

[seal -- Chief,
For. Trade Dept.]

**REGULATIONS IMPLEMENTING
TITLE I OF LAW 19,912 AND
REQUIREMENTS FOR THE
PREPARATION, ADOPTION AND
APPLICATION OF TECHNICAL
REGULATIONS AND CONFORMITY
ASSESSMENT PROCEDURES**

[seal – Legal Counsel]

SANTIAGO, February 25, 2004

No. 77 /

PURSUANT TO: Article 32(8) of the Political Constitution of the Republic of Chile; the Agreement on Technical Barriers to Trade of the World Trade Organization, which resulted from the Uruguay Round of Multilateral Trade Negotiations ratified by the Chilean Congress and promulgated through Supreme Decree No. 16 of 1995 of the Ministry of Foreign Relations; and Article 5 of Law No. 19,912 bringing said legislation into compliance with the World Trade Organization Agreements signed by Chile; and

WHEREAS:

The Ministry of Economy, Development and Reconstruction is the Chilean entity responsible for administering the World Trade Organization Agreement on Technical Barriers to Trade (“TBT Agreement” of Annex IA of the WTO Agreement), hereinafter the TBT Agreement, and the Point of Contact on bilateral or regional agreements relating to these subjects;

It is necessary to ensure fulfillment of the obligations derived from this Agreement and related bilateral or regional agreements on the preparation, adoption and application of technical regulations and the respective conformity assessment procedures;

It is necessary to establish criteria for preparing, adopting and applying the technical regulations and conformity assessment procedures relating to those regulations in order to ensure that they do not become unnecessary technical barriers to trade.

T/R 03.06.04

[seal – REGISTRY
UNDERSECRETARIAT OF
ECONOMY, DEVELOPMENT
AND RECONSTRUCTION
08 JUN 2004
PROCESSING DESK

[seal – REGISTRY
OFFICER w/
initials]

[seal – Undersecretary
of Economy
w/ initials]

DECREE

SCOPE

Article 1. These regulations shall be applied in the preparation, adoption and application of technical regulations and conformity assessment procedures in a manner consistent with the provisions of the TBT Agreement.

The term “adoption” is used to refer to the point in time at which the legal processing of technical regulations and/or conformity assessment procedures has been completed and they are published in the Official Gazette.

The word “application” is used to refer to the point in time as of which compliance with a technical regulation or conformity assessment procedure may be required.

In the event that laws establish special procedures, this decree shall be applied on a supplemental basis.

The following definitions shall apply for the purposes of this decree:

Technical regulation: A directive, compliance with which is mandatory, whereby the competent authority, through an administrative action, establishes the characteristics of a product or the production processes or methods relating to the product, including applicable administrative provisions. It may also include, or exclusively address, requirements in the areas of terminology, symbols, packaging, branding or labeling applicable to a product, production process or method. Preparation, adoption and application shall be the responsibility of the respective Ministries or agencies duly authorized for this purpose.

Conformity assessment procedure: Any procedure used, directly or indirectly, to determine that relevant requirements for technical regulations are fulfilled. Conformity assessment procedures include procedures for sampling, testing and inspection; evaluation, verification, and assurance of conformity; and registration, accreditation and approval, whether separately or in different combinations.

PRINCIPLES

Article 2. When technical regulations and/or conformity assessment procedures are needed and relevant international standards already exist or their final formulation is imminent, the Ministries or agencies duly authorized to adopt them shall use those international standards or the relevant parts of them as the basis for their technical regulations or procedures except in the case where such institutions believe that those international standards or the relevant parts thereof are not an effective or appropriate means for achieving legitimate objectives pursued. It shall be understood that the adoption of international standards as national fulfills the requirements of this article.

[seal – Undersecretary
of Economy
w/ initials]

Article 3. Technical regulations and/or conformity assessment procedures shall not restrict trade more than is necessary to achieve legitimate objectives, taking into account the risks that not achieving them would create. Such objectives include national security requirements, protection of human health or safety, protection of animal or plant life or health, or protection of the environment or the prevention of potentially deceptive practices. Relevant elements to be considered when evaluating these risks include, *inter alia*, available scientific and technical information, related processing technology or the intended end uses of products.

Article 4. Technical regulations shall be prepared, adopted and applied so that imported products are accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country. In addition, conformity assessment procedures shall be prepared, adopted and applied so as to grant access to suppliers of like products originating in other countries under conditions that are no less favorable than those accorded to the suppliers of like products of national origin or like products originating in any other country, under comparable circumstances.

Article 5. Whenever appropriate, technical regulations based on product requirements shall be defined on the basis of properties in terms of product performance rather than on the basis of product design or descriptive characteristics.

PROCEDURES

Article 6. The preparation, adoption and application of technical regulations and/or conformity assessment procedures, as well as amendments thereto, shall be subject to the following provisions:

- (a) Except as provided in Article 7, the Ministry or agency with regulatory powers shall publish, through a notice placed in a communications medium with national distribution or on its web site, the draft technical regulation or conformity assessment procedure it is proposing to adopt.
- (b) The above-mentioned notice must include, at the least, an abstract of the draft technical regulation or conformity assessment procedure and in such case must indicate the place where the complete text can be consulted. The abstract must indicate the purpose of the draft regulation or procedure and the reasons for the approach adopted. Copies of the abstract and the draft regulation must at the same time be submitted to the Ministry of Economy, Development and Reconstruction for the purposes established in Article 9.
- (c) As of the date the notice indicated in (a) above is published, the competent authority must keep on file for access by interested parties a report which must contain a succinct explanation of the purpose of the measure that it wants to implement and its

content; of the alternatives considered and the reasons for rejecting them; a description of the advantages and disadvantages and technical feasibility of verifying compliance with the measure; and the existence of applicable international standards on the subject.

(d) The notice indicated in (a) above must be published sufficiently in advance of the date the measure is adopted so that anyone can submit written comments within a period of no less than 60 days, attaching any background material he or she deems necessary.

The Ministry or agency with regulatory powers shall analyze and take into account said written comments. In addition, it must make available to the public the responses to any significant comments it received, at the same time as the final technical regulation or conformity assessment procedure is published.

Notwithstanding the provisions of the preceding paragraph, the competent authority shall in no way be required to provide confidential information whose disclosure could constitute an obstacle to compliance with laws, could be otherwise contrary to the public interest, or could damage the legitimate commercial interests of public or private companies.

(e) Technical regulations and/or conformity assessment procedures must allow a reasonable time between the date of their adoption and their application. A reasonable time shall be understood to mean a period of no less than six months, except when this would be an ineffective means for achieving legitimate objectives.

Article 7. In the event that duly substantiated urgent problems relating to safety, health, environmental protection or national security arise or threaten to arise, the Ministry or agency with regulatory powers may omit the steps provided for in the preceding article and must inform the Ministry of Economy, Development and Reconstruction that the regulations are being put into effect.

Article 8. Notwithstanding the provisions of the preceding article, once technical regulations and/or conformity assessment procedures have been adopted in the cases indicated in that article, the competent authority must provide sufficient opportunities for anyone to submit written comments, attaching the background material he or she deems necessary.

The Ministry or agency with regulatory powers shall analyze the comments received and take said written comments into account. In addition, it must make available to the public responses to any significant comments it received.

Article 9. The Ministry of Economy, Development and Reconstruction must comply with the relevant measures for notifying other members of the World Trade Organization of draft regulations and/or conformity assessment procedures and for receiving comments from them, as established in Article 2, paragraph 9; Article 3,

paragraphs 2 and 3; Article 5, paragraph 6; and Article 7, paragraphs 2 and 3 of the TBT Agreement, as applicable.

Except in the cases indicated in Article 7, those technical regulations and/or conformity assessment procedures that are reported to the World Trade Organization in accordance with the above-mentioned provisions may be issued by the authorized agencies only after at least 60 days have elapsed since they were reported to the WTO by the Ministry of Economy, Development and Reconstruction, which event shall be reported on a timely basis by that Ministry.

Under the situations described in Article 7, the Ministry of Economy, Development and Reconstruction must comply with the measures for reporting regulations and/or conformity assessment procedures and receiving comments, as established in Article 2, paragraph 10; Article 3, paragraphs 2 and 3; Article 5, paragraph 7; and Article 7, paragraphs 2 and 3 of the TBT Agreement, as applicable.

Article 10. Technical regulations and/or conformity assessment procedures must include the following information, as applicable:

- (a) Identification of the product, including its classification according to the Harmonized Commodity Description and Coding System (HS), and the purpose of the measure;
- (b) Specifications and characteristics relating to the product, method or process established in the regulations in accordance with its purpose;
- (c) Conformity assessment methods;
- (d) Data and other information products must display, or if not applicable, then packaging or packing and labeling requirements, as well as the size and characteristics of the various labels, as appropriate;
- (e) The degree of conformity with international standards and guidelines used as the basis for preparing them;
- (f) Designation of the institution or institutions that will monitor compliance with the regulations, with the understanding that this requirement is also considered satisfied when the technical regulation makes reference to some legal provision in which the supervisory institution is identified; and
- (g) Other information deemed necessary for the proper understanding and scope of the regulation.

The requirement of including one or more of the items of information identified above shall be considered to have been met when they are contained in one or more of the

standards to which the technical regulation or conformity assessment procedure makes reference..

Article 11. Technical regulations and/or conformity assessment procedures that are adopted must have the following supporting documentation, which shall be available to anyone who requests them:

- (a) Technical bases for the authority's decision, including the targeted policy objectives and a description of how the technical regulation will contribute to their achievement;
- (b) Description of the options analyzed by the responsible authority and their advantages and disadvantages, including background information relating to the most relevant international practices, as well as reasons explaining the decision that was made;
- (c) Process for receiving comments, including a description of the stages in the process starting with the published notice that initiated the process, [and] a list of institutions that participated in the preparation of the technical regulation;
- (d) A description of changes made to the original draft as a result of the comments process;
- (e) A description, at least in qualitative terms, of the potential impact on the domestic market, costs of implementation, and compliance-monitoring costs;
- (f) A description, at least in qualitative terms, of the impact on small and medium-sized enterprises, as applicable; and
- (g) The responses to the comments received during the period for commenting, in accordance with the provisions of Article 6(d) and Article 8 of this Decree.

TO BE NOTED, RECORDED AND PUBLISHED IN THE OFFICIAL GAZETTE.

[seal –
Undersecretary
of Economy]

[seal – Ministry of Economy,
and Energy]

/s/

RICARDO LAGOS ESCOBAR
PRESIDENT OF THE REPUBLIC

/s/

JORGE RODRIGUEZ GROSSI
MINISTER OF ECONOMY & ENERGY

Transcribed for your information.
Respectfully,

[seal – Ministry of Economy,
Development and Reconstruction
Undersecretary]

/s/

ALVARO DIAZ PEREZ
Undersecretary of Economy,
Development and Reconstruction