

Standards

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Overview

Traditionally, the Government of Mexico (GOM) had been the primary actor in determining product standards, labeling and certification policy, with little input from the private sector and less from consumers. As a result, independent standards and certification organizations like those in the United States were virtually non-existent in Mexico. In 1992, the Ministry of Economy (SE-*Secretaría de Economía*) initiated efforts to reverse this situation, shifting the responsibility for the formulation of voluntary standards to the private sector or to mixed commissions.

In 1992, the Mexican Government undertook an ambitious project to revamp its entire system for formulating product standards, testing, and labeling and certification regulations. The cornerstone of this review is the Federal Law of Standardization and Metrology (LFMN - *Ley Federal de Metrología y Normalización*) enacted on January 26, 1988 and updated in 1992. It provided for greater transparency and access by the public and interested parties to the standards development process, and has resulted in a reduction of obligatory product standards. This process is not without its problems, but the Mexican Government has been receptive to U.S. concerns and willing to resolve these problems.

The SE, through the Mexican Bureau of Standards (DGN - *Dirección General de Normas*), is the organization with the authority to manage and to coordinate the standardization activities in the country. Its authority is derived from the LFMN. The implementing regulations (*Reglamento de la Ley Federal sobre Metrología y Normalización*) were published in Mexico's Official Gazette (DOF - *Diario Oficial de la Federación*) on January 14, 1999. In accordance with the Federal Law, the Law of Metrology and Standardization and its Regulation (*Reglamento de la Ley Federal sobre Metrología y Normalización*), the National Program of Standardization (PNN - *Programa Nacional de Normalización*) is published annually in the DOF, which is the official document used to plan, inform and coordinate the standardization activities, both public and private, carried out by the Mexican Government.

Finally, two definitions are important to keep in mind:

1. NOMs – literally: Mexican Official Standards – these are Technical Regulations, including labeling requirements, issued by government agencies and ministries. Compliance is mandatory.
2. NMX – Mexican “Voluntary” Standards – these are voluntary standards issued by recognized national standards-making bodies. Compliance is mandatory only when a claim is made that a product meets the NMX, when a NOM specifies compliance, and whenever applicable in government procurement.

Standards Organizations

The Mexican government entities that develop NOMs – Technical Regulations include:

- ECONOMIA (Commerce)
- SAGARPA (Agriculture)
- STPS (Labor)
- SCT (Communications & Transportation)
- SECTUR (Tourism)
- SEDESOL (Social Development)
- SEMARNAT (Environment)
- SENER (Energy)
- SSA (Health)

The DGN publishes the National Standardization Plan (PNN – *Plan Nacional de Normalización*) twice a year. It is available on the DGN website. Contact information is listed at the end of this chapter.

Organizations that develop NMX – Mexican “Voluntary” Standards include:

- ANCE (Electrical)
- IMNC (Quality Systems)
- INNTEX (Textiles)
- ONNCCE (Construction)
- NORMEX (Food Products and Quality Systems)
- NYCE (Electronics)

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Conformity Assessment

Under the NAFTA, Mexico was required, starting January 1, 1998, to recognize conformity assessment bodies in the United States and Canada on terms no less favorable than those applied in Mexico. After years of negotiations, two U.S. certification bodies were finally accredited. More recently, on August 17, 2010, the Secretariat of Economy published in the Mexican Official Gazette an agreement and amendments to the foreign trade general regulations to unilaterally accept as equivalent product certifications from U.S. and Canadian certifying bodies. The three Mexican technical regulations included in this equivalency agreement are NOMs 001-SCFI (audio and video equipment), 016-SCFI (office electrical appliances) and 019-SCFI (information technology equipment-safety). This agreement is expected to facilitate U.S. exports to Mexico.

Currently, only certificates issued by the following three U.S. - based certifying bodies have been accepted as equivalent by the Mexican government:

- 1) Intertek Testing Services NA, Inc.
- 2) TÜV Rheinland of North America, Inc.

3) Underwriters Laboratories, Inc.

However, given the differences between US and Mexican conformity assessment systems, significant custom-import logistical challenges remain unresolved.

Based on agreements with other agencies, as well as with other certification organizations, the DGN has established procedures for the certification of products to both Technical Regulations (NOMs) and Voluntary Standards (NMXs).

Conformity Assessment procedures issued by the SE/DGN tend to be more fully developed and cover a significantly greater range of NOMs than those of other ministries that develop NOMs.

Product Certification

For the purposes of the certification procedure, the following definitions are issued:

Product Certification: Proof of compliance with the applicable Mexican standard. An accredited certification body must issue these certificates.

DGN: General Bureau of Standards, Ministry of Economy (SE). This agency authorizes the operation of certification and calibration laboratories and verification units, according to the Federal Law of Standardization and Metrology.

Accredited Laboratory: Institutions authorized to test or calibrate products subject to Mexican standards.

Accredited Unit for Sampling Verification: Third-party authorized inspection and product sampling.

NOM: Technical Regulation (mandatory)

NMX: Mexican Standard (voluntary)

Product Certification Organization: Product Certification Organization accredited by DGN through EMA (*Entidad Mexicana de Acreditación* – Mexican Accreditation Agency)

Quality System Certification Organization: Organization accredited by DGN through EMA to certify Quality Assurance Systems.

MRAs (mutual recognition agreements)

There is a significant number of MRAs (mutual recognition agreements) between Mexican and U.S. organizations. However, at present, none of these agreements exempt U.S. products from complying with all applicable Mexican technical regulations and product certification requirements. MRAs are mainly to recognize testing procedures. U.S. exporters should check with the appropriate Mexican certification body as to the existence of any MRAs.

Accreditation

In 1999, the Mexican government authorized the first private organization to accredit conformity assessment bodies (calibration laboratories, certification bodies, testing laboratories, and verification/inspection units). This private non-profit institution is known as EMA (*Entidad Mexicana de Acreditación* - Mexican Accreditation Entity).

Calibration Laboratories:

Calibration laboratories are responsible for transferring the precision of reference standards to the measurement instruments used in the commercial and industrial sectors. The calibration laboratories can be sponsored by public or private organizations, including universities, professional associations and private companies. Individuals interested in performing calibration activities can obtain certification after meeting the certification requirements set by law. Committees, made up of technicians and specialists in metrology, evaluate applications for certification as calibration laboratories. These committees make recommendations to the DGN for final decisions on certification. The committees also establish the technical specifications for the evaluation of calibration laboratories, set the precision requirements for the calibration chains and set the methods for comparison of standards.

Certification Bodies:

EMA has accredited several organizations for certifying compliance in different fields. The accreditation list includes but it is not limited to the following organizations:

ANCE – *Asociación de Normalización y Certificación* (product certification body for the electric sector NOMs)

CALMECAC - *Calidad Mexicana Certificada, A.C.* (Certified Mexican Quality).

CNCP - *Centro Nacional Para la Calidad del Plástico* (Mexican Center for the Quality of Plastic).

CRT - *Consejo Regulador Del Tequila* (Tequila Regulation Council).

IMNC - *Instituto Mexicano De Normalización y Certificación, A.C.* (Mexican Institute of Standardization and Certification).

INNTEX - *Instituto Nacional De Normalización Textil, A.C.* (Mexican Institute of Textile Standardization).

NORMEX - *Sociedad Mexicana de Normalización y Certificación, S.C.* (Mexican Society of Standardization and Certification).

NYCE - *Normalización y Certificación Electrónica* (Electronic Standardization and Certification).

ONNCCE - *Organismo de Normalización y Certificación de la Construcción y Edificación* (Building and Construction Standardization and Certification Body)

UL de Mexico - Underwriters Laboratories de Mexico, S.A. de C.V. (Product certification body for electric and electronic equipment)

Intertek (Product certification body for electric and electronic equipment)

On July 6, 2007, the Secretariat of Economy published foreign trade rules and general criteria in the DOF, which lists all products by tariff number that must comply with a NOM at the point of entry into Mexico. This document is constantly updated to reflect cancellations or changes in NOMs or the application of new ones.

Testing Laboratories:

Testing laboratories are responsible for certifying that products meet Mexican standards and are normally commercial entities that make a profit from the testing of samples. The DGN through EMA is responsible for granting authorizations to test laboratories after receiving the recommendations of the Testing Laboratory Evaluating Committees (*Comités de Evaluación de Laboratorios de Pruebas*).

Each committee oversees a group of evaluators who visit the testing laboratories, review their organization, capabilities, staffs, etc. Testing laboratories must fully comply with standard NMX-EC-17025-IMNC-2006/ISO 17025:2005, which sets the requirements testing laboratories must comply with. Once the evaluators have made their review, they submit a report to the committee. Then, the committee writes its recommendations to the DGN, which, in turn, informs the laboratory of the results. Those applicants not receiving authorization are permitted to make the necessary modifications to their facilities in order to comply with standard NMX-EC-17025-IMNC-2006/ISO 17025:2005. After the committee verifies that the laboratory meets the requirements, a second report is prepared for the DGN.

Authorizations as testing laboratories are valid for two years and can be renewed upon written request. Testing laboratories are required to maintain their technical capabilities and to make any modifications that the committee may set. Testing laboratories must notify the DGN of any change in equipment, location, and administration. Laboratories have the option to withdraw their certification.

Verification Units:

Verification or inspection units check and provide a report or proof of compliance corroborated either visually or by sampling, measuring, testing in laboratories, or examining documents. Labeling NOMs, for example, do not require products to obtain a certificate of compliance; however, verification units can determine whether or not a technical regulation has been correctly applied.

On June 18, 2001, the Mexican standard NMX-EC-17020-IMNC-2000 (equivalent to ISO/IEC 17020:1998) went into effect to make the accreditation process of verification units consistent with international standards. Therefore, as of January 2002, the procedure to evaluate and accredit verification units became effective.

Publication of Technical Regulations

Publication of Proposed Technical Regulations:

In accordance with the Regulation of the Federal Law of Metrology and Standardization (*Reglamento de la Ley Federal sobre Metrología y Normalización*, LFMN), the National Program of Standardization (*Programa Nacional de Normalización*, PNN) is the official document used to plan, inform and coordinate the standardization activities, both public and private, carried out by the Mexican government. The PNN is made up of a list of topics that will be developed into technical regulations (NOMs), Mexican Standards (NMX's), and Reference Standards (NRF's)--as well as approximate a working calendar for each respective topic. The program is equally composed of information from the National Consulting Standardization Committees (*Comités Consultivos Nacionales de Normalización*), which are responsible for the creation of NOMs; the Technical Committees of National Standardization (*Comités Técnicos de Normalización*

Nacional) and the National Standardization Bodies (*Organismos Nacionales de Normalización*), both of which are responsible for the creation of NMXs; and 2 Standardization Committees (*Comités de Normalización*), responsible for the creation of NRF's - standards created by governmental entities for government procurement.

The PNN is annually developed by the Technical Secretariat of the National Standardization Commission, revised by the Technical Council of the aforementioned entity, and approved by the National Standardization Commission (CNN, *Comisión Nacional de Normalización*) in its first meeting of every year.

The LFMN and its Regulation establish a time frame for each step of the NOM-making process (development, draft publication in the DOF, and publication of modified and definitive technical regulations and standards) and within the PNN framework. The accomplishment of these tasks is limited to the span of a year. The actual NOM-making period, however, is contingent upon various factors, including the complexity of the topic and the uncertain period between each step (i.e. publishing period in the DOF, draft response, comments, and final technical regulation and standard). Therefore, evaluations of the PNN indicate, more often than not, that the standardization process requires more than a year in order to adequately meet its objectives.

U.S. entities can participate in the process in several ways. They can:

- Review the PNN to learn about the proposed standards.

- Participate in the applicable technical working group(requires physical presence).

- Submit commentaries during the 60-day public consultation period.

- Solicit the making, modification, or cancellation of technical regulations and standards (NOM and NMX) to the appropriate government office or to a National Standardization Body.

Labeling and Marking

All products intended for retail sale in Mexico must bear a label in Spanish prior to their importation to Mexico. Products that must comply with commercial and commercial/sanitary information NOMs must follow the guidelines as specified in the applicable NOM. Most NOMs require commercial information to be affixed, adhered, sewn, or tagged onto the product, with at least the following information in Spanish:

- Name or business name and address of the importer,

- Name or business name of the exporter,

- Trademark or commercial name brand of the product,

- Net contents (as specified in NOM-030-SCFI-2006 DOF November 4, 2006),

- Use, handling, and care instructions for the product as required,

- Warnings or precautions on hazardous products.

This information must be attached to the product, packaging or container, depending on the product characteristics. This information must be affixed to products as prepared for retail sale. Listing this information on a container in which a good is packed for shipment will not satisfy the labeling requirement.

NOMs do not explicitly state that country of origin is required on the label prior to importation. However, Mexican fiscal regulations do require country of origin designation, and the U.S. Department of Commerce recommends that exporters include this information, in Spanish, on the labels they are preparing for goods destined for retail sale in the Mexican market. Including the importer's taxpayer number (commonly known as RFC) is also recommended.

The commercial and commercial-sanitary NOMs currently in force are:

NOM-003-SSA1-2006, Environmental health - Sanitary requirements with which paints, inks, varnishes, lacquers, and enamels must comply, published in the DOF on August 4, 2008.

NOM-004SCFI-2006, Commercial Information - Labeling of textile products, garments and accessories, published in the DOF on June 21, 2006.

NOM-015-SCFI-2007, Commercial Information - Labeling of toys, published in the DOF on April 17, 2008.

NOM-020-SCFI-1997, Commercial Information - Labeling of leather and leather-like goods, shoes and accessories published in the DOF on April 27, 1998.

NOM-024-SCFI-1998, Commercial Information for packaging, instructions, and warranties of electric and electronic products and appliances, published in the DOF on January 15, 1999.

NOM-046-SSA1-1993, Pesticides - products for household use - labeling, published in the DOF on October 13, 1995.

NOM-050-SCFI-2004, Commercial information- General labeling of products, published in the DOF on June 1, 2004.

NOM-051-SCFI/SSA1-2010, General labeling specifications for pre packed food products and non-alcoholic beverages, published in the DOF on April 5, 2010.

NOM-055-SCFI-1994, Commercial Information - Fire retardants or inhibitors - published in the DOF on December 8, 1994.

NOM-072-SSA1-1993, Labeling of medicines, published in the DOF on April 10, 2000.

NOM-084-SCFI-1994, Commercial Information - Commercial and sanitary information specifications for pre packed tuna and bonito food products, published in the DOF on September 22, 1995.

NOM-116-SCFI-1997, Automotive industry - Commercial information of lubricant oils for gasoline or diesel engines, published in the DOF on May 4, 1998

NOM-120-SCFI-1996, Commercial Information - Labeling of agricultural products - Grape, published in the DOF on November 22, 1996.

NOM-128-SCFI-1998, Commercial Information - Labeling of agricultural products - Avocado, published in the DOF on August 31, 1998.

NOM-129-SCFI-1998, Commercial Information - Labeling of agricultural products - Mango, published in the DOF on August 31, 1998.

NOM-137-SSA1-2008 Regulatory information - general labeling specifications for medical devices, whether or not imported, published in the DOF on December 12, 2008.

NOM-139-SCFI-1999, Commercial Information - Labeling of vanilla extract, derivatives and substitutes, published in the DOF on March 22, 2000.

NOM-141-SSA1-1995, Goods and services - Labeling of pre packed perfumery and beauty products, published in the DOF on July 18, 1997.

NOM-142-SSA1-1995, Goods and services. Alcoholic beverages. Sanitary specifications. Sanitary and commercial labeling published in the DOF on July 9, 1997.

NOM-189-SSA1/SCFI-2002, Products and services. Labeling and packaging of household cleaning products, published in the DOF on December 2, 2002.

Contacts

The following is key contact information for the most relevant organizations in both the public and private sectors. For additional organizations, please contact the post.

Mexican Public Sector:

SE-*Secretaría de Economía* (Secretariat of Economy)

DGN-*Dirección General de Normas* (Mexican Bureau of Standards)

URL: <http://www.economia.gob.mx/?P=85>

SEMARNAT- *Secretaria de Medio Ambiente y Recursos Naturales* (Secretariat of the Environment and Natural Resources)

URL: <http://www.semarnat.gob.mx>

SCT – *Secretaria de Comunicaciones y Transportes* (Secretariat of Communications and Transportation)

URL : <http://www.sct.gob.mx>

COFEPRIS (FDA's Mexican Counterpart)

URL: <http://www.cofepris.gob.mx/wb/cfp/ingles>

Mexican Private Sector:

ANCE – *Asociación de Normalización y Certificación del Sector Eléctrico, A.C.*
(National Association for the Standards & Certification of the Electrical Sector)

URL: <http://www.ance.org.mx>

COMENOR - *Consejo Mexicano de Normalización y Evaluación de la Conformidad, A.C.*
(Mexican Council of Standardization and Conformity Assessment)

URL: <http://www.comenor.org.mx>

NYCE – *Normalización y Certificación Electrónica, A.C.*
(Electronic Standards & Certification)

URL: <http://www.nyce.org.mx>

INMC – *Instituto Mexicano de Normalización y Certificación, A.C.*
(Mexican Standards & Certification Institute)

URL: <http://www.imnc.org.mx>

NORMEX – *Sociedad Mexicana de Normalización y Certificación, S.C.*
(Mexican Standards & Certification Society)

URL: <http://www.normex.com.mx>

ONNCCE – *Organismo Nacional de Normalización y Certificación de la Construcción y Edificación, S.C.* (National Body for the Standardization and Certification of Construction and Buildings)

URL: <http://www.onncce.org.mx>

INNTEX- *Instituto Nacional de Normalización Textil, A.C.*
(National Institute of Textile Standards)

URL: <http://www.cniv.org.mx/inntex>

Post Standards Contacts:

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