



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:

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.

to promote the implementation of relevant international basic standards;

to attain a uniform use of terms;

to achieve compatibility with other relevant international standards adopted or in course of preparation;

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 Standards⁴

The Working Party on Regulatory Cooperation and Standardization Policies,,

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

- (a) Contributes to preventing or eliminating unnecessary technical barriers to trade by facilitating regional and international harmonization of technical regulations and standards;
- (b) Increases transparency and accountability of legislative and regulatory work
- (c) Facilitates the review of technical regulations to take into account effectively technological progress and changes in societal and consumer expectations;
- (d) Allows authorities to take advantage of the knowledge and expertise incorporated in the results of the work of standardization bodies;

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

Recommends that:

- D.1** Regulatory authorities should, in conformity with the principles enshrined in the World Trade Organization (WTO) Agreement on Technical Barriers to Trade and observing the relevant decisions by the WTO Committee on Technical Barriers to Trade, whenever possible make use of international, regional and national standards in regulatory work.

⁴ Recommendation adopted in 1974, revised in 1980, 1984, 1988, 1995 and 2013.

D.2 Regulatory authorities should endeavour to apply “references to standards” methods that respect their voluntary nature, such as:

- Indicative reference, which retains the voluntary application of the standard.
- Only when indicative reference is considered unsuitable, regulatory authorities should make use of exclusive reference, which renders the standard or parts of the standard mandatory.

D.3 When choosing among the various methods of “reference to standards”, regulatory authorities should ideally adopt a method that would allow them to make optimal use of standardization work.

D.4 In regulatory, surveillance and legislative work, regulatory authorities should observe principles 1 to 5 of *ISO/IEC code of principles: “reference to standards” (ISO/IEC Guide 15:1977)* and take note of international best practice on using and referencing international standards for technical regulations.

D.5 Regulatory authorities should consider the following options to facilitate and optimize interaction with standardization bodies:

(a) Where reference to standards is considered an appropriate option for achieving the regulatory objective, regulatory authorities should request information from national standardization bodies related to potentially relevant standards at international, regional or national level;

(b) Participation in standards development.

(c) They should discuss with standardization bodies ways to facilitate the use of standards as reference in legislation. For example, where legislative interest is restricted to certain aspects of a standard, they should explore the possibility of including these in a separately identified section of a standard.

(d) Agree on ways to ensure that referenced standards are made available to all potentially interested foreign and domestic parties in the least restrictive manner possible. Regulatory authorities shall comply with the intellectual property rights and respect the copyright of standardization bodies when considering how to increase the accessibility of standards;

D.6 International bodies, such as UNECE, should continue to promote:

(a) A better understanding by regulators of the different options available for making use of standards;

(b) Education and capacity-building in this area for all stakeholders, in particular regulators, business and small and medium-sized enterprises, consumers and non-governmental organizations such as chambers of commerce and business associations, research institutions and academia;

(c) Better mutual understanding among stakeholders, including from different jurisdictions, through developing harmonized terminology and repositories of good practice.



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E.

Treatment of Imported Products, Processes and Services⁵

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

⁵ Recommendation adopted in 1970, revised in 1976.

meet the requirements of standards and technical regulations that are more stringent than those set by the importing country.



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F.

Creation and Promotion of International Agreements on Conformity Assessment⁶

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:

⁶ 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 Results⁷

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.

⁷ 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 Regulations⁸

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.

⁸ Recommendation adopted in 1988.



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■ Education on standards-related issues¹

The Working Party on Regulatory Cooperation and Standardization Policies,

Recognizing the role and place of standards and of quality infrastructure in accompanying or controlling products during their life cycle,

Underlining the important contribution of standards and regulatory framework (technical regulations, metrology, conformity assessment, accreditation, market surveillance) in the attainment of national and international development goals (including the United Nations Millennium Development Goals) and in promoting sustainable development,

Recommends that—in collaboration with appropriate intergovernmental and other organizations and academia, and taking into account the activities of global, regional and national standards bodies—Governments should encourage, wherever feasible and where the national legal framework permits:

- (a) the introduction by educational establishments of the subject of standardization into the curricula of educational establishments and particularly of universities for students majoring in technical and scientific subjects, as well as in legal, economic and management studies;
- (b) the vocational education and training of specialists in standardization;

¹ Recommendation adopted in 1970 and revised in 2012.

- (c) the enhancement of awareness-raising activities targeted to the business community and regulatory authorities (in particular, trade and customs officials);
- (d) the further study of standardization issues in order to identify best practices in ensuring that standardization and regulatory regimes contribute to meeting the legitimate concerns of society (e.g. human safety, environment) without creating unnecessary technical barriers to trade.”



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J.

Definitions⁹

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 UNECE¹⁰;

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;

⁹ Recommendation adopted in 1988 and revised in 2006.

¹⁰ 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 Testing¹¹

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:

¹¹ Recommendation adopted in 1988, revised in 2008.

- K.1** ECE Governments should support the development and implementation of fully harmonized standards¹², 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;

¹² 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.



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on
Regulatory Cooperation and
Standardization Policies

International Model for Transnational Regulatory Cooperation Based on Good Regulatory Practice¹³

The Working Party, noting that:

there is a clear market need from trade and industry and a positive interest from Governments in further reducing trade barriers and facilitating market access and

- the “International Model” developed by the United Nations Economic Commission for Europe provides a voluntary framework for regulatory cooperation that facilitates market access through the use of good regulatory practice and options for establishment of sectoral arrangements between interested UN member countries
- the “International Model” provides good regulatory practices that facilitates global harmonization of national or regional regulation
- the experience gained so far with the “International Model” and developments in international and regional fora shows the importance of a flexible voluntary mechanism for market access of products following relevant international standards and related practices.

¹³ Recommendation adopted in 2001 and reviewed in 2015.

Recommends:

- that regulators use the process outlined in Annex A to develop cooperation based on good regulatory practice in regulatory fields and accompanying trade and industry sectors
- that countries wishing to go further and establish special operational transnational sectoral arrangements use the process outlined in Annex B.

ANNEX A

Principal elements for regulatory harmonization based on good regulatory practice in regulatory fields and accompanying trade and industry sectors.

1. The principal issues to be addressed by interested regulators in a Common Regulatory Arrangement (CRA) document, would include:

- Legitimate regulatory objectives that usually relate to public health, safety or environmental protection, etc.;
- Applicable international standards that contain requirements for systems, processes, products and services;
- Ways of assuring and demonstrating compliance with the regulatory objectives;
- Provisions on third-party-assessment bodies, when recourse to third party assessment is needed;
- Provisions for post-market surveillance.

2. The CRA would specify the following principal elements:

Scope statement

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

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

Product requirements

5. Legitimate regulatory objectives reflect the requirements 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.

6. The detailed provisions on how to meet the requirements of the regulatory objectives should preferably be specified in applicable international standards. Such standards will be referenced in the CRA.

Reference to standards clause

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

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

Compliance clause

9. The CRA should contain a provision on how compliance is demonstrated.

10. Regulators should agree on the range and contents of possible conformity assessment procedures that are considered to give the necessary level of protection under the CRA. The CRA 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.

11. In considering such options regulators should aim to avoid duplicative conformity assessment testing and certification for products (and replacement parts that are included in the product certification) that add unnecessary costs and time delays.

12. When applicable, the CRA 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 clause

13. Regulators having agreed on CRA are responsible for market surveillance on their territory and have the right to withdraw products from their markets if these are not in compliance with the CRA.

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

15. In a case where products are in conformity with the CRA or the applicable international standard but are still found to endanger legitimate objectives, the regulator having agreed on a CRA 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 regulator using it should indicate the reasons for this decision.

ANNEX B

Administrative Procedures and Institutional Provisions

Article 1

General Institutional Framework

1.1 The process of registering Common Regulatory Arrangements (CRAs) and interpreting the provisions of the “International Model” shall be the task of the UNECE Working Party on Regulatory Cooperation 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 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 CRA. Countries wishing to join the work under such a Call should respond to the secretariat, stating their interest to participate in the work.

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 a CRA 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 Arrangements

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

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

3.3 The agreed CRA specified in the paragraph above shall contain the principal elements as set out in annex B to the “International Model”. The CRA 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 CRA (as specified in the Model) are met, the CRA 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 a CRA, append copies of all relevant documentation to that CRA. 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 CRA should follow procedures as specified under Article 2 above.

Article 4

National adoption and notification of application of Registered Common Regulatory Arrangements

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

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

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 CRA in the UNECE Registry, adopted the CRA into its legislation, shall report on the status of the CRA 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 CRA without adopting the CRA 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.

List of abbreviations used in the “International Model”

CAB	Conformity Assessment Body
CRA	Common Regulatory Arrangement
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



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 Goods¹⁴

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,

¹⁴ 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.



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on
Regulatory Cooperation and
Standardization Policies

N.

Good Market Surveillance Policies and Practices*

The Working Party on Regulatory Co-operation and Standardization Policies

Recognizing the need to ensure that products placed on the market or imported meet legal requirements on safety, health, environment, fair competition between economic operators, and any other aspects of public interest (hereinafter “legal requirements”).

Noting that market surveillance is an essential public response to addressing that need.

Noting the existing differences in both legal, administrative and operative means for carrying out market surveillance among United Nations Member States.

Noting the lack of systematic guidance for setting up structures that meet basic and essential criteria for the enforcement of legal requirements on products made available on the market.

Considering the best practice developed internationally, including by the Advisory Group on Market Surveillance (MARS Group) and the Working Party on Regulatory Cooperation and Standardization Policies.

In the light of the General Assembly decision 54/449 of 22 December 1999 (United Nations Guidelines for Consumer Protection).

* Recommendation adopted in 2011

Recommends that Governments should:

- N1.** Organize market surveillance to ensure that products meet the legal requirements.
- N2.** Give priority to establishing a legal basis for market surveillance activities, including adequate legal requirements for cooperation with economic operators and proceedings for application of proportionate restrictive measures in relation to marketing of products.
- N3.** Appoint competent authorities to carry out market surveillance activities.
- N4.** Consider risks identified and political priorities and provide for adequate and sufficient administrative capacities, resources and powers for market surveillance authorities to ensure fulfilment of the requirements set for products.
- N5.** Establish effective mechanisms for horizontal and sectoral cooperation and coordination among market surveillance authorities, customs authorities and other stakeholders concerned at the national and international level.
- N6.** Together with market surveillance authorities take advantage of and contribute to channels for co-operation and information exchange internationally.
- N7.** Together with market surveillance authorities should participate in regional and international cooperation efforts such as joint market surveillance actions.
- N8.** Set national priorities for market surveillance according to the market conditions in the country, taking into account available information from regional and international information sources on products risks, and on product related non-compliances.
- N9.** Set annual and/or multi-annual plans at general and sectoral level for market surveillance.
- N10.** Together with market surveillance authorities, when planning and carrying out market surveillance activities, take into account established principles of risk assessment.
- N11.** Encourage donors to recognize market surveillance as a priority in devising bilateral and multilateral technical assistance and cooperation projects.

Checklist for the implementation of the Recommendation N

A. Legal basis

A1. Available legislation on consumer and user protection, including methods for collecting and informing of dangerous and non-compliant products (nationally/internationally).

A2. Available horizontal or sector-specific legislation on enforcement of products

defining:

- product sector(s)
- essential product requirements
- responsible authority /authorities
- powers of authorities
- applicable penalties based on risk assessment of products
- mechanisms to ensure confidentiality
- mechanisms to ensure traceability
- cooperation (a) between market surveillance and other relevant authorities and (b) between market surveillance authorities and other national stakeholders, including in methods for collecting and informing of dangerous and non-compliant products (nationally/internationally).

A3. Legislation covering cross-border measures and cooperation mechanisms between market surveillance authorities and customs authorities.

A4. Explicitly address possible interactions between product legislations at national and or regional level and other national laws (i.e. criminal law).

B. Political priorities

B5. Available national statement (priority) of product safety, health, environment and any other aspect of public concern, including fair competition among economic operators.

B6. Established national quality infrastructure, including a functioning system for accreditation and conformity assessment (inspection, certification, testing) and market surveillance.

- B7.** Annual and/or multi-annual (e.g. 3-year) national market surveillance plans reflecting national priorities.
- B8.** Participation in technical assistance and cooperation projects in market surveillance.
- B9.** Participation in standardization work at the national, regional and international level.

C. Best practices

- C10.** National enforcement plans reflecting surveillance priorities, for instance according to the UNECE “MS Model”.
- C11.** For national legislation and other documents related to market surveillance the terminology listed in the UNECE A Glossary of Market Surveillance Terms should be used.
- C12.** Availability of sector-specific surveillance plans and priorities.
- C13.** Enforcement methods comprising reactive and active surveillance techniques, as well as continuous follow-up routines.
- C14.** Methods for enforcement prioritization and surveillance prioritization, including risk assessment.
- C15.** Availability of information-technology tools for documentation, reporting, follow-up and statistical analysis of market surveillance activities.
- C16.** Penalties for economic operators are proportionate to the risks and dissuasive.
- C17.** Cooperation with stakeholders nationally (e.g. consumer and business organizations, industry, customs).
- C18.** Cooperation with other stakeholders internationally.
- C19.** Training of market surveillance officers and inspectors.
- C20.** Joint actions to assess risks of products as a basis for planning proactive market surveillance activities. Participation of non-EU countries should be supported.



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on
Regulatory Cooperation and
Standardization Policies

P ■ Crisis Management within a Regulatory Framework*

The Working Party on Regulatory Cooperation and Standardization Policies,

Recognizing the role of technical regulation, conformity assessment and market surveillance in preventing and addressing crises in various fields,

Noting that some risks are almost impossible to identify, and that all risks, even if identified, cannot be totally mitigated,

Recognizing the common interest of all regulatory stakeholders, including economic operators and consumers, in developing and applying tools that allow to effectively anticipate, and if necessary, resolve situations of crises,

Stressing that in many cases crises have led to imposing disproportionate regulations,

Underlining that risks that are identified and accepted within a regulatory system require developing or updating contingency plans that can be applied by regulators and other stakeholders,

Stressing that “crisis management” is an integral function of the risk management process of any regulatory framework¹⁶, and that effective preparedness and/or response to crises requires systemic management of risks, and vice versa,

* Recommendation adopted in 2011

Taking into account international and national standards related to risk management, such as, for example, ISO 31000:2009, AS/NZS 5050:2010, ISO 9001:2008 and ISO 27001:2005,

And with the objective of promoting a culture of responsible management of risks and increased preparedness for crises, including more effective coordination among all parties that can be involved in crises.

Recommends that:

P1. Regulatory authorities should recognize that there are situations which are beyond the capacity of normal organizational structures and processes. This situation can best be managed when sufficient resources are available and prior planning in accordance with available international best practice has been made.

P2. Regulatory authorities should design and implement crisis management functions as an integral part of the risk management process of a regulatory framework.

P3. Regulatory authorities, taking into account the internal and external context of a regulatory system, available resources, regulatory objectives, communication technologies, lessons learned, and other factors, should design the crisis management function so that it provides effective coordination of the actions taken by various stakeholders, including conformity assessment bodies, market surveillance authorities, economic operators and citizens in a situation of a crisis. The crisis management processes should permit managing the following phases: preparation for a crisis, stabilization, continuing critical functions, recovery and follow-up.

P4. Crisis management should be described in the legislation that establishes regulatory practice.

P5. A crisis management unit (or any other form of assigning responsibility for crisis management) functioning within a regulatory system should be endowed with the necessary resources, which may include:

- (a)** Access to emergency funding;
- (b)** People with the required skills, experience and competence;
- (c)** Tools, methods and supporting infrastructure for managing a crisis;
- (d)** Communication systems;
- (e)** Information and knowledge management systems.

P6. Regulatory authorities establish contingency plans and build contingent capacity that can be quickly released in a crisis as a tool to reduce the impact of a crisis situation. Regulators, in coordination with relevant stakeholders, develop, test and implement:

16 The definition of Crisis management is one that is used in the respective sector/industry.

(a) Generic contingency plans with general responses for risks, whether or not they were identified, to allow effective responses to any incidents in the early hours of a crisis;

(b) Where appropriate, specific contingency plans for risks identified and processed within the system.

Contingency plans specify¹⁷:

- i.** Version, date and issuing authority;
- ii.** Purpose and scope;
- iii.** Activation criteria;
- iv.** Cross-reference and linkages to other plans;
- v.** Roles, accountabilities and responsibilities;
- vi.** Process descriptions;
- vii.** Details for accessing resources;
- viii.** Communication and consultation requirements;
- ix.** Schedules of critical information including contact lists, maps and plans;
- x.** Description of possible techniques for:
 - Stabilization;
 - Continuing critical functions;
 - Recovery;
 - Implementation of lessons learned.
- (c)** Regulatory authorities as a part of implementation of contingency plans organise training for personnel to ensure that:
 - xi.** The staff is familiar with the procedures
 - xii.** The contingency plans are realistic, complete and uploaded.

P7. Regulatory authorities prepare communication and consultation processes as a part of crisis management in order to:

(a) Build awareness, confidence and understanding of crisis management processes by regulatory system stakeholders;

17 For details, please see AS/NZS 5050:2010.

- (b) Effectively exchange information and consult with stakeholders in situations of crises, in particular to provide information to stakeholders in early hours after the crisis occurs;
- (c) Encourage, where appropriate, the use of opportunities provided by alternative media.

P8. Regulatory authorities ensure that in situation of a crisis appropriate mechanisms are established for, at least, the following:

- (a) Providing immediate focus on affected individuals;
- (b) Launching of reliable data collection processes;
- (c) Activating a crisis management team (which may include subject experts, top management, crisis people, affected individuals, etc);
- (d) Organizing a follow-up to a crisis.

P9. In organizing a follow-up to a crisis, regulatory authorities should gather the related data and analyse the causes of the crisis, as well as effectiveness and relevance of actions taken during the immediate response period. Data related to a crisis constitute an input into regular risk identification performed within a regulatory framework¹⁸. Adoption and continuation of regulatory measures related to crisis are subject to the normal review processes.

P10. Regulatory authorities should participate in regional and international cooperation efforts and implement international best practice in the field of crisis management.

P11. Donors should give top priority to capacity-building activities for crisis management and contingency planning, especially to train officers responsible for technical regulation, conformity assessment and market surveillance activities.

¹⁸ See ECE/TRADE/C/WP.6/2011/4 (draft of the general recommendation “Risk Management in Regulatory Systems”).



UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE

Recommendations on regulatory cooperation and standardization policies

Working Party on
Regulatory Cooperation and
Standardization Policies

R ■ Managing Risk in Regulatory Frameworks*

The Working Party on Regulatory Cooperation and Standardization policies,

Recognizing that mitigating risk that may affect society and hamper economic development is an important goal for policy-making,

Underlining that risk management is an important tool for promoting regulatory convergence at international and regional levels,

Emphasizing the role of risk management in achieving sustainable development goals, Stressing that risk-management tools are essential to enhancing the efficiency of regulatory action and of regulatory systems,

Recognizing the need of regulatory authorities, standardization, conformity assessment and accreditation bodies, as well as market surveillance authorities, economic operators, consumers, as well as other regulatory stakeholders, in promoting coherent, consistent, efficient, effective and systemic application of risk management in regulatory systems,

Taking into account international standards related to the management of risk, such as ISO 31000:2009, ISO 9001:2008, ISO/IEC 17000:2004, and other standards, including sector-specific standards, such as ISO/IEC 27001:2005,

Underlining that regulation in many cases may not be the best response to risk, and that absolute safety cannot be a regulatory outcome, as it is impossible, as well as undesirable to make the world risk-free,

Stressing that risk management in regulatory frameworks:

- (a) Makes regulatory processes more transparent;
- (b) Represents a more proactive approach to regulation and to regulatory reform;
- (c) Forms the basis for the interaction among the stakeholders and is a tool to involving the stakeholders more closely in the regulatory processes;
- (d) Makes the functions of the system easier to understand;
- (e) Improves regulatory cooperation and harmonization at a regional and international level;
- (f) Is indispensable for increasing the efficiency and resilience of the regulatory system;

Recommends that:

R1. Regulatory authorities and other regulatory stakeholders should use the concept of “risk” to evaluate how balanced regulations are against two extremes:

- (a) Excessive or over regulation, i.e. regulations that are too stringent with respect to the risk they set out to address;
- (b) Insufficient regulations that fail to address risk and unnecessarily or inordinately expose citizens and economic operators to threats.

R2. All functions of the risk management process, as they are presented in the text of this recommendation, should be consistently described in legislation that lays out the regulatory framework at a general level or for a specific sector. Legislation should specify allocation of responsibilities for performing the risk management functions outlined in the model.

R3. Taking into account the level of risk tolerance of various regulatory stakeholders, regulatory authorities should establish, implement and maintain, a process for determining, analysing, reviewing and monitoring an acceptable level of risk within a regulatory framework.

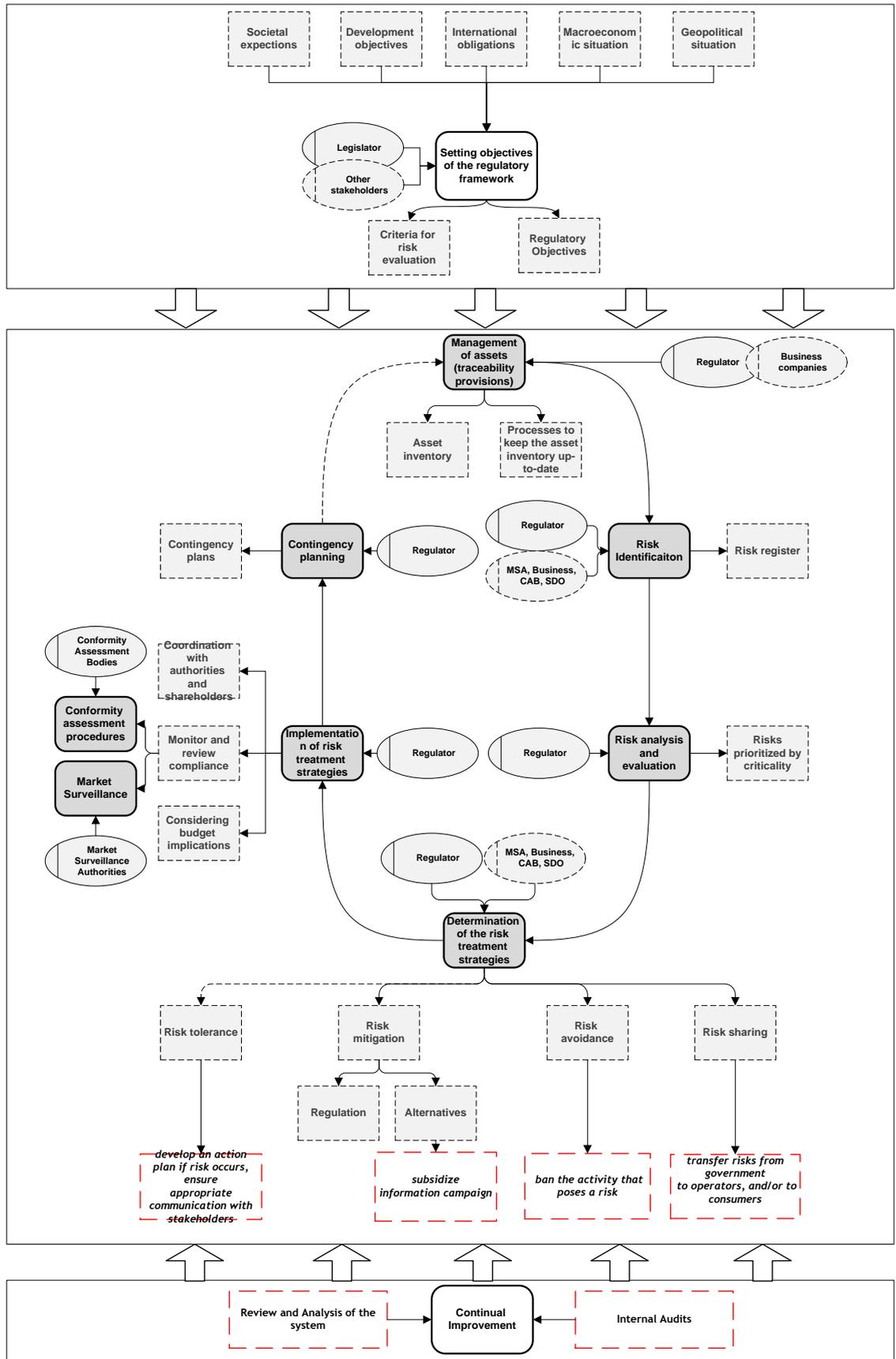
R4. Regulatory stakeholders, as well as international organizations and other interested parties, should apply the following criteria when evaluating regulatory systems:

* Recommendation adopted in 2011

- (a) Risks are timely identified, and identification covers as many risks as possible including rare risk events and emerging risks and takes into account their relationships;
- (b) Taking into account the different risk perceptions of the involved stakeholders, risks are properly analysed and evaluated and the most critical risks are given the highest priority;
- (c) Balanced risk treatment is chosen;
- (d) Risk treatment is efficiently implemented;
- (e) Ongoing monitoring of risk treatment strategies through regulatory activities is carried out and is effective;
- (f) Contingency plans are developed, tested and remain relevant; resources are available to implement them.

R5. Where appropriate, regulatory authorities implement the following functions within regulatory frameworks described in the explanatory remarks below:

- (a) Setting the regulatory objectives;
- (b) Management of assets (traceability provisions): identifying and managing the assets being protected;
- (c) Identifying the risks to these assets;
- (d) Analysing and evaluation the most important risks;
- (e) Choosing risk treatment strategies;
- (f) Implementing risk treatment strategies;
- (g) Crisis management (including developing a plan to deal with disruption related risk);
- (h) Monitoring, reviewing and improving the risk management process.



R.5.1. Setting objectives of the regulatory framework

The system is based on the regulatory objectives identified by the regulator. Regulatory and societal objectives are used for setting the criteria against which the risk is evaluated. Absolute safety is not regarded as a regulatory goal. Appropriate criteria are selected to decide which risks are tolerable, and risk tolerance is used as a method for achieving a regulatory balance. The regulatory objectives are drawn up in consultation with all relevant stakeholders.

R.5.2. Management of assets (traceability provisions) within regulatory frameworks

A process of communication and consultation of regulators with stakeholders sets out to identify the relevant assets or objects, which the framework sets out to protect. One of the ways in which the communication process can be structured is by introducing traceability requirements, so that where appropriate products on the market can be traced back. It allows regulatory stakeholders to get information on processes, original materials and components used in the production.

R.5.3. Risk identification

Risks are identified starting with the most crucial ones. Regulators cooperate effectively with other stakeholders in identifying risks, as it increases the resilience of the framework by reducing the chances that certain risks might be overlooked. All stakeholders in the system are allowed to participate in identifying risks for the following reasons:

- (a)** Not only regulations but also voluntary standards help business and society deal with risk. National Standards development organizations can provide important input for risk identification;
- (b)** For market-surveillance authorities, properly identifying the risks that products placed on the market may cause is a prerequisite for developing timely and appropriate measures and ensuring marketplace safety;
- (c)** Conformity-assessment procedures act as risk mitigation tools by reducing the risk of placing dangerous products on the market. Conformity-assessment bodies see the risks that the regulator may not be able to identify;
- (d)** Business operators may also inform the regulator about risks that in their view require regulatory intervention.

R.5.4. Risk analyses and risk evaluation

No matter from which source the regulator or other stakeholder learns about a risk, a risk analyses and evaluation must follow, ranking the risk according to its seriousness. This step ensures that critical risks are dealt with in a timely manner.

If the regulator is not willing or is unable to take measures to reduce the probability of the expected impact of a risk, it should consider if and how this information should be communicated to relevant parties. It should also become an input into the contingency planning function;

R.5.5. Determining a risk treatment strategy

On the basis of the results of the risk assessment, and acting in consultation with the systems' stakeholders, the regulator chooses an appropriate risk management treatment. This can be:

- (a)** Avoiding the risk by banning activities or processes where it has occurred;
- (b)** Sharing the responsibility for managing the risk, including bearing responsibility if it occurs, to economic or social actors (families, firms);
- (c)** Mitigating the risk: developing a regulatory or non-regulatory response to reduce the probability and the expected impact of a risk:
 - (i)** A regulatory action implies not only developing a new or reforming an existing regulation, but also choosing appropriate conformity-assessment procedures and market-surveillance measures;
 - (ii)** Non-regulatory action, on the other hand, includes options such as educational or information campaigns, and subsidies or incentives to economic operators' activities.

R.5.6. Implementing the risk treatment strategy

Implementing risk-management treatment within a regulatory framework, regardless of the strategy chosen, requires monitoring compliance, evaluating the effect of a risk management treatment on other regulatory processes, other stakeholders and areas of activities. This involves:

- (a)** Integrating the regulatory and other measures with existing ones;
- (b)** Performing regulatory impact assessment;
- (d)** Establishing coordinating mechanisms among competent authorities and stakeholders;
- (e)** Giving guidance and establishing an appropriate budget for the institutions responsible for monitoring compliance (conformity assessment and/or market surveillance authorities);

- (f) Deciding on penalties for non-compliance.

R.5.7. Crisis management

Since there are risks that are unavoidable and some are almost impossible to forecast, the regulator prepares a plan setting out: if the harm associated with the risk occurs, what is to be done, who should do it and how. The need for developing contingency plans to manage disruption related risk is widely recognized; however, these will be only be efficient if they are prepared within a framework where contingency planning is an integral part of risk management treatment.

R.5.8. Monitoring and review of the system

Regulators or other interested parties also run processes necessary for continual improvement of the risk management processes implemented within a regulatory framework. These may include performing regular internal audits, analysis and review of processes and methodologies that function within the whole system. The purpose of these activities is to raise the efficiency of process interfaces and to provide common understanding of the regulatory system policy among all regulatory stakeholders.

General implementation principles

The Working Party trusts that:

R6. The reference model set out here provides an overview of how the risk management process can be used in designing regulatory frameworks. It could serve as a concept model for initiating a set of projects with an overall objective of increasing the maturity of risk management application throughout regulatory frameworks.

R7. The recommendation describes the model which can be applied in three interdependent set of activities:

- (a) Developing recommendations on implementing risk-management tools in the activities of each of the regulatory stakeholders;
- (b) Developing specific recommendations on each of the functions of the risk-management process;
- (c) Developing a comprehensive methodology for managing risks within a regulatory framework.

R8. The implementation of this recommendation by Member States will be an important step in promoting regulatory convergence. For example, the recommendation can be used to structure the international regulatory cooperation, across the board as well as in specific sectors. Consistent application of risk management tools in regulatory frameworks will allow regulators to use the target level of risk as one of the tools for proving equivalency of technical regulations.

R9. Regulatory authorities participate in regional and international cooperation efforts and implement international best practice in the field of risk management in regulatory frameworks.

R10. Donors give priority consideration to capacity-building activities related to the management of risks within regulatory frameworks, especially to train officers responsible for technical regulation, conformity assessment and market surveillance activities.