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Committee on Technical Barriers to Trade

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## IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE

### COMMUNICATION FROM COLOMBIA

#### *Supplement*

The following communication, dated 6 October 2015, is being circulated at the request of the delegation of Colombia.

1.1. In accordance with Article 15.2 of the WTO Agreement on Technical Barriers to Trade (TBT Agreement) and the transparency commitments undertaken by Colombia, the Government of the Republic of Colombia hereby informs the Committee on Technical Barriers to Trade of the following measures relating to standardization, technical regulations, accreditation, conformity assessment and metrology, as well as implementation and administration of the TBT Agreement:

1.2. On 5 August 2015, the National Government issued Decree No. 1595 "*Adopting regulations for the National Quality Subsystem and amending Chapter 7 and Section 1 of Chapter 8 of Title 1 of Part 2 of Book 2 of the Single Decree Regulating the Commerce, Industry and Tourism Sector, Decree No. 1074 of 2015, and adopting other provisions*", which came into force on 6 October 2015. The following are among its provisions:

#### **ARTICLE 1.1.3.19 Colombian Technical Standards and Certification Institute – ICONTEC**

The Colombian Technical Standards and Certification Institute – ICONTEC – shall be the body responsible to the National Government for evaluation and coordination in the area of technical standardization; (...)

#### **ARTICLE 1.1.3.20 National Accreditation Organization**

Colombia's National Accreditation Organization – ONAC – shall be the entity responsible for accrediting the technical competence of conformity assessment bodies. (...)

### **1 CHAPTER 7: NATIONAL QUALITY SUBSYSTEM**

#### **1.1 SECTION 1: GENERAL PROVISIONS**

##### **Article 2.2.1.7.1.1 Purpose**

The purpose of this Chapter is to restructure the National Quality Subsystem – SNCA in relation to standardization, technical regulations, accreditation, conformity assessment, metrology, monitoring and control. (...)

##### **ARTICLE 2.2.1.7.1.5 Objectives of the SNCA**

The following are the basic objectives of the National Quality Subsystem (SNCA):

1. To promote the safety, quality, trustworthiness, innovation, productivity and competitiveness of production sectors and importers of products in the market.
2. To protect the interests of consumers.
3. To facilitate market access and trade.

4. To assist the system's users to protect the health and life of persons and animals and the conservation of plants.
5. To protect the environment and national security.
6. To prevent practices likely to mislead consumers.

## 1.2 SECTION 2: DEFINITIONS

### ARTICLE 2.2.1.7.2.1 Definitions

Without prejudice to the provisions in Andean decisions and legislation, for the purposes of this Chapter the definitions below shall be used and, where these differ from the definitions in ISO/IEC, BIPM or OIML international standards, including VIM and VIML, the latter shall prevail: (...)

*Legal time in the Republic of Colombia.* This is the legal time in effect throughout the territory of the Republic of Colombia, determined by the National Government and disseminated by the National Institute of Metrology. (...)

*Regulatory impact analysis report (RIA).* Document to be drawn up by the competent regulatory authorities in order to summarize the procedure and the results obtained from the regulatory impact analysis when preparing and issuing technical regulations, based on the format laid down by the Ministry of Commerce, Industry and Tourism. (...)

*List of problem areas.* Document identifying the products associated with the major problems jeopardizing Colombia's legitimate objectives under the WTO Agreement on Technical Barriers to Trade, to be used as input when preparing the Annual Regulatory Impact Analysis Plan – PAAIN. (...)

*Colombian technical standard.* Technical standard approved or adopted as such by Colombia's National Standardization Organization.

*International standard.* Technical standard adopted by an international standardization organization and made available to the public. (...)

*Conformity certificates information system – SICERCO.* Public register administered by the Supervisory Authority for Industry and Trade in which accredited certification and inspection bodies register the conformity certificates and inspection reports, as applicable, issued by them for products subject to compliance with technical regulations monitored by the Supervisory Authority.

*SUIN – JURISCOL.* Single System of Regulatory Information of the Colombian State, administered by the Ministry of Justice and Law. (...)

## 1.3 SECTION 3: STANDARDIZATION

### ARTICLE 2.2.1.7.3.1 Standardization

Colombia's technical standardization shall be developed by the National Standardization Organization, which shall have the responsibilities set out in this Chapter.

The Colombian Technical Regulations and Certification Institute – ICONTEC shall act as the National Standardization Organization. (...)

### ARTICLE 2.2.1.7.3.9 Incorporation of technical standards in technical regulations

Where a Colombian technical standard is utilized as a whole or in part as the basis for a technical regulation or other mandatory measure, the regulatory entity may incorporate it in full or in part in the technical regulation or in another mandatory measure. For these purposes, the National Standardization Organization shall supply the corresponding standard. (...)

## 1.4 SECTION 5: TECHNICAL REGULATIONS

### ARTICLE 2.2.1.7.5.1 Guidelines for technical regulations

Regulatory entities shall adopt good technical regulation practices in such a way that they have neither the intention nor the effect of creating unnecessary obstacles to trade.

The provisions contained herein supplement those on transparency, consultations and good international practices.

**ARTICLE 2.2.1.7.5.2 Reference to national and international technical standards**

Technical regulations shall be based on international technical standards. Likewise, national technical standards harmonized with international technical standards may serve as a reference for technical regulations. The foregoing shall apply unless one or the other proves ineffective or inappropriate for the protection of the legitimate objectives indicated in the World Trade Organization's Agreement on Technical Barriers to Trade. In such cases, the technical regulation shall be backed up by scientific evidence. (...)

**ARTICLE 2.2.1.7.5.6 Request for a prior opinion**

In order to proceed with notifying a draft technical regulation or conformity assessment procedure, in the terms of the World Trade Organization's Agreement on Technical Barriers to Trade, regulatory entities shall seek the opinion of the Department of Regulation of the Ministry of Commerce, Industry and Tourism as regards compliance with the guidelines of the National Quality Subsystem and the potential for creating unnecessary technical barriers to trade with other countries. Such a request shall be accompanied by a list of problem areas and the PAAIN. (...)

**ARTICLE 2.2.1.7.5.10 Notification**

All draft technical regulations and conformity assessment procedures shall be notified through Colombia's enquiry point to Members of the World Trade Organization, the Andean Community and countries with which Colombia has signed trade agreements in force which contain a notification clause.

For this purpose, each regulatory entity shall send to the Department of Regulation of the Ministry of Commerce, Industry and Tourism the draft technical regulation or conformity assessment procedure for the corresponding notification. Any amendments to draft technical regulations or conformity assessment procedures shall also be notified if their impact makes the situation more onerous for the person regulated or for users.

Paragraph 1. Any amendment or addition to the content of a technical regulation that has not been notified shall require notification of the technical regulation in full.

Paragraph 2. After a technical regulation has been issued, the regulatory entity shall forward the corresponding administrative act to Colombia's TBT/SPS enquiry point for notification.

Paragraph 3. Pursuant to Article 72 of Law No. 1480 of 2011, no technical regulation may be published in the Official Journal, and consequently may not enter into force, without the certification issued by Colombia's TBT/SPS enquiry point, except for the adoption of emergency or urgent technical regulations. (...)

**ARTICLE 2.2.1.7.5.13 Determination of equivalence**

Regulatory entities shall have authority to determine the equivalence of technical regulations, following a technical study substantiating it. If new equivalence is found subsequent to the issue of a technical regulation, the regulator responsible shall incorporate it into the technical regulation by means of an amendment thereto. (...)

**1.5 SECTION 6: PREPARATION AND ISSUE OF TECHNICAL REGULATIONS****ARTICLE 2.2.1.7.6.6 Risk levels**

In analysing the regulatory impact, regulatory entities shall identify and define the risks according to the appropriate levels of protection relating to the legitimate objectives. Risk levels are classified as follows:

Low risk: Little likelihood of occurrence and low impact.

Medium risk: High likelihood of occurrence and low impact or low likelihood of occurrence and high impact.

High risk: High likelihood of occurrence and high impact.

If the measure to be adopted is a technical regulation, except in special and justified cases identified by the regulator, the risk level identified in the regulatory impact analysis shall be used as a general criterion when determining conformity, for example:

1. Low risk: First party conformity declaration according to the terms and conditions in Colombian Technical Standard NTC-ISO/IEC 17050, parts 1 and 2, and updates or amendments thereto; and
2. Medium and high risk: Third party Conformity Certificate by accredited body.

**Paragraph.** With the submission of a first party conformity declaration, it is assumed that the declarant has itself undertaken the verification, inspection and testing required by the technical regulation and shall, therefore, be responsible for the products' conformity with the specific requirements in the pertinent technical regulation, in accordance with NTC-ISO/IEC 17050 – parts 1 and 2 and updates or amendments thereto. (...)

## 1.6 SECTION 7: ACCREDITATION

### ARTICLE 2.2.1.7.7.1 Purpose of accreditation

The purpose of accreditation is to issue a third party declaration regarding a conformity assessment body which provides formal proof of its competence to conduct specific conformity assessment activities.

### ARTICLE 2.2.1.7.7.3 Function of the National Accreditation Organization

The principal function of the National Accreditation Organization is to provide accreditation services to conformity assessment bodies, in accordance with national and international accreditation standards whose scope includes technical regulations, technical standards and other regulatory documents. (...)

### ARTICLE 2.2.1.7.7.5 Recognition of accreditation

Accreditation shall be recognized within the National Quality Subsystem – SNCA provided that it has been granted by Colombia's National Accreditation Organization or by public bodies which legally exercise such responsibilities, or by foreign accreditation bodies recognized under multilateral recognition agreements, as provided in Section 9 of this Chapter.

### ARTICLE 2.2.1.7.7.6 Representation by the National Accreditation Organization

Colombia's National Accreditation Organization shall represent and act on behalf of Colombia in the Andean Community and multilateral accreditation forums and shall take part in regional and international institutions and activities involved in accreditation, without prejudice to the competence of government bodies in this sphere. (...)

## 1.7 SECTION 8: CONFORMITY ASSESSMENT BODIES

### ARTICLE 2.2.1.7.8.1 Action by conformity assessment bodies

Conformity assessment bodies situated in Colombia shall be accredited by the National Accreditation Organization by means of a regulatory document for the purpose of conducting conformity assessment activities in respect of a technical regulation, for example, certification, inspection, sampling/testing and calibration, or the conduct of proficiency tests and other accreditation activities. If the National Accreditation Organization does not possess the technical competence to accredit a body in a particular field, it may turn to the system defined for cross-border accreditation in order to provide the service in Colombia. Conformity assessment bodies situated abroad shall be subject to the provisions in Article 2.2.1.7.9.2, paragraphs 2, 3 and 4 of this Decree.

**Paragraph.** Entities which have engaged in advisory or consultancy work for the same natural or legal person in relation to any aspect concerning the subject of the conformity assessment may not conduct certification and inspection activities.

### ARTICLE 2.2.1.7.8.2 Issue of conformity certificates

Certification bodies shall issue a conformity certificate after examining compliance with the specified requirements. Supporting documents for the issue of certificates of conformity with technical regulations shall contain as a minimum: objective proof of verification of all the requirements specified for the technical regulation, with the corresponding documentary records, the testing methods, the sampling programme, the results of the assessment, identification of the products or categories of product, the period and scheme of certification used, in accordance with NTC-ISO/IEC 17067 or its replacement. (...)

## 1.8 SECTION 9: CONFORMITY ASSESSMENT PROCEDURE

### ARTICLE 2.2.1.7.9.2 Procedure for assessing the conformity of products

Pursuant to the World Trade Organization's Agreement on Technical Barriers to Trade, prior to marketing, domestic producers and importers of products subject to technical regulations shall obtain the relevant conformity certificate, which shall be valid in Colombia provided that it has been obtained using one of the following alternatives:

1. It has been issued by a certification body accredited with the National Accreditation Organization and the scope of accreditation includes the product and the technical regulation.
2. It has been issued by a foreign certification body, accredited by an accreditation body recognized under the multilateral recognition agreements to which Colombia's National Accreditation Organization is party, provided that the issuing country accepts Colombian certificates for domestic products. The Ministry of Commerce, Industry and Tourism shall be responsible for regulating this aspect. The regulatory entity may require an additional verification procedure at the national level.
3. It has been issued by a certification body accredited by an accreditation body recognized under a multilateral recognition agreement to which the National Accreditation Organization is not party. Such conformity certificates may be recognized subject to evaluation by certification bodies accredited in Colombia whose scope includes the product and technical regulation. The certification body accredited in Colombia shall verify the scope of the accreditation and may declare conformity with the requirements specified in the corresponding Colombian technical regulation and those accepted as equivalents. The conformity assessment body in Colombia which recognizes the results of conformity assessment issued by a foreign accredited conformity assessment body shall prove to the National Accreditation Organization that it has an agreement with its counterpart guaranteeing its competence to carry out the conformity assessment abroad.
4. It has been issued under a mutual recognition agreement signed between Colombia and another country and in force.

**Paragraph 1.** It shall be understood that a conformity assessment body which recognizes the certificates of a third party shall assume responsibility for such certificates so that it has the same responsibilities as those for certificates it issues directly.

**Paragraph 2.** Regulatory entities shall include in technical regulations the alternatives provided in this Article and shall determine the documents valid, together with an applicable NTC-ISO/IEC 17067 certification scheme to prove the product's conformity with the relevant technical regulation.

**Paragraph 3.** Domestic producers and importers of products subject to technical regulations in force which do not specify the type of conformity certificate shall apply one of the schemes determined in NTC-ISO/IEC 17067 and additions or amendments thereto, as well as the provisions in this Article.

**Paragraph 4.** If a conformity certificate issued in accordance with this Article proves compliance with a normative reference which partly fulfils the requirements laid down in a technical regulation, compliance with the technical regulation's remaining requirements shall be proved using any of the methods provided in this Chapter. In any event, the products may not be marketed or made available to third parties under any circumstances until the certificate proving full compliance with the technical regulation has been issued by a competent body in accordance with the provisions in this Chapter.

After the conformity certificate has been obtained, the importer shall attach it to the import licence or registration when submitting it to the Single Window for Foreign Trade – VUCE. (...)

## 1.9 SECTION 11: SCIENTIFIC AND INDUSTRIAL METROLOGY

### ARTICLE 2.2.1.7.11.1 National authority for scientific and industrial metrology

National Institute of Metrology – INM shall be the authority responsible for coordinating the conduct of scientific and industrial metrology at the national level, in accordance with the provisions in Decree No. 4175 of 2011.

The National Institute of Metrology shall provide laboratories, research centres and industry with reference materials, proficiency testing/inter-laboratory comparison and calibration with measurement standards if these cannot be provided by accredited laboratories or service suppliers composing the network. (...)

#### **ARTICLE 2.2.1.7.11.6 Dissemination and disclosure of the International System of Units – SI**

The National Institute of Metrology – INM shall be responsible for disseminating metrological traceability to the International System of Units – SI and for its disclosure, meaning the base and derived units defined by the General Conference on Weights and Measures.

In order to ensure the disclosure and dissemination of the International System of Units, the National Institute of Metrology – INM shall determine with the competent authority the mechanisms needed to facilitate import and export procedures for measurement standards, artefacts, measuring instruments, specimens, reference material and inputs for production, for its exclusive use.

Paragraph. After hearing the opinion of the National Institute of Metrology – INM, the Supervisory Authority for Industry and Trade shall determine the use of customary measuring units that do not form part of the International System of Units – SI, which shall be expressed in units of measurement of both systems. (...)

#### **ARTICLE 2.2.1.7.12.6 Legal time in the Republic of Colombia**

In accordance with the indications in paragraph 14 of Article 6 of Decree No. 4175 of 2011, the National Institute of Metrology – INM shall be responsible, *inter alia*, for maintaining, coordinating and disseminating legal time in the Republic of Colombia. Accordingly, companies, entities or organizations whose services communicate or make use of it in any way shall utilize the legal time coordinated by the INM. (...)

### **1.10 SECTION 14: LEGAL METROLOGY**

#### **ARTICLE 2.2.1.7.14.1 Metrological control authorities**

The Supervisory Authority for Industry and Trade shall have competence for drawing up and issuing metrological technical regulations for measuring instruments subject to metrological control.

The Supervisory Authority for Industry and Trade and municipal authorities shall exercise metrological control directly or with the support of authorized metrological verification bodies and/or conformity assessment bodies in the territory under their jurisdiction. Likewise, when the Supervisory Authority for Industry and Trade decides to carry out metrological control campaigns in certain regions of the country, it shall coordinate with local authorities the controls and inspections deemed necessary.

The Supervisory Authority for Industry and Trade may also utilize the technological and informatics tools it deems necessary in order to ensure appropriate metrological control and shall determine the manner in which producers, importers, repairers and those responsible for measuring instruments shall forward information to the system.

Monitoring by the Supervisory Authority for Industry and Trade in relation to metrological control shall also cover those in possession of measuring instruments, repairers, authorized metrological control bodies and conformity assessment bodies. (...)

#### **ARTICLE 2.2.1.7.14.3 Measuring instruments subject to metrological control**

Measuring instruments used for measuring, weighing or counting and having the following as their purpose, *inter alia*, shall be subject to compliance with the provisions in this Chapter:

1. Engaging in trade transactions or determining the price of services.
2. Remunerating or calculating professional work in any way.
3. Providing public at-home services.
4. Engaging in activities that may affect life, health or physical integrity, national security or the environment.
5. Providing expertise, carrying out judicial or administrative acts.
6. Assessing the conformity of products and facilities.



7. Determining the quantity of components of a product whose price or quality depends on those components. (...)

**ARTICLE 2.2.1.7.15.6 Obligation to register**

Pursuant to the provisions in Article 17 of Law No. 1480 of 2011, prior to introducing or importing products subject to a technical regulation, any producer or importer shall register with the Register of Producers and Importers of products subject to compliance with technical regulations, established by the competent authority for this purpose.

**1.11 SECTION 16: VOLUNTARY CONFORMITY ASSESSMENT**

**ARTICLE 2.2.1.7.16.1 Voluntary conformity assessment**

Conformity certification within the National Quality Subsystem may be obtained for goods and services not subject to technical regulations.

**ARTICLE 2.2.1.7.16.2 Quality of transactions**

Compliance with technical standards and the use of conformity certificates issued by the accredited bodies referred to in this Chapter may be required for commercial or administrative transactions.

**1.12 SECTION 17: SUPERVISION AND CONTROL**

**ARTICLE 2.2.1.7.17.1 Powers of the Supervisory Authority for Industry and Trade**

The Supervisory Authority for Industry and Trade shall undertake the relevant administrative investigations into conformity assessment bodies in respect of compliance with requirements applicable to the conformity certificates or conformity assessment documents they have issued in connection with government procurement-related technical regulations or technical standards.

The Supervisory Authority for Industry and Trade shall also undertake the relevant administrative investigations into metrological control bodies; authorized repairers which fail to comply with the responsibilities incumbent upon their function; producers, importers, dealers and those responsible for measuring products or instruments, for failure to comply with their obligations laid down in this Chapter or in the relevant technical regulations.

The foregoing in accordance with the provisions in Articles 73 and 74 of Law No. 1480 of 2011.

The Supervisory Authority for Trade and Industry, in exercise of the powers conferred by Law No. 1480 of 2011, may undertake investigations into persons which, when importing or marketing products subject to government procurement-related technical regulations or technical standards, submit conformity certificates, declarations of conformity or results of laboratory tests in respect of which there is a suspicion of deception or adulteration and, as a result of such investigations, may impose the sanctions provided in Article 61 of Law No. 1480 of 2011. The foregoing without prejudice to the corresponding criminal proceedings. (...)

**ARTICLE 2.2.1.7.17.5 Creation of the Conformity Certificates Information System - SICERCO**

The Conformity Certificates Information System - SICERCO is hereby created, to be administered by the Supervisory Authority for Industry and Trade, in which certification and inspection bodies accredited by the National Accreditation Organization shall register electronically all the conformity certificates they issue for products subject to compliance with technical regulations. The Supervisory Authority for Industry and Trade shall be responsible for regulating the System.

The Conformity Certificates Information System – SICERCO is a public register and may be consulted on the website of the Supervisory Authority for Industry and Trade.

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