented by the governmental officials and standardization community participating at the Working Party on Regulatory Cooperation and Standardization Policies;

Noting also that ISO/IEC Guide 2:2004 and ISO/IEC standard 17000:2004 "were prepared in close cooperation and with contribution from standards-setting bodies of the UNECE member States;

¹ Recommendation adopted in 1988 and revised in 2006.

² The work on definitions started at the beginning of the 1970s under the auspices of the ECE Group of experts ("Government Officials Responsible for Standardization" – a predecessor body of the Working Party on Regulatory Cooperation and Standardization Policies (WP.6)). It continued later on as a joint activity with ISO (and then it was finally transferred to ISO) to be published in 1976 as the first guide on definitions - ISO Guide 2 "General terms and their definitions concerning standardization and related activities".

Emphasising that the World Trade Organization Agreement on Technical Barriers to Trade makes an explicit reference to the ISO Guide 2:1991 as a basis for definitions to be used by Governments, thus necessitating regular updating of legal and other documents making reference to international documents on definitions;

Considering that the said Guide and standard well meet the requirements of the UNECE Governments and other United Nations Governments for an international terminology for standardization and related activities;

Has agreed to recommend that:

- J.1** UNECE Governments and other United Nations Governments should endorse ISO/IEC Guide 2:2004 “Standardization and related activities - General vocabulary” and ISO/IEC international standard ISO/IEC 17000:2004 “Conformity assessment-Vocabulary and general principles”.
- J.2** UNECE Governments and other United Nations Governments should encourage their national standards bodies to publish ISO/IEC Guide 2:2004 and standard ISO/IEC 17000:2004 as national guides or standards translated into their national languages.
- J.3** UNECE Governments and other United Nations Governments should promote the use of the terms in ISO/IEC Guide 2:2004 and in standard ISO/IEC 17000 and as defined in national legislation, standardization and related activities as well as in relevant international cooperation.



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K.

Metrological Assurance of Conformity Assessment and Testing¹

The Working Party on Technical Harmonization and Standardization Policies,

Recognizing that results of measurements are the basic facts on which decisions are taken in conformity assessment and testing;

Noting that metrological assurance serves as a means for establishing confidence in the necessary quality of conformity assessment and testing;

Considering that there may be differences between principles, methods and means for estimating the uncertainty of measurement results;

Realizing that such differences can create non-tariff barriers to international trade;

Taking into consideration that the harmonization of the above-mentioned principles, methods and means is required for:

- (a) Creating preconditions for the mutual recognition of conformity assessment and test results by establishing confidence in the results of measurements which serve as their basis;
- (b) Ensuring the possibility of independent assessment and documentary confirmation of the competence of conformity assessment bodies and testing laboratories.

Recommends that:

¹ Recommendation adopted in 1988, revised in 2008.

- K.1** ECE Governments should support the development and implementation of fully harmonized standards², guides and technical regulations promoting methods and means of metrological assurance on the basis of the international documents and recommendations of the International Organization of Legal Metrology (OIML) as well as the standards and guides of the International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC).
- K.2** National technical regulations relevant to international trade and industrial cooperation should contain requirements for the technical competence of conformity assessment bodies and test laboratories for different types and categories of tested products, particularly with regard to the methods and means of obtaining measurement information used for the estimation of the uncertainty of measurement results which are the basis for conformity assessment decisions and test results.
- K.3** The appropriate level of competence of conformity assessment bodies and test laboratories and, consequently, the metrological assurance level should be established according to criteria that ensure a high level of confidence when estimating parameters characterizing the products from the point of view of their safety, influence on health and environment and consumer protection.
- K.4** General stipulations, rules and requirements in national standards and technical regulations should cover, as far as appropriate, the following types of metrological activities:
- Metrological control procedures (type approval, verification, calibration, periodic re-verification or recalibration), or servicing, including the corresponding verification or calibration of auxiliary or supplementary measuring instruments used in conformity assessment and for testing;
 - Metrological qualification of measuring instruments and associated test equipment (stands, set-ups, chambers intended for reproduction of test modes and conditions);
 - Traceability to international or national measurement standards;
 - Metrological validation of test methods (procedures) and computer software used in conformity assessment and testing;
 - Estimation of the uncertainty associated with measurement results used as the basis for conformity assessment and test results;

² In science and technology, the English word "standard" is used with two different meanings: as a widely adopted written technical standard, guide, technical regulation or similar document (in French "norme") and also as a measurement standard (in French "étalon"). This Recommendation is concerned with both meanings and the qualifier "written" is generally omitted for brevity.

- Processing and recording of measurement and test results;
 - Application of conformity decision rules in relation to applicable maximum permissible errors or tolerances.
- K.5** When working out national standards and technical regulations the bodies concerned should take into account that each accredited conformity assessment body and test laboratory must have a set of measurement standards traceable to national or international measurement standards. Documents on methods of validation of test procedures and estimation of the uncertainty of measurement results should be submitted to the accrediting body including results of interlaboratory comparisons. Preference should be given to harmonized methods and procedures as laid down in OIML recommendations and documents based on the use of certified reference materials and recognized national or international standard methods and procedures.
- K.6** With the aim of facilitating mutual recognition of conformity assessment and test results, documents should be presented in connection with the accreditation of conformity assessment bodies and test laboratories, confirming their technical competence including the limiting values (for instance, the lowest uncertainty of measurement results), methods and means of their achievement and confirmation.
- K.7** Manufacturers, suppliers or customers submitting products for testing have the right to check the documentation of the test laboratory and/or its claim of being capable of achieving the desired level of technical competence required for measurement and testing.



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International Model for Technical Harmonization Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards^{1 2}

Note by the secretariat

1. This paper contains a recommendation based on the proposal for an "International Model", as submitted to the UNECE Working Party on Technical Harmonization and Standardization Policies at its eleventh session in October 2001 (documents TRADE/WP.6/2001/8, TRADE/WP.6/2001/8/Corr.1 and TRADE/WP.6/2001/8/Add.1). The proposal for an "International Model" was prepared by the ad hoc Team of Specialists on STandardization And Regulatory Techniques ("START" Team).

At this session, the Working Party decided:

- (a) that there is a clear market need and interest from Governments in further reducing trade barriers and facilitating market access;
- (b) that the elaborated "International Model" provides a voluntary framework which could contribute to facilitating market access through the establishment of sectoral agreements between interested member countries;
- (c) to request the secretariat to include the text of the "International Model" in the set of UNECE Recommendations on Standardization Policies

¹ Recommendation adopted in 2001.

² See annex A for a list of the abbreviations used in this recommendation.

- (d) to call on the “START” Team:
 - (i) as a follow-up to requests from the UNECE Committee for Trade, (see ECE/TRADE/280, paragraph 64), to explore with UNECE Subsidiary Bodies the possibilities of using the principles and concept of the “International Model” in their areas of competence so as to identify potential pilot projects;
 - (ii) to assist with sectoral initiatives based on the “International Model” as forthcoming from interested parties and as requested.

Background

2. Regulators can deploy a number of means to prevent technical regulations from constituting unnecessary barriers to trade. The World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) explicitly refers to using international standards as a basis for technical regulations (cf. Art. 2.4 and cf. Art. 2.6) and to accepting as equivalent the technical regulations of other Members (cf. Art. 2.7). It also encourages the use of relevant international guides or recommendations as a basis for conformity assessment procedures (cf. Art. 5.4), and the conclusion of agreements for the mutual recognition of the results from each other’s conformity assessment procedures (cf. Art. 6.3).

3. At the First Triennial Review, the WTO/TBT Committee reiterated that good regulatory practice for the preparation, adoption and application of technical regulations was a priority for Members to facilitate trade, and it was agreed at the Second Triennial Review to continue an information exchange in this regard while noting that minimizing the use of mandatory technical regulations and using voluntary international standards, where appropriate, could reduce the regulatory burden and open up market access opportunities. WTO members also agreed on this occasion that regular information exchange between the Committee and other relevant bodies would be useful.

4. The Working Party on Technical Harmonization and Standardization Policies (WP.6) has for more than 30 years provided an interface between the regulatory and the standardization community; for instance, by keeping a standardization list by which regulators can flag areas where they would consider it useful for voluntary standards to be developed, possibly for subsequent use in relation with technical regulations. The United Nations Economic Commission for Europe (UNECE), under which Working Party 6 operates, also has a longstanding record of offering member countries a platform for the harmonization of national technical regulations such as is done in the area of motor vehicles (Working Party 29 - World Forum for Harmonization of Vehicle Regulations).

5. However, international technical harmonization could be even further advanced by reducing the regulatory burden and using international standards where appropriate. For this purpose, in 1999, Working Party 6 established an ad hoc team of specialists on Standardization and Regulatory Techniques (the "START" Team).

6. The “International Model” recognizes that a framework for ensuring that technical regulations and standards do not create barriers to trade exists in the WTO Agreement on TBT. The Model adds to this framework by suggesting solutions for the practical implementation of technical harmonization and draws from existing schemes for good regulatory practice to be used in the process of international technical harmonization.

7. It provides a set of voluntary principles and procedures for sectoral application. Countries that would like to harmonize their technical regulations may wish to implement the principles and procedures as suggested by the “Model”. To this end the details of procedures for such application will have to be drawn up by the interested countries.

Introduction

8. Discussions within different international organizations and forums show a clear desire for the convergence of technical regulations with a view to limiting obstacles to international trade and to facilitating market access. Some international technical regulations exist, but they tend to be cumbersome and burdened with details. They have also proven to be difficult to prepare. As a consequence, such regulations, once in place, can be difficult to amend. Detailed agreements between a large number of regulatory authorities are frequently difficult to obtain, and such regulations tend not to achieve full consensus.

9. A regulatory framework comprising broad common regulatory objectives might be easier to compile and might more easily find consensus. For the detailed requirements that implement common regulatory objectives recourse could be made to established mechanisms of international standardizing bodies, which provide a forum for all interested parties (including regulatory authorities), and have established a degree of trust at the international level.

10. These problems have been recognized by Working Party 6, which at its ninth session in 1999 commissioned a team of specialists to investigate the question. This team was established under the acronym “START” (STandardization And Regulatory Techniques), and the UNECE Committee for Trade, Industry and Enterprise Development confirmed its formation. The work of the Team is intended to provide guidance for good regulatory practice and a mechanism for cooperation between regulatory authorities, standardisers and industry, so that legislation can make appropriate use of standards.

11. There are major efforts regarding the elimination of technical barriers to trade, particularly under the WTO/TBT Agreement, and it is appropriate to further develop the practical dimensions of procedures that are complementary to and coherent with the TBT Agreement. This could be done by way of a general mechanism for linking harmonized technical regulations and international standards. Information used in the development of the following proposed, provisional “International Model” was also derived from useful work undertaken in other international fora. These include the WTO work on trade policy review, the OECD work on regulatory reform and international standards, and Asia-Pacific

Economic Cooperation's (APEC) and the Asia-Europe Meeting (ASEM) work on creating guidelines on good regulatory practice.

12. It is, for example, assumed that whenever a new or revised technical regulation is being prepared, regulators should follow the principles found in the WTO/TBT Agreement. In particular, it is assumed that technical regulations should be based on relevant international standards, when they exist or their completion is imminent, except when such standards would be ineffective or inappropriate for the technical regulation in question; that technical regulations should not be more trade-restrictive than necessary and that they should be non-discriminatory.

13. Where harmonization is considered useful by interested countries, the “International Model” provides practical steps aimed at facilitating and accelerating the harmonization of technical regulations by agreeing on Common Regulatory Objectives (CROs) for applicable products or product areas (sectors).

Proposal for a Model for the Harmonization of Technical Regulations and Free Circulation of Compliant Products

Basic elements for harmonization and free circulation

14. The “International Model” addresses the steps to be followed when harmonization of technical regulations is favoured by a number of United Nations member countries. The nature of such harmonization should preferably be limited to agreeing on CROs. Such objectives will address legitimate concerns of governments, for instance, those related to public health, safety or the protection of the environment. The principal elements to be included in a CRO are set out in annex B. The CRO shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. The CROs would be transposed into technical regulations at national level by those countries who agreed on them. The mechanism for national transposition of CROs is to be defined by individual United Nations member countries according to their national legal practice. For demonstration of compliance with CROs, a possible means could be recourse to relevant international standards.

15. A distinction should be made between the specifications applicable to products, as such, and the conformity assessment requirements to be used to ensure that the products placed on the market conform to the characteristics required. The CROs shall cover these issues.

16. If the system of CROs is to be effective in facilitating trade, there would need to be mechanisms to ensure that products falling within the scope of the CRO, that complied with its terms, and were properly attested as doing so, could be placed on the market in the countries that have agreed on the CRO.

17. Countries that have agreed on a CRO would assure that products which comply with the CRO could be placed on their market for free circulation without being subject to any additional product or conformity assessment requirements (e.g. testing or certification).

18. If a country imposes additional requirements, despite having agreed on a CRO, it shall inform the other countries through UNECE. The other countries would, under such circumstances, be free to take appropriate measures and ultimately restrict the free circulation on their markets of relevant products from the country that has approved additional requirements.

Identification of the need for harmonization

19. The responsibility for technical regulations and their harmonization lies with national regulatory authorities. The need for harmonization might, for instance, be identified by one, of the following "trigger" mechanisms:

- (a)** Studies by specialists from a particular sector/industry that are specially commissioned by Governments, international organizations, business groups, or non-governmental organizations (NGOs) and raised in national, regional or international forums;
- (b)** Through initiatives by one or more particular countries to harmonize their technical regulations at an international level;
- (c)** Through "complaint-based" initiatives when a country is responding to complaints from foreign or national business operators concerning its technical regulations regime;

20. When it concerns new or revised technical regulations, the existing notification procedures under the WTO/TBT Agreement require proposed technical regulations/conformity assessment procedures to be systematically notified. This might also be regarded as a "trigger" mechanism for examining the need for a technical regulation. If this need is recognized by other countries, they might be willing to state their interest in having the proposed technical regulation internationally harmonized.

Process of establishing a CRO

21. A United Nations member country interested in using the mechanism of this "International Model" for harmonizing technical regulations through establishing CROs could address the United Nations Economic Commission for Europe (UNECE) to launch a Call for Participation by other member countries of the United Nations (procedures to be elaborated in annex C). The purpose of such a Call would be to explore the interest in international harmonization via agreed upon CROs for the products or product area in question. If such a Call were positively responded to by other member countries of the United Nations, the countries concerned would cooperate in formulating CROs.

22. The procedure proposed for the preparation or revision of CROs and legal formats for their approval is set out in annex C. Based on the proposal for CROs, interested countries, (effectively, any country that had responded positively to a call for participation) shall cooperate in formulating CROs. During the preparation of CROs by the group of interested countries, any other United Nations member country could join this group or participate in the work as an observer.

23. Upon completion of the text of the CROs, the United Nations member countries having agreed on them would, with a view to having an open and transparent process, announce to the UNECE their intention to implement them nationally in national technical regulations. Other member countries of the United Nations would be invited, on a voluntary basis, to implement them either immediately or in due time. The United Nations would register the CROs and their implementation in national technical regulations. Such information would be made publicly accessible.

24. 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.

25. 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.

Determining and assuring conformity with a CRO

26. The CRO should contain requirements related to how conformity with its terms is to be assured and demonstrated. Whenever appropriate, the means of assuming compliance should be a Supplier's Declaration of Conformity (SDoC). However, in other cases, particularly when safety and health concerns are important, the United Nations member countries agreeing on a CRO may find it necessary to make recourse to more stringent conformity assurance procedures. In either case - where the SDoC is considered sufficient, or where a more stringent procedure is required, the procedures should be specified in the CRO. If third party assessment is deemed necessary, the CRO should state that compliance be assessed and attested by recognised conformity assessment bodies (RCABs).

Recognized Conformity Assessment Bodies

27. The requirements with regard to the technical competence of the Conformity Assessment Bodies (CABs) in the field defined by the CRO should be set out as an integral part of the CRO. The countries that have agreed on the CRO could designate

CABs as recognized for performing assessment and attestation under the CRO. A list of such recognized bodies (RCABs) should be made publically available, for instance, by annexing it to the CRO and such bodies should be registered by the UNECE.

Claim of conformity with a CRO by the supplier

28. Products covered by the scope of a CRO would carry some means (e.g. SDoC or a certificate of conformity) demonstrating either that the supplier claims conformity with the CRO or that conformity has been assessed and attested to by an RCAB. In either case, documented evidence should be provided with the product. The type of such evidence should be specified in the CRO. All claims of compliance must include the reference to the applicable CRO, for example, the registration number allocated by UNECE for the applicable CRO.

Market surveillance and protection clause

29. Countries having agreed on CROs are responsible for market surveillance on their territory and have the right to withdraw products from their national markets if the products are not in compliance with the CRO.

30. In cases where a product is in conformance with a CRO but is found to endanger health and safety or other legitimate objectives, a country can take steps to withdraw such a product from the market or restrict its free circulation by evoking the protection clause of a CRO (for details see annex B).

31. Countries should report such actions relating both to domestic and foreign products to UNECE and indicate the reasons for this decision.

ANNEX A

List of abbreviations used in the “International Model”

CAB	Conformity Assessment Body
CRO	Common Regulatory Objective
ISB	International Standardizing Body
PC	Protection Clause
RCAB	Recognized Conformity Assessment Body
SDoC	Supplier’s Declaration of Conformity
TR	Technical Regulation
UNECE	United Nations Economic Commission for Europe

ANNEX B

Principal elements to be included in a Common Regulatory Objective

A Common Regulatory Objective (CRO) is a mutually agreed document registered by the United Nations Economic Commission for Europe (UNECE) and publicly available. By establishing such a document the interested countries agree on elements such as:

Scope statement

A statement of the products or product areas that are covered by the CRO.

Countries should agree on the products for which legitimate regulatory objectives are required. For this purpose countries may use international classification schemes such as the harmonized commodity description and coding system.

Product requirements

Legitimate regulatory objectives reflect the requirements of Governments to protect public interest in areas such as human health or safety, animal or plant life or health or the environment. The requirements needed for protection of legitimate objectives should lay down the principal issues of concern and be specified in terms of performance requirements rather than design or descriptive characteristics. Requirements should be limited to relevant aspects and be proportionate to the hazard inherent in a given product or product area.

The detailed provisions on how to meet the requirements of the CRO should preferably be specified in international standards. Such standards will be referenced in the CRO.

Reference to standards clause

The CRO should contain a list of applicable international standards that correspond as a whole or partially to the requirements.

The CRO may contain a provision that products complying with the referenced international standards are presumed to comply with the requirements.

Compliance clause

The CRO should contain a provision on how compliance is demonstrated.

Countries should agree on the range and contents of possible conformity assessment procedures that are considered to give the necessary level of protection under the CRO. The CRO should also specify the conditions under which suppliers can make a choice if more than one option is provided for. Such options are, for instance, supplier's declaration of conformity, third party certification or inspection.

When applicable, the CRO should also contain provisions on the conformity assessment bodies that are recognized to assess and attest compliance as well as the competence criteria to be fulfilled by such bodies.

Market surveillance and Protection clause

Countries having agreed on CROs are responsible for market surveillance on their territory and have the right to withdraw products from their national markets if these are not in compliance with the CRO.

The CRO should contain a provision (protection clause) that if a country finds products claiming conformity with a CRO that do not conform to its requirements, the country may, with the intention to preserve legitimate objectives, withdraw such a product from its market. Furthermore, the CRO should contain a provision that the country using the Protection Clause should state, to the UNECE, specifically what products have been removed from the market and what requirements of the CRO have been claimed to be met but have not been met.

In a case where products are in conformity with the CRO or the applicable international standard but are still found to endanger legitimate objectives, a country having agreed on a CRO could withdraw such products from the market or restrict free circulation. In this case, the use of the Protection Clause should also be subject to the condition that the country using it should declare its use to the UNECE and indicate the reasons for this decision.

ANNEX C

Administrative Procedures and Institutional Provisions (including the call for participation in formulating “Common Regulatory Objectives” and the preparation of these Objectives)

Article 1

General Institutional Framework

1.1 The process of registering Common Regulatory Objectives (CROs) and interpreting the provisions of the “International Model” shall be the task of the UNECE Working Party on Technical Harmonization and Standardization Policies (Working Party 6-WP.6) which shall ensure coordination of the work on requests for technical harmonization received by the UNECE secretariat. If deemed appropriate, Working Party 6 could set up groups of experts to monitor and implement such work in practice.

Article 2

Call for Participation

2.1 Country/Countries (at least three wishing to harmonize their technical regulations according to the “International Model” and to invite other countries to join such a process) shall make a “Call for Participation” through the UNECE secretariat to all United Nations Member States. The Call should contain the necessary information for formulating a CRO (cf. annex B). Countries wishing to join the work under such a Call should respond to the secretariat within three months (from the date of the transmission of the Call by UNECE secretariat), stating their interest to participate in the work. The countries that expressed an interest in joining the work can start the technical harmonization process three months after the date of transmission of the Call.

2.2 Based on responses to the Call, an open-ended task force composed of interested countries shall be set up with the purpose to jointly develop CROs regarding the safety, health, environmental protection and other legitimate concerns of governments regarding the products or group of products in question.

2.3 These open-ended task forces should work in a transparent way and participation in them shall be open at any moment to any other United Nations Member State that expresses the wish to join the work. The task forces will agree on their own working procedures. The task forces should inform the UNECE secretariat about their work which will be made publicly available by appropriate means (for example, via the internet).

Article 3

UNECE Registry of Common Regulatory Objectives

3.1 A registry shall be created and maintained by the UNECE secretariat for the CROs developed under the “International Model”. The registry shall be known as the “UNECE Registry for CROs”.

3.2 The countries that agreed on a CRO shall submit it to Working Party 6 through the UNECE secretariat.

3.3 The agreed CRO specified in the paragraph above shall contain the principal elements as set out in annex B to the “International Model”. The CRO shall not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

3.4 If formal elements in the agreed CRO (as specified in the Model) are met, the CRO shall be considered to be established in the UNECE Registry on the date of its submission to the UNECE secretariat.

3.5 The secretariat shall, when registering the CRO, append copies of all relevant documentation to that CRO. All documentation received by the UNECE secretariat under the provisions of this Article shall be made publicly available by appropriate means (for example, via the Internet).

3.4 The process of the further revision of the already agreed CROs should follow procedures as specified under Article 2 above.

Article 4

National adoption and notification of application of Registered Common Regulatory Objectives

4.1 A country that has agreed on a CRO shall submit the CRO to the process used by it to adopt technical requirements specified in the CRO into its own legislation. Any other country at any time may inform the UNECE secretariat about its intention to implement and use the CRO (and, thus, it will follow the procedures as specified under this Article).

4.2 A country that adopts a CRO into its own legislation shall notify the UNECE secretariat in writing of the date on which it will begin to apply that CRO. The notification shall be provided by the country within 60 days after adoption of the CRO.

4.3 A country that is specified in paragraph 1 of this Article and that has not, by the end of the one-year period after the date of the registration of the CRO in the UNECE

Registry, adopted the CRO into its legislation, shall report on the status of the CRO in its domestic process. A status report shall be submitted for each subsequent one-year period if no such action has been taken by the end of that period.

4.4. A country that is specified in paragraph 1 of this Article and that accepts products that comply with the technical requirements of a registered CRO without adopting the CRO into its own legislation shall notify the UNECE secretariat in writing of the date on which it began to or will begin to accept such products.



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on
Regulatory Cooperation and
Standardization Policies

M.

Use of Market Surveillance Infrastructure as a Complementary Means to Protect Consumers and Users against Counterfeit Goods¹

The Working Party on Regulatory Cooperation and Standardization Policies,

Recognizing consumer-protection concerns of the United Nations Member States and tasks for international organizations as highlighted in the General Assembly decision 54/449 of 22 December 1999 (United Nations Guidelines for Consumer Protection),

Stressing the necessity to set up efficient domestic market surveillance system to ensure that goods placed on the market meet public legitimate objectives such as public health protection and safety and that business transactions take place in compliance with the principle of fair competition,

Stressing the importance of intellectual property rights protection for the economic and industrial development of countries, and for international trade,

Noting existing deficiencies in the protection and enforcement of intellectual property rights (trademarks, copyrights, patents, designs, geographical indications) in international trade and the threats to health and safety of consumers and users posed by counterfeit goods,

Underlining that setting up an administrative and legal framework to protect IPR, including penalties, and building a coordinated network of cooperation between all core stakeholders, namely State authorities (e.g. customs, police and intellectual property agencies/patent offices), industry, consumers and users, are key elements to solve the problems of counterfeit goods,

¹ Recommendation adopted in 2007

Taking into account the legal and technical differences which may exist between the administrative and legal framework and individual technical regulations as well as the implementation tools when looking at protecting intellectual property rights compared to ensuring market surveillance,

Considering the role of the Working Party on Regulatory Cooperation and Standardization Policies in improving the current administrative and legal framework to enable business to trade safe and reliable products and services,

Recommends that:

M.1 Governments explore the possibility, wherever feasible and where the national legal framework permits, to involve their market surveillance authorities in the fight against counterfeit goods - in a complementary way to existing national legal mechanisms - by implementing the following procedures:

- (a) To provide mechanism for cooperation and coordination of market surveillance activities on the national level between market surveillance, customs and other authorities concerned,
- (b) To give the possibility to right holders to inform (with documented proof) the market surveillance and other relevant state authorities on counterfeit goods,
- (c) To enable market surveillance authorities to identify suspected counterfeit goods made available on the domestic market (in cooperation with other relevant authorities) during market surveillance activities, including, where appropriate, resorting to laboratories to test the goods,
- (d) After having examined the compliance with all applicable requirements of the national legislation, also to enable market surveillance authorities to check if the goods might infringe intellectual property rights, and, whenever feasible and without prejudice to the national legislation on confidentiality, to involve other relevant authorities and intellectual property right holders,

Trusts that:

M.2 implementation of these procedures should neither create financial burdens for market surveillance authorities nor replace or duplicate existing intellectual property rights enforcement tools. It would be rather beneficial to consumers/users, and conducive to establishing “rule of the law” principles in society and to fair competition and business development.