RESEARCH REPORT (*relatório de pesquisa*)

PROJECT BRAZIL- ARGENTINA ON REGULATORY CONVERGENCE:

Regulatory convergence in Brazil-Argentina integration:

technical, sanitary, phytosanitary and environmental measures and their supporting standards

Product 5: Final document consolidating the results, information and analysis obtained in previous steps; policy indications

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This research report was developed with resources from the Institute of Applied Economic Research (IPEA) and resulted from the Terms of *Reference titled 18*-Economic Commission for Latin America and the Caribbean-95059-Consultant, under the ECLAC-IPEA Technical Cooperation Agreement.

REGULATORY CONVERGENCE IN BRAZIL-ARGENTINA INTEGRATION: TECHNICAL, SANITARY, PHYTOSANITARY AND ENVIRONMENTAL MEASURES AND THEIR SUPPORTING STANDARDS

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LIST OF ABBREVIATIONS

ABIA Brazilian Association of Food Industries
ABIQUIM Brazilian Chemical Industry Association
ABIFINA Brazilian Association of Fine Chemical Industry
ABNT Brazilian Association of Technical Standards
AITA Association of Automotive Engineers and Technicians
ACE Economic Complementation Agreement
ALADI Latin American Integration Association
ANA Brazilian Water Agency
ANATEL National Agency of Telecommunication
ANFAVEA Brazilian Association of Automotive Vehicle Manufactures
ANMAT National Drugs, Food and Medical Technology Administration
ANP Brazil National Agency of Petroleum, Natural Gas and Biofuels
ANVISA Brazilian Health Regulatory Agency
ANTT Brazilian Land Transport Agency
ASTM American Society for Testing and Materials
BPL Good Laboratory Practices
CGN General Committee on Standards (*Comitê General de Normalización*)
CAMEX Brazil Foreign Trade Chamber
CEN European Committee for Standardization
CENELEC European Committee for Electrotechnical Standardization
CMC Common Market Council, Mercosul
CNA Brazilian Confederation of Agriculture and Livestock
CNB Committee of Biregional Negotiations
CNBS Brazilian Council on Biosafety
CNI Brazilian National Confederation of Industry
CNTBio Brazilian Technical Commission on Biosafety
CONAL National Food Commission
COPANT Pan American Commission on Technical Standards
CONMETRO Brazil National Metrology, Standardization and Industrial Quality Council
CORPROSAL Commission on Health Products
CSM Mercosul Sectorial Committees
CSA Commission for Animal Health
CSV Commission for Vegetal Health
DECEX Department of Foreign Trade Operations, MDIC
DFPC Controlled Products Oversight Board
DIPOA Department of Inspection of Products of Animal Origin, SDA, MAPA
EFTA European Free Trade Association
ETSI European Telecommunications Standards Institute
EU European Union
FDA US Food and Drug Administration
FDI Foreign Direct Investment
FIESP Federation of Industries of the State of São Paulo
FNDCT Brazilian Fund of Scientific and Technological Development
GMC Common Market Group, Mercosul
GMP Good Manufacturing Practices
GMO Genetically Modified Organisms
GTP CV Permanent Working Group on Plant Quarantine
HS Harmonized System
IAF International Accreditation Forum
IBAMA Brazilian Institute of the Environment and Renewable Natural Resources
ILAC International Laboratory Accreditation Cooperation
ILO International Labor Organization
INMETRO Brazil National Institute of Metrology, Quality and Technology
IPI Brazilian Manufactured Products Tax
IEC International Eletrotechnical Commission
ISO International Standardization Organization
INAL National Food Institute
INTI National Institute of Industrial Technology
INV Wine Production Institute

IRAM Argentine Standards and Certification Institute
MAD Agreement of Mutual Acceptance
MAPA Brazil Ministry of Agriculture, Livestock and Food Supply
MCR Adjusts the General Norms
MDIC Brazil Ministry of Industry, Foreign Trade and Services
MERCOSUL Common Market of the South
MMA Ministry of Environment
MME Ministry of Mines and Energy
MRA Mutual Recognition Agreement
MRL Maximum Residue Levels
NAL Non Automatic Licenses
NAFTA North American Free Trade Agreement
NIP National Implementation Plan
NM Mercosul Standard
NR Regulatory Standard
NMC Common Nomenclature of Mercosul (*Nomenclatura Comum do Mercosul*)
OAA Argentine Accreditation Agency
OIML International Organization of Legal Metrology
OIE World Organization for Animal Health
PHPC Personal Hygiene, Perfumery and Cosmetics
POP Persistent Organic Pollutants
PROCONVE Brazilian Program for the Control of Pollution by Motor Vehicles
PROMOT Brazilian Program for the Control of Pollution by Motorcycles and Similar Vehicles
PRONAF Brazil National Program to Strengthen Family Agriculture
PRONAR Brazilian National Program for Air Quality Control
RDC Resolution of the Board of Directors, ANVISA
RENAVAM Brazilian National Registry of Motor Vehicles
RIEMA Brazilian Internal Regulation of Environmental Emergencies
SDA Secretariat of Agricultural Defense, MAPA
SDCI Secretariat of Industrial Development and Competitiveness, MDIC
SENASA National Service of Health and agro-Food Quality
SIMI Import Monitoring System (*Sistema Integral de Monitoreo de Importaciones*)
SGT Working Subgroup, GMC, Mercosul
SIEMA Brazil National Environmental Emergency System
SMC Secretariat of Social Mobility, Rural Producer and Cooperativism, MAPA
SNVS Brazilian National Health Surveillance System
SPA Secretariat of Agricultural Policy, MAPA
SPS Sanitary and Phytosanitary Measures
SRI Secretariat of Agribusiness International Relations, MAPA
SUS Unified Health System
TBT Technical Barriers to Trade
UNECE United Nations Economic Commission for Europe
WP 29 UN World Forum for Harmonization of Vehicle Regulations
WTO World Trade Organization

PROJECT BRASIL-ARGENTINA ON REGULATORY CONVERGENCE:

Regulatory convergence in Brazil-Argentina integration:

technical, sanitary, phytosanitary and environmental measures and their supporting standards

EXECUTIVE SUMMARY AND MAIN CONCLUSIONS

At the present time, due to the relative success in the elimination or reduction of tariffs on trade, the efforts of liberalization are focused in other aspects that interfere with trade flows. Now the focus is on the existence of non-tariff barriers, especially technical barriers to trade (TBT), sanitary and phytosanitary measures (SPS) or environmental measures that affect the flow of goods. The proliferation of these non-tariff barriers to trade, which in certain situations may constitute a new wave of protectionism, results from the intense regulatory activity of the states, which are demanded by society to regulate, through normative instruments, the most varied dimensions of the economy, including trade.

The importance of non-tariff barriers is already identified in the multilateral framework of trade, in several rules and activities of the World Trade Organization (WTO) and in the various preferential agreements, including regional integration projects such as Mercosul. At the same time, the negative impacts of countries' regulatory policies on their trade can be evaluated by comparative analysis between domestic regulatory regimes of trading partners. Such an analysis makes possible the understanding of the dynamics of bilateral trade flows, as well as their trade relations with third countries. This report aims a comparative analysis between Brazilian and Argentine regulatory systems in the context of international trade and integration.

Brazil and Argentina have important similarities in their economic structures. These similarities are the result of shared characteristics with many developing countries. Both countries share: the colonial condition in the past, the primary-export vocation, the state-induced late industrialization, the process of import substitution. Among the most recent similarities, it should be mentioned the lack of competitiveness in the production of manufactured goods, the economic opening of the 1990s and, after the globalization process after the 80’s, the rapid deindustrialization, inferred by the loss of participation of the secondary sector in the gross domestic product. In terms of international trade specifically, both countries have a very common profile among developing countries. Both are major exporters of commodities and other primary or low-processed goods, such as soybeans, meats, and crude oil. The two are importers of manufactured goods, acquiring more sophisticated products with higher technological intensity from European, Asian and North American markets.

However, at the regional level, this general profile of the two countries changes substantially. Brazil and Argentina, within the framework of the Latin American Integration Association and Mercosul, become important exporters of manufactured goods, including more sophisticated ones, such as automobiles, machinery and chemicals.

Even in bilateral trade, Brazil and Argentina develop bilateral exchange predominantly of manufactures. In view of this, regional and, in particular, bilateral trade is of great qualitative importance for the two economies.

Despite the similarity of economic trajectory and the undeniable relevance of bilateral trade, Brazil and Argentina do not fully exploit the economic potentials of their commercial partnership. Both the volume of products and the variety of products could be substantially increased with a few domestic or regional initiatives. One of the reasons that hamper the increase of trade between the two countries is the difference in the regulatory framework, such as regulation of technical, sanitary, phytosanitary and environment aspects related to international trade, as well as different conceptions in the standardization and conformity assessment systems. After almost three decades of economic integration, Mercosul is still in the preliminary steps of regulatory convergence. Indeed, there are important differences in the regulatory systems of the two countries, which often lead to difficulties in bilateral, regional and third-country international trade. These difficulties can explain why the achievements on regulatory convergence in Mercosul are so meagre, even when Brazil and Argentina are the most important partners of Mercosul.

The research

The purpose of this research is to develop a comparative framework between the regulatory systems of Brazil and Argentina in order to verify possible non-tariff barriers to bilateral trade and trade with third countries. Three dimensions were concomitantly evaluated: strict regulation (mandatory), standardization activities (voluntary) and conformity assessment procedures. These three dimensions provide a general picture of non-tariff barriers experienced by the economic actors of the two countries in international trade.

In order to concentrate efforts on the essential aspects related to trade, some economic sectors in Brazil and Argentina were selected, based on economic and trade relevance. The criteria for choosing these sectors, as clarified in the first technical document of this research, were of two types: participation in the export agenda of Brazil and Argentina and potential to have non-tariff difficulties in international trade, demanding an effort to advance regulatory convergence among the parties.

Some relevant sectors are analyzed on this research, namely: machinery, vehicles, electrical products, medical devices, cosmetics, pharmaceuticals and food and beverage industry.

Once the sectors were selected, the research focused on the identification of technical regulations (and other mandatory rules), technical standards (voluntary) and conformity assessment procedures established in the two countries. Based on this identification, it exam the possible lack of convergence between the trade regulatory framework of Brazil and Argentina, especially with regard to the supporting standards of both regulations and domestic standards. One goal was to identify the degree of internalization or globalization of these supporting standards, or the use of international and global sectorial standards as technical support to regulations issued by the State or by regulatory agencies or decentralized institutions, endowed by the State with regulatory powers.

Two important concepts used in this project are international standards and global standards. International standards are those produced by international organizations, such as the International Standardization Organization (ISO), the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), Codex Alimentarius Commission, World Organisation for Animal Health (OIE) and International Plant Protection Convention (IPPC). The first two institutions are not international organizations *stricto sensu*, but they are private organizations recognized by international agreements negotiated by the major trading partners. The ITU is an international organization *stricto sensu* and is part of the legal and institutional system of the United Nations. Codex, OIE and IPPC are also international organizations *stricto sensu*. International standards are generally produced in accordance with the Code of Good Practice set out in Annex 3 of the Agreement on Technical Barriers to Trade (TBT Agreement).

Global sectoral standards are private standards developed by relevant standardizing bodies and relevant to international trade. Some examples are those produced in the United States of America (US), as the American Society for Testing and Materials (ASTM), American Petroleum Institute (API), American Society of Mechanical Engineers (ASME) and Underwriters Laboratories (UL). They are produced by American national standardization bodies, but in practice, they are widely used by the private sector and by a significant part of the technical regulation of many States. These organisms, many of them originating under the US law, do not follow the provisions of the Code of Good Conduct for standards makers. Nevertheless, these standards have *de facto* importance due to their quality and wide use, characteristics that allow privileged access to different markets in the world.

Alongside these global technical standards, there are important technical standards produced and used regionally. The most important regional standards are those produced by European Union standardization bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), European Telecommunications Standards Institute (ETSI). European standards are essential for the functioning of the EU integrated market and are widely used as the model influencing many standardization and regulatory work in several countries of the world. For Brazil and Argentina, European standards are an important source of technical content for the regulatory practices of their governments and for the activities of their main standardization bodies. Several provisions of the Brazilian technical regulation concerning machinery and mechanical devices safety, and the Argentine regulation for motor vehicles, make direct reference to the European technical standards produced by CEN.

Some juridical explanations

To understand the regulatory frameworks of the two countries, the first step is to identify their main regulatory actors: authorities, agencies and government bodies and some private bodies with regulatory responsibilities.

The research identified the main regulatory actors for each country and grouped them on the following categories: public authorities, non-governmental bodies and private actors. Examples of public authorities issuing mainly mandatory rules are ministries, committees inside ministries, secretariats, departments inside secretariats, regulatory agencies and

autarchies. Examples of non-governmental bodies issuing mainly non-mandatory rules are the ones that regulate technical standards. The private actors consist of sectorial associations and committees working alone or coordinated with ministries. Despite the private juridical nature of those entities, they can interfere on the regulatory system of the countries and also affect the regulatory activities.

The regulation in Brazil and in Argentina differs according to the allocation of competences established on the constitution of each country. In Brazil, laws can be national, state or municipal. In Argentina, laws can be national, provincial and municipal.

In Brazil, the main regulations are created by the federal government, but their contents reflect on the competences attributed to subnational governments. The different public bodies inside the Brazilian regulatory systems are: National System of Metrology, Standardization, and Industrial Quality (SINMETRO); National Health Surveillance System (SNVS); Unified Agricultural Health Care System (SUASA) and National Environment System (SISNAMA). State and municipal governments are competent in strategic regulatory issues that affect the sectors analyzed in this project. For these reasons, the review of the regulation produced by each system is not exhaustive, but encompasses the most relevant technical regulations in force in Brazil.

In Argentina, provinces retain the competences that were not delegated by the Constitution to the federal government and those reserved by special covenants on the time of their incorporation to the Federation. They are competent, for example, to complement national laws on different issues as the environment. Each province, moreover, creates its own constitution and thus guarantees the municipal autonomy and regulates its scope on the institutional, political, administrative, economic and financial order. In addition, delegating regulatory authority to executive agencies is rarer in Argentina, which gives power to state political bodies, such as Ministries and Secretaries.

Initiatives on convergence

This research aims to analyze de degree of convergence of specific regulatory issues for each of the selected sectors in Brazil and Argentina.

In the process of identifying the elements of regulatory systems and specifying the difficulties involved, the regulatory convergence instruments developed in the Latin American regional context were explored. The initiatives examined were basically two: ALADI and Mercosul. In the area of ALADI, an agreement was negotiated among its members to overcome technical barriers, without this implying a broadening or deepening of commitments made at the multilateral level. The results achieved till now are more political than economic.

In Mercosul, there are important measures of regulatory convergence aiming the inception of a concrete common market. Through the institutional legal framework established by the organization's founding treaties and the community law of the main bodies of the regional organization, members try to overcome technical barriers to trade. In this case, the work of the Common Market Group (GMC, according to initials in Portuguese), as well as of the Working Subgroup n. 3 n.8 and n.11 are specifically highlighted. They have the responsibility for the elaboration of harmonized technical regulatory measures to be approved by the GMC. The option of harmonization adopted

by Mercosul depends essentially on the concerted performance of these bodies, establishing a procedure that is only partially technical and political in the majority of times. The research identified that political interests and the capture by segments of interested parts influence the regional production of regulation and obstruct the automaticity of the process that should be technical harmonization. The influence of this non-technical pressure also explains the irregularity in the time of the harmonization measures of the regulation within the bloc.

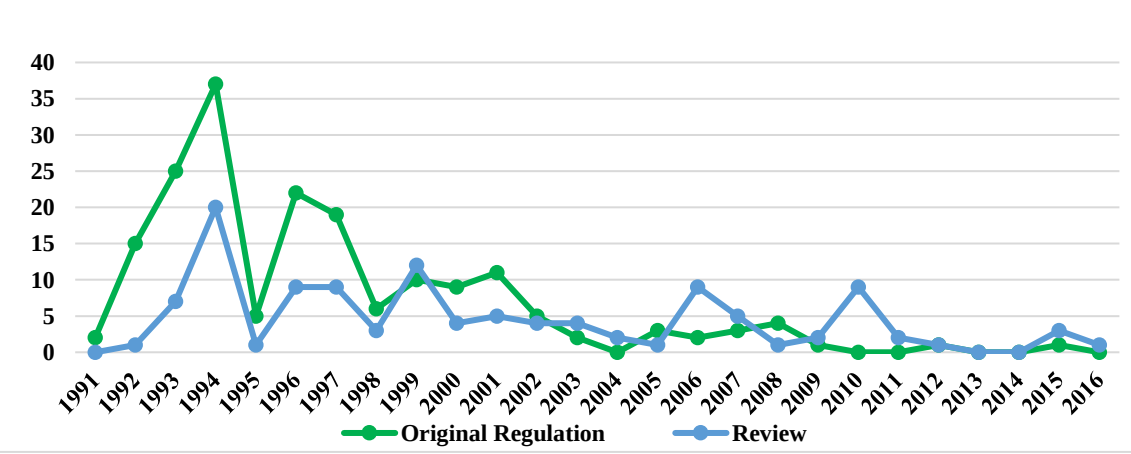
Given the importance of the regional institutional framework to implement the regulatory convergence initiative between Brazil and Argentina, the direct reference to other regulatory convergence models entrenched in regional integration initiatives was inevitable at some point in the research. The solutions adopted within the European Union in the building of common market were therefore an important comparative model, since it established a successful way to reduce the impacts of the heterogeneity of domestic regulation.

There are substantial differences between the EU and Mercosul systems. There are fundamental points in the three dimensions of the regulatory framework. As regards regulation, the EU regulates only general aspects of products, which are addressed in the form of large family of products. In the case of Mercosul, even if a similar strategy was adopted, much effort is expended in updating and reviewing already harmonized regulations.

In part, this problem stems from the weakness of the Mercosul regional standardization structure, in contrast to the vigorous performance of the European standardization bodies. Because of the lack of interest in the private sector, the Mercosul Standardization Association (AMN) lost its impetuous and produces few standards; only a small number of them are effectively used with the objective of harmonizing regulations of the bloc. In addition, AMN acts together with SGT n. 3 (Technical Barriers) but the technical regulation of Mercosul can have effective origin in other subgroups of work, as, for example, subgroups no. 8 (Agriculture) and n. 11 (Health).

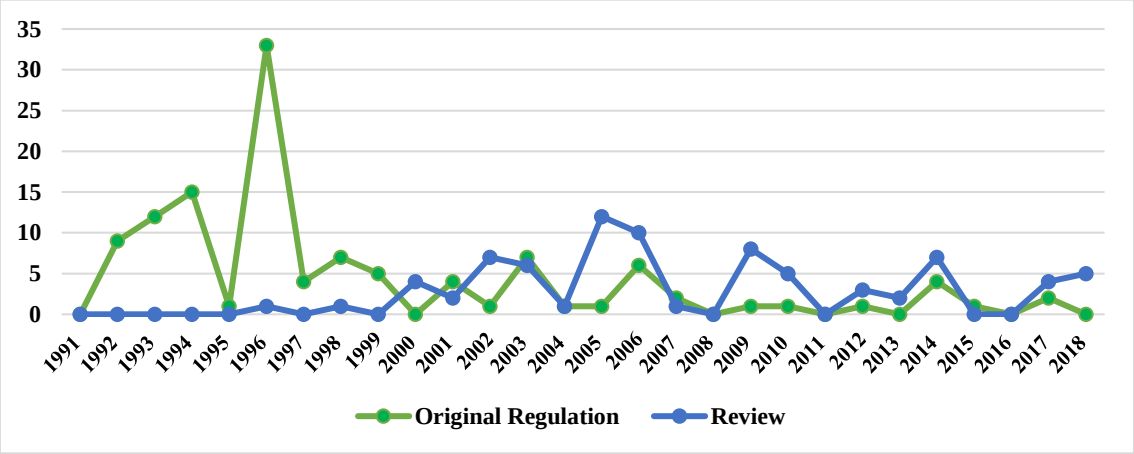
The following graphs present an overview of regulatory activity of SGT n. 3, 8 and 11:

Figure 1 - Technical regulation with origin in SGT n. 3 (Technical Barriers)



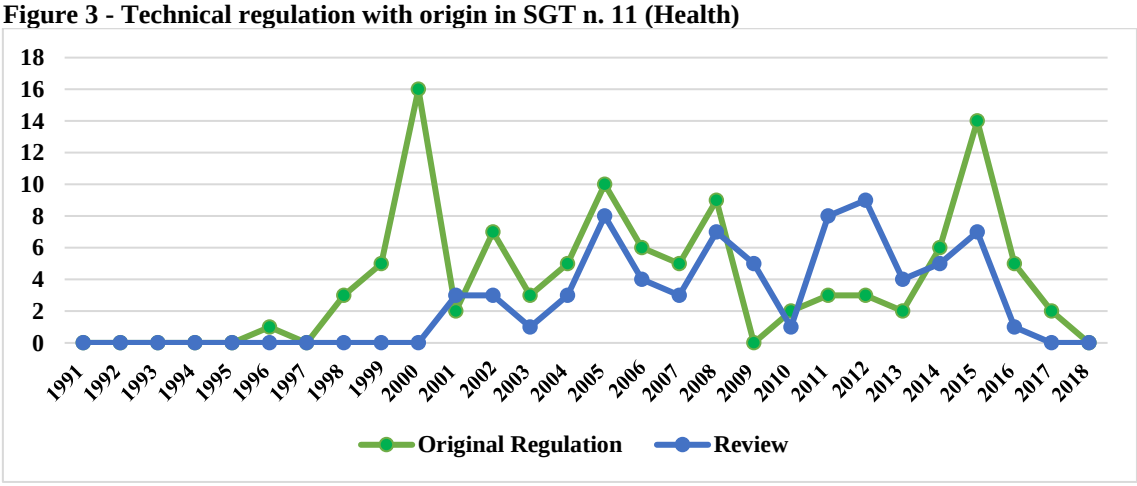
Source: Mercosul. Elaborated by CCGI-EESP/FGV.

Figure 2 - Technical regulation with origin in SGT n. 8 (Agriculture)



Source: Mercosul. Elaborated by CCGI-EESP/FGV.

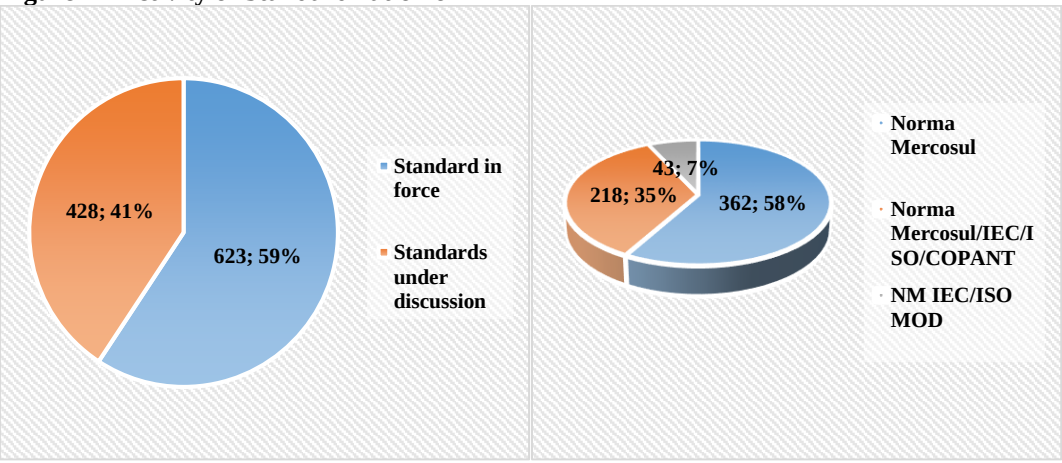
Figure 3 - Technical regulation with origin in SGT n. 11 (Health)



Source: Mercosul. Elaborated by CCGI-EESP/FGV.

The following graphs present an overview of regulatory activity of AMN, and show a comparison among some standardization bodies.

Figure 4 - Activity of Standardization of AMN



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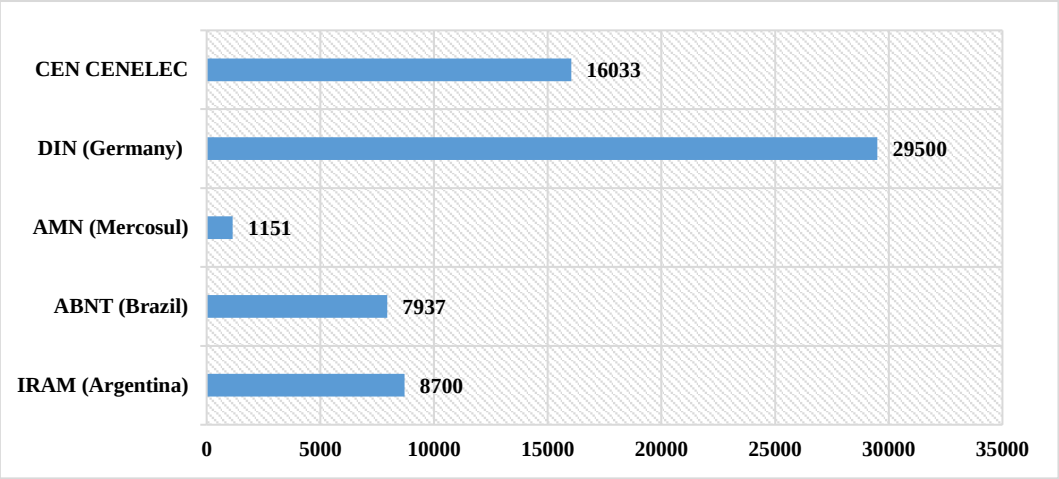


Source: AMN, IRAM, ABNT, DIN, CEN/CENELEC. Elaborated by CCGI-EESP/FGV.

This tables present a clear evidence that Mercosul activities on regulatory convergence are facing real problems. After almost 30 years of integration, the results presented in the development of common regulations and common standards are quite small. Time has come for a revision of the regulatory process in Mercosul.

Conformity assessment

The third dimension of regulatory framework is related to the conformity assessment procedures. Again, after almost 30 years of its creation, the fact that there is no common conformity process is a good example on how weak is the Mercosul integration process.

A comparison with the EU experience can clarify the challenges ahead. The EU adopts a self-declaration and a post-market surveillance. Mercosul and its members adopt pre-market control to reinforce the quality of the products released in the market. The burden of this pre-market control is the increase of time and costs of the process, and more difficulties to put products in the market, especially in the markets of the bloc's partner countries.

There are several ways to assess the conformity of a product against a standard. The broader categories of classification of conformity assessment procedures are based on the kind of actor performing the task. Bearing in mind the contractual relationship acquisition of goods and services, two parties are identified a priori: supplier and buyer. If the conformity assessment is carried out by the supplier, this procedure is classified as first party assessment. If the buyer conducts the conformity assessment, there is a second-party assessment. The procedure can also be performed by an external actor to the main contractual relationship and, therefore, formally neutral and disinterested in the accomplishment of the legal business. In this case, the procedure is classified as a third party procedure. The most common third-party procedure is certification, which usually involves an accredited body to perform this type of procedure.

Differences in the functioning of European and Mercosul regulatory framework systems are directly related to the choice of the predominant national and regional conformity assessment procedures. While the EU understands that the completion of the common market would be better served by a system based predominantly on first-party evaluation (supplier's declaration, for example), Mercosul members understands that the

predominance of third-party evaluation procedures should be maintained domestically and in regional level. The Mercosul option emphasizes pre-market practices (the product is evaluated before it is put on the market), which hampers the free movement of products within the common market. The EU option makes trade faster and the first-party assessment creates presumption of compliance in any member country of the bloc. The European system works because it is heavily based on post-market control, with the possibility of speedy adoption of legal measures against the supplier falsely claiming to comply with a particular European technical standard. Regardless of the structural aspects that underpin the European model, it seems to be more suited to a logic of integration and consolidation of the single market.

The fact that trade between Brazil and Argentina is still based in a double conformity process is a question to be re-discussed. Again, after almost 30 years of Mercosul, it is time to rethink the experience and adjust the framework.

Although Mercosul is the most advanced institutional framework for regulatory convergence between Brazil and Argentina, it has presented limited results. Parallel initiatives may be important to make the regulatory framework systems of the two countries more compatible. The objective of this study is to exam the question of regulatory convergence and provide some suggestions to improve the economic integration of Brazil and Argentina envisaging a better integration of Mercosul.

Methodological note on the scope and purpose of this research

This study consists of the analysis of technical regulation, standardization and conformity assessment procedures of different sectors of the Brazilian and Argentine economies. The purpose of the study is to find evidence of the degree of regulatory convergence of some of the main Brazil and Argentine industrial sectors. A first step to this goal is to study the use of international or global supporting standards in Brazil and Argentine through compulsory technical regulations and as a technical basis for the elaboration of voluntary standards. The utilization of international and global standards in Brazil and Argentina can be considered as an indicative of regulatory convergence.

The sectors were selected based on the importance in Brazilian and Argentinean foreign trade. The study considered the broader classification of the harmonized system (HS - two digits). Official sites of Argentina and Brazil, such as *Instituto Nacional de Estadística y Censos de la República Argentina*, INDEC, https://www.indec.gob.ar/), and COMEXSTAT (http://comexstat.mdic.gov.br/pt/home) provided information on trade flow, including disaggregated data.

The sectors analyzed on this research are, namely: machinery, vehicles, electrical products, medical devices, cosmetics, pharmaceuticals and food and beverage industry.

- **Regulations**

The identification and mapping of technical, sanitary and phytosanitary regulation in Brazil and Argentina are twofold: analysis of notifications to an international body and identification of Brazilian and Argentinean domestic regulation through analysis of the activity of the main domestic regulatory agencies. The first part reviews the notifications made by Brazil and Argentina to the WTO Committee on Technical Barriers to Trade

(CTBT) and the Committee on Sanitary and Phytosanitary Measures (CSPS). As provided in art. 2.9. of the TBT Agreement and paragraph 5 of Annex B of the SPS Agreement, such notifications, which express compliance with the WTO principle of transparency, would indicate if the regulation or technical standard are different from international standards and potentially relevant to international convergence. Since identification through analysis of notifications allow the contact only to a portion of regulations and standards of a given sector, the research also sought to identify sectoral regulations and standards through an independent search on official websites of Brazilian and Argentinean government, including decentralized bodies.

In practical terms, in the analysis of notifications, the research used three distinct means of searching, since none of them alone would provide satisfactory information. Firstly, the research directly accessed the WTO's information management system (IMS) websites (CTBT: http://tbtims.wto.org/ and CSPS: http://spsims.wto.org/). From this search it was extracted information on regulations and standards notified by Brazil and Argentina. Frequently, such prescriptive documents were in draft stage or public consultation stage, in accordance with the mentioned provisions of the TBT and SPS Agreements. However, not all notifications provided complete information on the notified regulation. In the case of SPS, only the latest notifications contained complete references to the notified regulation, project or consultation.

TBT and SPS notifications were also collected at the sites of focal points of Brazil and Argentina, in compliance with provision WTO TBT and SPS Agreements, regarding the obligations of national enquiry points. Based on the information of these sites, which reproduces and reorganizes the information notified to TBT and SPS Committees the research identified the domestic regulation notified by Argentina and Brazil. In the case of TBT, in the website of enquiry points, the research found not only the form sent to the TBT Committee, but also the file of the normative acts that was object of the notification. It should be noted that a similar website was not found for regulations concerning sanitary and phytosanitary measures.

The third source for the search and analysis of notifications was the website of the Latin American Integration Association (ALADI), which contains a copy of the notifications sent to the TBT Committee in a friendlier virtual environment. The search on the ALADI website was mainly aimed at verifying the fulfillment of the commitments made under the Framework Agreement for Trade Promotion by Overcoming Technical Barriers to Trade (*Acuerdo Marco para la Promoción del Comercio Mediante la Superación de Obstáculos Técnicos al Comercio*, 1997), which acquired the status of Regional Agreement no. 8 (AR 8).

Parallel to the research based on the notifications to the TBT and SPS Committees, a separated search was made for the domestic regulations and standards for each sector. In Brazil and Argentina, many public bodies and agencies issue technical regulations for different economic sectors. Therefore, to identify the main regulation (including those not notified to WTO Committees), the research had to go through different search tools in different governmental websites to put together relevant technical regulations for the economic sectors analyzed. It means that, with current searching tools available to present day, it is not possible to guarantee that tables with those regulations introduced in the reports are exhaustive lists.

The regulatory authority varies according to the sector. Some authorities have the competence to regulate more than one sector, such as ANMAT the National Drugs, Food and Medical Technology Administration in Argentina and ANVISA the Brazilian Health Regulatory Agency in Brazil, that are responsible for the regulation of pharmaceutical and cosmetic goods. The regulation of other industrial sectors sometimes overlaps with standards developed by national standardization bodies. In fact, the regulatory agencies can build the technical regulation with reference to standards or the agency can design itself the technical prescription with no reference to standards.

- **Standards**

The research also scrutinized the standardization policies in Brazil and Argentina assessing the portfolio of *Instituto Argentino de Normalización y Certificación* (IRAM) standards and *Associação Brasileira de Normas Técnicas* (ABNT). ABNT and IRAM do not provide a public list of all international and global standards adopted in full. The search tool available requires a keyword search that goes from product to product at ABNT and IRAM's website. Therefore, the research had to refine a keyword search in order to gather a list with relevant supporting standards for each of the economic sectors analyzed. IRAM Catalog with all searching tools is available here. ABNT catalog can be found here.

Additionally, it is relevant to point out that accessing the content of standards issued by ABNT and IRAM is not free. In the same way as European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), American Society for Testing and Materials (ASTM) and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT and IRAM. The costs vary depending on the standard. Therefore, going on an analysis whether the supporting standards are only based or have some degree of modification with international or globalized standards or how different original standards issued by ABNT and IRAM are in comparison with international standards is a very complex task to pull through. For that matter, the research focused on the summaries of each relevant supporting standard to put together a list of supporting standard by analyzed sector and to provide a first assessment on their compatibility with international standards as a measure of the degree of convergence for the regulatory framework of Brazil and Argentina.

In any case, there are no official lists determining which regulations or standards are based on international or global standards and to what extent each one adopts *ipsis literis* the international or global standard; or which are grow-made domestically created.

In order to facilitate the qualitative analysis of regulations and technical standards, the researchers made use of a specific computational tool, the Atlas TI. The Atlas TI is a qualitative research software, used for studies that require comparative analysis of large mass of text and other non-numeric material, making possible the creative and efficient reorganization of the primary research sources.

Finally, it should be noted that the analysis of the degree of utilization of international and global supporting standards in the Brazilian and Argentine regulatory and standardization system provides only an indication of the degree of convergence and internationalization of the industrial regulatory framework, since there was no

comparison of technical content between international and Brazilian/Argentine standards and regulations. In other words, the constant reference to international and global standards in Brazilian and Argentine regulations and standards indicates the internationalization and convergence of a certain sector, but the lack of references does not lead to any conclusion in the opposite direction. Therefore, the absence of such reference to international standards does not necessarily indicate the incompatibility between the Brazilian and Argentine and other countries' regulation or standardization. In such cases of tacit compatibility, which were not tracked in this research, the absence of explicit reference to the international standard is compensated by the similarity of technical content of the prescriptive texts. More research is needed to clarify the issue.

A synthesis of the main results

In order to present the main data collected on each sector for both countries, a synthesis is proposed according to the structure of this project. The main categories explored on each selected sector are the following: authorities, regulation and standards. The paragraphs below explain the main elements identified on each category.

The supporting standards to be described on the synthesis tables are those mentioned in the technical regulations notified to the TBT Committee and to the SPS Committee of the WTO. The standards can be either national, regional, international or sectoral with global reach. Focal points are the bodies responsible to notify regulations to WTO committees. In Brazil, INMETRO is the focal point responsible to provide information in the case of technical measures and MAPA and ANVISA have the same responsibility in the case of sanitary and phytosanitary measures. In Argentina the focal point is constituted by experts from ministries. Several other regulations can also issue regulations and standards and shall notify the WTO on a regular basis. In Brazil and Argentina, ABNT and IRAM creates standards in a participatory and consensual manner in conformity with international standards.

This mapping allows conclusions based on the degree of utilization verified (as percentages of the total number of standards identified) and on the information obtained from sectorial reports. Standards can be the basis to the formulation and implementation of rules for the solution or the prevention of problems with the cooperation of the all concerned. The standardization process addresses the conditions for a product to meet determined purposes.

For each selected sector the research obtained the following results:

Vehicles

The vehicle sector in Brazil is basically regulated by public authorities, which take the form of ministerial organs of the direct administration and autarchies, constituents of the indirect administration. Examples of these authorities are the Brazilian National Environmental Council (CONAMA), the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), the Brazilian National Traffic Council (CONTRAN) and the Brazilian National Institute of Metrology, Quality and Technology (INMETRO).

The regulation is limited to ordinary laws and ordinances mainly on car safety and pollution issues. In terms of standardization, ABNT creates standards for the sector and promotes private and international standards in the area. Considering notified standards, around 60% per cent of them were created by ABNT and the remaining ones are either international, American or European.

In Argentina the automotive sector is regulated mainly by public entities, namely the Ministry of Production, the Ministry of the Environment and Sustainable Development and the Ministry of Transport. In certain specific situations, the power of regulation is delegated to private sector entities. The sector is regulated by different normative sources as ordinary laws and resolutions and encompasses different types of standards. A great variety of standards was notified to the TBT Committee and these standards can be national (e.g. IRAM-AITA standards), regional (e.g. European directives) and international (e.g. ISO standards).

Machinery

In Brazil, the main regulatory authority is the Ministry of Labor, which regulates aspects concerning the safety of the machine and the safety of machine operator. Ordinary laws and ordinances are the legal instruments used to regulate the sector and aim to guarantee worker safety, machine safety and consumer safety. The standards notified are national as ABNT standards or international as IEC and ISO standards. Often, domestic and international standards are combined in an atypical way, causing compliance problems, especially for foreign companies. The main objectives of the notified standards are safety, environmental protection, conformity assessment and metrology and other less relevant topics.

The machinery sector in Argentina is regulated by different authorities, which encompass, public actors, ministries as the Ministry of Production, two autarchies, the National Institute of Industrial Technology (INTI) and the National Entity Regulator of Gas (ENARGAS), and one non-governmental actor. Ordinary laws are the main source of the regulation for the sector. The supporting standards of regulation notified to WTO are either national (IRAM standards), regional (CEN standards) or international (ISO and IEC standards).

Electrical products

In Brazil, the electrical products sector is regulated by ministerial and autarchic authorities, namely the Ministry of Mines and Energy (MME), Ministry of Science, Technology and Innovation (MCTI), Ministry of Labor and Employment (MTE), Ministry of Industry, Trade and Services (MDIC), through its interministerial committee, the Energy Efficiency Indicators Management Committee (CGIEE), the National Institute of Metrology, Quality and Technology (INMETRO) and the National Agency of Telecommunication (ANATEL).

Brazilian regulations include ordinary laws, treaties with the status of ordinary law and different infra-legal norms as ordinances, and resolutions. The supporting standards used in the regulation and notified to the TBT Committee are mainly homegrown ABNT standards, but also include American ASTM standards and international ISO and IEC standards.

In Argentina, the sector is regulated by public entities as the Ministry of Production and private entities with regulatory powers, as a result of legal provision as the Argentine Electrotechnical Association (AEA). The sector is regulated by one ordinary law with general provisions about electrical facilities and infra-legal norms, which use different types of supporting standards. The standards can have different natures: national (IRAM standards), regional (Mercosur standards) and international (ISO and IEC standards).

Medical Devices

In Brazil, concerning medical devices, public actors as ANVISA and INMETRO perform their functions together with private actors. The technical regulation on medical devices is constituted by ordinary laws, INMETRO ordinances, ANVISA resolutions and normative instructions. The supporting standards notified to the TBT Committee are still in force. The last ones are either national ABNT standards or international ISO or IEC standards. The main objectives of these standards are the following: metrology, human health and safety issues.

The medical devices sector in Argentina is regulated by public entities as the State Secretariat of Public Health through ordinary laws and few infra-legal norms. The stock of sectorial standards notified to the TBT Committee is constituted mainly by IRAM homegrown standards and international ISO standards. A data worth mentioning is the high percentage of notified technical regulations that do not mention standards.

Cosmetics

The most important institution in the sector is ANVISA that conducts the registry, control and monitoring of cosmetics. ANVISA also performs a simplified registration procedure for cosmetic products that do not produce any harm or create any risk to human health. The sector is regulated by one ordinary law and different infra-legal norms, such as ordinances and resolutions. Public actors from direct and indirect administration enact such rules, which are compulsory for all the entities in Brazilian territory.

The standards of this sector were notified to the TBT Committee and to the SPS Committee. The standards notified to the TBT Committee are either national, American or international. The majority of standards notified to the SPS Committee do not make reference to international standards and are followed by WOAH standards, IPPC standards and Codex standards.

Argentine cosmetics sector has as its features a reduced number of authorities centered on ANMAT, a regulation through infra-legal norms as resolutions and provisions and specific standards. This sector's standards are notified to the TBT Committee and to the SPS Committee. Half of the technical regulations notified to the TBT Committee do not mention standards and the other half comprises regional NM standards, FDA standards and COLIPA standards (standards produced by a European Cosmetic Association).

Pharmaceuticals

On the Brazilian side, the main authorities are not limited to public actors as the Ministry of Health, but also reach a non-governmental actor, the ABNT and private actors as the

Brazilian Association of Chemical Industry (ABIQUIM) and the Brazilian Association of Fine Chemical Industry (ABIFINA). The regulation is mainly through federal laws and infra-legal norms and the main supporting standards deal with technical and sanitary and phytosanitary issues. The standards notified to the TBT Committee and to the SPS Committee refer to ISO and IEC standards and mention the Codex, the IPPC and the OIE.

The pharmaceuticals sector in Argentina has the following features: strong presence of public actors as ANMAT that incorporates on its structure the National Institute of Drugs (INAME) and regulation through ordinary laws and infra-legal norms. The public actors regulate medicines, food, medical technology and industrial property. Ordinary laws and resolutions are the main form or regulation.

IRAM figures out as the most relevant non-governmental actor, producing national standards for the sector. The majority of standards do not copy other standards and are not based on them. Analyzing the technical regulations notified to the TBT Committee, the great majority of them do not make reference to any standards and the remaining ones make reference to IUIS standards, IATA standards, FDA standards and EMA standards. Considering the technical regulations notified to the SPS, the situation is not different. The majority of the technical regulations do not follow standards, and some of them follow OIE standards and IPPC standards.

Food and beverage

The Brazilian food and beverage industry sector comprises mainly public actors, especially the Brazilian Health Regulatory Agency and the Ministry of Health, authorities related to the guarantee of public health and health surveillance. The Brazilian sectorial report reveals that the most relevant regulations are federal laws and decrees, but the annexes to the report reveals the huge number of ordinances, regulatory instructions and resolutions. Half of the sectorial standards notified to the TBT Committee is Codex standards and the other half comprises national standards as the ABNT NBR standards or international standards as the ISO and IEC standards.

Data collected about the food and beverage industry in Argentina reveals that the main authorities are public actors as government agencies within the Ministry of Agroindustry and the Ministry of Health, the main regulation is a specific ordinary law, the Argentine Food Code, and that the majority of standards is national. The Argentine Food Code is an ordinary law that incorporates rules agreed upon within Mercosur and is constantly updated by joint resolutions. A specific decree also regulates imported food and beverage products.

An overview of the sectorial standards reveals that, besides the great number of national standards, there are also standards produced by AMN and ISO. The standards in the technical regulations are notified to the TBT Committee and to the SPS Committee. On the first institution, a diversity of standards is notified. These can be, for example, either national IRAM standards, regional NM standards, European standards, American FDA standards or international ISO and IEC standards. On the second institution, more than a quarter of technical regulations notified do not mention standards. The remaining standards in the technical regulation notified are either IPPC standards, Codex standards, OIE standards or IFCS standards.

The tables below provide a description and a comparison of the categories above mentioned on the 7 sectors analyzed on this research, namely: vehicles, machinery, electrical products, medical devices, cosmetics, pharmaceuticals and food and beverage industry. The tables also summarize the main results of the research.

General results by sectors: authorities, regulations and standards and their supporting standards

Table 1 - Vehicles

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: Ministry of Production, Ministry of the Environment and Sustainable Development, Ministry of Transport	Public actors: Brazilian National Environmental Council (*Conselho Nacional do Meio Ambiente* – CONAMA), Brazilian National Traffic Council (*Conselho Nacional de Trânsito* – CONTRAN). Non-governmental actors: Brazilian Association on Technical Standards (*Associação Brasileira de Normas Técnicas* – ABNT). Autarchies: Brazilian Institute of the Environment and Renewable Resources (*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis* – IBAMA), Brazilian National Institute of Metrology, Quality and Technology (*Instituto Nacional de Metrologia e Qualidade* – INMETRO).
PRODUCTS	Vehicles, auto parts, safety system, direction devices, emissions devices, speed devices, fuel tanks	Vehicles, auto parts, fuel tanks, braking system, safety system, light devices, vision devices, direction devices, emissions devices, speed devices
REGULATION	4 ordinary laws 2 decrees 18 resolutions 4 provisions	4 ordinary laws 1 decree 1 resolution 4 ordinances
STANDARDS	Notification to TBT Committee Total: 430 (29% UNECE; 20% European directive; 15% IRAM-AITA; 10% NM; 6% FMVSS; 5% Others; 4% IRAM; 3% ISO; 2% EURO III; 2% None; 1% EURO IV; 1% NAG; 1% SAE; 1% EURO V	Notification to TBT Committee Total: 66 (52% ABNT NBR ISO; 8% NBR ISO 5% ABNT NBR ISO/IEC; 5% ABNT NBR NM; 5% ABNT NBR NM ISSO; 5% ASTM; 5% INMETRO GPCR; 3% ECE; 3% FMVSS; 3% ISSO; 1% ABNT ISO/IEC; 1% ABNT NBR ISSO; 1% ALAPA; 1% DIN; 1% ISO-TS; 1% NIE-DINQP

Table 2 - Machinery Sector

	ARGENTINA	BRAZIL
AUTHORITIES	**Public actors**: Ministry of Production, National Institute of Industrial Technology (*Instituto Nacional de Tecnología Industrial – INTI*) **Autarchies**: National Entity Regulator of Gas (*Ente Nacional Regulador del Gas* – ENARGAS) and National Entity Regulator of Electricity (*Ente*	**Public actors**: Ministry of Mines and Energy (Ministério de Minas e Energia – MME) **Non-governmental actors**: Brazilian Association of Technical Norms (*Associação Brasileira de Normas Técnicas* – ABNT) **Autarchy**: INMETRO

	Nacional Regulador de la Electricidad – ENRE)	
PRODUCTS	Agricultural machinery – tractors, combine harvesters, automotive agricultural implements, seeders and sprayers – and mechanical equipment on public works.	Heating equipment, centrifugal equipment, refrigerator and domestic machines, machines for liquefied petroleum gases (LPGs) and sound equipment
REGULATION	6 ordinary laws 2 resolutions	3 ordinary laws 1 treaty 6 ordinances 22 INMETRO ordinances 1 INMETRO ministerial act 1 IBAMA ordinance 3 CONTRAN resolutions 22 technical standards 2 technical notes
STANDARDS	Notification to TBT Committee Total: 86 (22%: ASTM; 16%: IRAM 16%: None; 10%: ISO; 7%: IEC 6% IRAM-IAP; 5% EN; 2% AR; 2% CNC; 2% UNE EN; 1% AERNO; 1% ANSI; 1% CEN; 1% IRAM-DEF; 1% IRAM-IAPG; 1% IRAM-ISO; 1% NAG; 1% ORSNA; 1% SAE	Notification to TBT Committee Total: 32 (66% ABNT NBR; 13% General rules; 3% ABNT NBR ISO; 3% ABNT NBR ISO/IEC; 3% ABNT NBR NM ISO 3% IEC; 3% ISO; 3% ISO/IEC; 3% NBR ISO)

Table 3 - Electrical products

	ARGENTINA	**BRAZIL**
AUTHORITIES	Public actors: Ministry of Production, Ministry of Energy and Mining, National Institute of Industrial Technology (*Instituto Nacional de Tecnología Industrial – INTI*) Autarchies: National Entity Regulator of Gas (*Ente Nacional Regulador del Gas* – ENARGAS) and National Entity Regulator of Electricity (*Ente Nacional Regulador de la Electricidad* – ENRE)	Public actors: Ministry of Mines and Energy (MME), Ministry of Science, Technology and Innovation (MCTI), Ministry of Industry, Trade and Services (MDIC), through its interministerial committee, Energy Efficiency Indicators Management Committee (CGIEE), Ministry of Labor and Employment (MTE) Autarchies: National Agency of Telecommunication (ANATEL) and INMETRO. Non-governmental actors: Brazilian Association of Technical Norms (*Associação Brasileira de Normas Técnicas* – ABNT)
PRODUCTS	Electric cable and conductors; engines and propellers; lighters.	Compact fluorescent lamps with integrated reactor; light emitting diodes; discharge lamps and fluorescent lamps; electric motors and generators, specific for three-phase electric engines of induction; electrical cables and flexible cords electrical; optic fiber cables; power cables with PVC extruded solid isolation; radio-communication systems; restricted radiation radio communications equipment; light-emitting diodes; transmission apparatus for radio or television; wires, cables and electric flexible cords
REGULATION	1 ordinary law 2 decrees	3 ordinary laws 2 decrees

	46 AEA resolutions	2 CONFEA resolutions 28 regulatory standards (*normas regulamentadoras* – NRs) 7 ILO conventions 86 ILO technical conventions 26 ordinances 5 ANATEL ordinances notified 21 INMETRO ordinances 23 INMETRO ordinances (annex 1) 1 MME ordinance 6 ordinances 22 INMETRO ordinances 1 INMETRO ministerial act 1 IBAMA ordinance 3 CONTRAN resolutions 22 technical standards 2 technical notes
STANDARDS	Notifications to TBT Committee Total: 181 (60%: IRAM; 12%: IRAM NM; 11%: NM; 7%: ISO; 3%: IEC; 2%: None; 2%: AR; 1%: IRAM-IAS; 1%: NAG; 1%: DIN	Notifications to TBT Committee Total: 124 (62%: ABNT NBR; 10%: IEC; 5%: ISO; 4%: General rules; 4%: ABNT NBR-IEC; 4%: ABNT NBR NM; 2%: UL; 1%: ASTM ABNT-ISO-IEC; 2%: CISPR; 2%: ABNT NBR-ISSO; 1%: ISO-IEC; 1%: CIE; 1%: ABNT NM-IEC

Table 4 - Medical Devices

	ARGENTINA	**BRAZIL**
AUTHORITIES	Public actors: National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* – ANMAT), Secretariat of Health Policy and Sanitary Regulation, Provincial Registry of Medical Equipment in Use and of Lenders, State Secretariat of Public Health, General Customs Direction, Ministry of Social Assistance and Public Health, Coordinating Unity of Evaluation and Execution of Health Technologies, Medical Argentine Association, Secretariat of Policies, Regulation and Institutes, National Coordinating Unity of Evaluation of Sanitary Technologies	Public actors: Ministry of Industry, Trade and Services (MDIC) and Brazil Ministry of Health (MS) Autarchies: ANVISA and INMETRO Non-governmental actors: Brazilian Association of Technical Norms (*Associação Brasileira de Normas Técnicas* – ABNT) Private actors: Brazilian Association of Medical, Dental, Hospital and Laboratory Equipment (ABIMO) and Brazilian Association of the High-Technology Industry for Health (ABIMED)
PRODUCTS	Gas facilities, implantable medical products, spectacles, measuring instruments and apparatus and speed measurement devices	Thermometers, in vitro diagnostics, needles
REGULATION	2 ordinary laws 1 Ministry of Health resolution 1 resolution 1 decree law 1 ANMAT disposition	3 ordinary laws 13 INMETRO ordinances 2 inter-ministerial ordinances 1 Ministry of Justice ordinance 1 decree 2 ANVISA normative instructions 1 MS normative instruction

Product 5: Final document consolidating the results, information and analysis obtained in previous steps; policy indications

		17 ANVISA resolutions 1 Mercosul GMC resolution
STANDARDS	Notifications to TBT Committee Total: 12 (59% None; 17% ISO 8% IRAM; 8% OIML; 8% NAG)	Notifications to TBT Committee Total: 13 (29% ISO; 24% ABNT NBR 23% General rules; 18% IEC; 6% ABNT NBR ISO)

Table 5 - Cosmetics

	ARGENTINA	**BRAZIL**
AUTHORITIES	Public actors: National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* – ANMAT), National Institute of Medicines (*Instituto Nacional de Medicamentos* – INAME)	Public actor: Ministry of Industry, Foreign Trade and Services (*Ministério da Indústria, Comércio Exterior e Serviços* – MDIC) Autarchies: National Agency of Sanitary Surveillance (*Agência Nacional de Vigilância Sanitária* – ANVISA) and Brazilian National Institute of Metrology, Quality and Technology (*Instituto Nacional de Metrologia e Qualidade* – INMETRO) Non-governmental actor: Brazilian Association of Technical Norms (*Associação Brasileira de Normas Técnicas* – ABNT) Private actors: Brazilian Association of the Cosmetic, Toiletry and Fragrance Industry (*Associação Brasileira da Indústria de Higiene Pessoal, Perfurmaria e Cosméticos* – ABIHPEC), Brazilian Association of Chemical Industry (*Associação Brasileira da Indústria Química* – ABIQUIM), National Confederation of the Industry (*Confederação Nacional da Indústria* – CNI) and Federation of the Industries of the State of São Paulo (*Federação das Indústrias do Estado de São Paulo*, FIESP)
PRODUCTS	Personal hygiene products, cosmetics, perfumes, plant products, products of animal origin	Personal hygiene products, cosmetics, perfumes, drugs, products of animal origin
REGULATION	4 resolutions 19 provisions	1 ordinary law 2 decrees 14 ANVISA resolutions and ordinances 9 INMETRO resolutions 48 Mercosul resolutions
STANDARDS	Notifications to TBT Committee Total: 10 (50% None; 20% FDA 20% COLIPA; 10% ISO; 10% NM) Notifications to SPS Committee Total: 7 (57% None; 29% No deviations; 14% OIE)	Notifications to TBT Committee Total: 43 (32% ABNT NBR ASTM; 19% General rules; 16% ABNT NBR; 9% None; 7% ASTM; 5% ABNT NBR ISO 5% ISO/IEC; 2% ABNT NBR ISO IEC 2% ISO/TS Notifications to SPS Committee Total: 39 (59% None; 26% WOAH; 10% IPPC; 5% Codex)

Table 6 - Pharmaceuticals

Product 5: Final document consolidating the results, information and analysis obtained in previous steps; policy indications

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* – ANMAT) and National Institute of Industrial Property (*Instituto Nacional de Propriedad Intelectual* – INPI) Non-governmental actor: Argentine Institute for Standardization and Certification (*Instituto Argentino de Normalización y Certificación* – IRAM)	Public actors: Ministry of Health, Ministry of Industry, Trade and Services (MDIC), Institute for Industrial Property (*Instituto Nacional de Propriedade Industrial* – INPI) Autarchies: ANVISA and INMETRO Non-governmental actor: Brazilian Association of Technical Norms (*Associação Brasileira de Normas Técnicas* – ABNT) Private actors: National Confederation of the Industry (Confederação Nacional da Indústria – CNI), Federation of the Industries of the State of São Paulo (*Federação das Indústrias do Estado de São Paulo*, FIESP), Brazilian Association of Chemical Industry (*Associação Brasileira da Indústria Química* – ABIQUIM) and Brazilian Association of the Industries of Fine Chemistry, Biotechnology and its Specialties (*Associação Brasileira das Indústrias de Química Fina, Biotecnologia e Suas Especialidades* – ABIFINA)
PRODUCTS	Mixed or non-mixed products for therapeutic or prophylactic ends, blood and bandages and analogous articles	Mixed or non-mixed products for therapeutic or prophylactic ends, blood, vaccines and glands
REGULATION	2 ordinary laws 7 decrees 2 joint resolutions 1 resolution 1 AFIP resolution 1 ANA resolution 1 ANMAT resolution 1 Ministry of Production resolution 16 ANMAT provisions 1 ministry regulation	4 federal laws 2 ordinances 36 resolutions
STANDARDS	Notifications to TBT Committee Total: 40 (82% None; 6% EMA; 6% IUIS; 3% FDA; 3% IATA) Notifications to SPS Committee Total: 14 (50% None; 29% No deviations; 14% OIE; 7% IPPC)	Notifications to TBT Committee Total: 43 (32% ABNT NBR ASTM; 19% General rules; 16% ABNT NBR; 7% ASTM; 5% ABNT NBR ISSO; 5% ABNT NBR ISO/IEC; 5% ISO/IEC; 2% ISO/TS Notifications to SPS Committee Total: 39 (59% None; 26% WOAH 10% IPPC; 5% Codex)

Table 7 - Food and beverage industry

	ARGENTINA	BRAZIL
AUTHORITIES	Public actors: Ministry of Agroindustry, Ministry of Health National Service of Agri-Food Health and Quality (*Servicio Nacional de Sanidad y Calidad Agroalimentaria* - SENASA), National Wine Institute	Public actors: Ministry of Agriculture, Livestock and Food Supply (*Ministério da Agricultura, Pecuária e Abastecimento* – MAPA), Ministry of Health (*Ministério da Saúde* – MS), Brazilian Institute of Environment and Renewable Natural Resources and

	(*Instituto Nacional de Vitivinicultura* - INV), National Administration of Drugs, Foods and Medical Devices (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* - ANMAT) and National Food Institute (*Instituto Nacional de Alimentos* – INAL)	Brazilian Institute of Environment and Renewable Natural Resources (*Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis* – IBAMA). Autarchies: ANVISA and INMETRO.
PRODUCTS	Soy, food based on soy, corn, alcoholic beverages and wine.	Animal origin products, fresh fruit and vegetables, alcoholic and nonalcoholic beverages, juices, grains, seeds, and animal feed (including pet food) and processed food products.
REGULATION	The Argentine Food Code (CAA) created by Law 18284/1969 and regulated by Decree 2126/1971 regulates locally produced and imported food products. The CAA is constantly being updated by joint resolutions. View latest CAA Modifications in http://www.conal.gob.ar/CAA_ultimas_modificaciones.php In particular, for food and beverage products, Decree 2092/1991 (supplemented by Decree 1812/1992) regulates all imported food and beverage products.	MAPA and ANVISA's regulations may be consulted on-line. On MAPA's website (www.agricultura.gov.br) the search tool SISLEGIS makes available the current regulations. A similar search tool called VISALEGIS can be found at ANVISA's website (www.anvisa.gov.br).
STANDARDS	Notifications to TBT Committee Total: 100 (23% ISO; 13% NM; 12% FDA; 7% Codex; 7% IRAM; 5% European Directive; 4% IEC; 4% ICMSF; 4% APHA; 3% OIV; 2% ASTM; 2% FSIS) Notifications to SPS Committee Total: 194 (27% None; 27% No deviations; 19% IPPC; 16% Codex; 10% OIE; 1% IFCS)	Notifications to TBT Committee Total: 24 (50% Codex; 17% FIL; 13% ABNT NBR; 8% ISO; 4% ABNT NBR ISSO; 4% IEC; 4% EPA SW)

Some evidences can be drawn from these tables:

- The degree of internationalization or globalization of the supporting standards used by Brazil and Argentina in their regulations and standards are relatively small.
- As a complement, the degree of grow-made or domestically-made standards are significant.
- A comparison of the supporting standards used by Brazil and Argentina shows that they came from different sources, each sector utilizing independently either the US or the EU models.
- The consequences of this strategy are the following: Brazil and Argentina create regulatory barriers against each other; the process of convergence is hampered; exports to third countries are made more difficult and costs of adaptation to external demands increase.

CONCLUSIONS AND PROPOSALS

Regulatory convergence is, at the present time, one of the most relevant issues to explain positive results in international trade. After years focused on tariff-barrier at the borders, trade analysis is reviewing barriers created by regulatory measures. On one hand, countries can determine the characteristics and degrees of confidence for consumer protection of goods and services. On the other hand, technical barriers can be considered a quite efficient barrier to trade.

Despite the efforts for the negotiation of the TBT and SPS Agreements in the WTO, technical, sanitary, phytosanitary and environment measures are being used as a new wave of protection or even protectionism under the pressure of domestic producers, consumers concern on quality, climate change, pollution, emissions, quality of water and air, labor and animal welfare. The WTO agreements on TBT and SPS, negotiated in 90´s, need an urgent review to take care of all these new concerns.

In relation to trade integration and preferential agreements, after the first phase of tariff elimination, regulatory convergence is the most important goal to achieve economic integration. Tariffs are easy to erase; regulatory convergence among partners is much more complex to achieve.

Concerning TBT and SPS measures, three different aspects should be examined: regulations (mandatory), standards (voluntary) and conformity assessment (certification).

However, the core issue to exam on convergence aspect is related to the "origin or model" of the supporting standards used to establish national regulations, national standards and conformity measures. They can be developed based in three main strategies: i) to use international standards created by international organizations such as ISO, IEC, ITU (industrial goods), or CODEX, OIE and IPCC (agriculture and food) as recommended by the WTO; ii) to follow some of the more globalized standards such as the American or European or someday the Chinese ones, considered more as the main "standard makers" of the world; iii) to develop its own domestic standards to create barriers to third countries; iv) to develop a technology and impose its own standards to the world. The main question to answer is what is the goal of each country: to close its market, to export or to participate in value global platforms.

The standardization policy of Brazil and Argentina have similarities and differences. Today, the process of regulatory convergence initiated by Mercosul in the 90´s reaches an impasse and is stalled. To break this impasse, governments, agencies and enterprises need to rethink the whole system or to accept its failure. A first step is to focus in two of its main members: Brazil and Argentina. In a second step to integrate the other members of Mercosul.

Point 1: Regulations

In Brazil, the main aspects of technical regulation are established by regulatory agencies. In the state reform introduced in the 90´s, ministries are in charge mainly of sectorial policies. Regulatory agencies were created with technical autonomy and independent

budget to regulate their respective areas of competence. This is not the case for autos (which have important regulation issued by DENATRAN, CONTRAN and Ministry of Environment) and machinery (Ministry of Labor), where the role of Ministries is still in force.

For agriculture there is no specific agency. The Ministry of Agriculture has the central role as policy determination, regulation and supervision. Today this old model is facing many challenges to take care of all three functions in a satisfactory way.

Among the agencies, INMETRO is central to core aspects related to mandatory regulation on TBT. As a public autarchy constituted in an old legal model, it performs its role as an executive agency. It acts in coordination with other public bodies when related to specific industrial goods. INMETRO is also responsible for the metrology and the accreditation procedures, which authorizes private bodies to develop certification, testing, calibration procedures. A question to ask is why in the process of the reform, INMETRO lost its role as the regulatory body for automobiles and machinery. Other important agencies are ANVISA for food and medicines and ANATEL for telecommunication goods.

In Argentina, the regulatory structure is different. Policies and regulations are subordinated to political bodies, driven directly by political authorities. The main role in the area of technical regulation is performed by the Ministry of Production. There are no independent agencies. Some important governmental bodies should be highlighted: INTI in the area of metrology, SENASA and ANMAT for sanitary, quality of food and medicines.

This difference of approach could explain part of the conflicting relationship between the formulation of policies and orientation for officials in charge of convergence negotiations by the two countries, mainly related to the activities of MERCOSUL SGT 3, 8 and 11. The small achievements of these groups show that the process of negotiation must be changed and adapted to face the real challenges of integration.

In relation to transparency, a concept considered as a pillar of good practices, both countries have problems. To make a research on regulations, standards and conformity assessment is a complex and discouraging task. The updating processes offered by both countries are less frequent than the necessary. Notifications to the WTO are non-uniform. Brazil notifies all technical regulations including drafts. Argentina only notifies some approved regulations, imposing further research to find all necessary regulations.

Point 2: Standards

Concerning the development of standards, Brazil has a centralized body in ABNT, a private organization, that coordinates more than a hundred committees covering different sectors. ABNT participates as the representative of Brazil in international initiatives in the area of standardization

In Argentina this role is played by IRAM, also a private body, which is responsible for the development of national standards. This activity is more decentralized than in Brazil, since many standards are published directly by the standardizing bodies of industry associations, for example, AITA, IAS in the sectors of steel and electric goods.

Transparency is also a major problem. Both countries offer some difficulties to access information in an understandable and organized way. Public information to clarify the issues are unavailable and costs involved to search more detailed information are significant.

Point 3: Conformity assessment

In Brazil, INMETRO, as a public agency is also responsible for the accreditation policy. This body participates in international initiatives in the area of accreditation and laboratory cooperation.

In Argentina, this task is performed by OAA, also a private body, that is responsible for the domestic accreditation system and international initiatives.

The conformity assessment system, especially the accreditation procedures for certification bodies, is similar in both countries. Brazil and Argentina have a large number of products that require compulsory certification, but this list is quite variable and usually regulated by non-statutory laws.

In the accreditation area, the fact that Brazil has a public body is in charge of accreditation and Argentina has private one presents a complex problem to solve. The dialogue is more complex.

The most pressing problem to solve among the two countries is the double certification imposition. Certification activities of each country are not accepted in the other country. This represent costs and the duplication of activities.

Point 4: Use of international standards

With regard to the internationalization of the regulatory system through the use of international standards made by ISO, IEC and ITU, each countries presents a very low average, with a clear preference for the use of domestic standards.

With regard to globalized standards produced by the main "standards-makers" of the world, Brazil and Argentina have a low level of utilization of this standards as their supporting standards. Both countries opted for the strategy of developing national standards. This preference is a consequence of the industrial policy adopted by Latin-American in the 60´s on import substitution. Many times, sectorial standards were captures by particular interests of national or multinational enterprises, with the consequence of closing the market for imports and new technologies, but also to exports.

However, at the present time, this strategy is fading away and has increasing costs. It hinders the insertion of products in the international market and the participation in global platforms. Most important – it even creates obstacles to bilateral trade.

This research revealed that for all sectors studied, the degree of internationalized or global standards are low and around only 40%.

Point 5: Regulatory convergence

Mercosul has more than 20 years of age. However, progress in trade integration was achieved only in the tariff related areas of agriculture and industrial goods. In the area of regulatory convergence, despite of the creation of sub-groups on technical barriers, agriculture and health, the results presented are very discouraging. Initiatives for the creation of common regulation are fading away, and despite pressure to reduce the time process, the number of positive results are only for a few products.

Efforts to produce regional regulations and technical regulations, including regulatory convergence efforts within Mercosul in different committees have been insufficient to guaranty the free movement of goods between members and, above all, to ensure exports from the region to other markets in the world.

AMN – Mercosul Association of Norms, a private standardizing initiative, has an important role to play. However, the results presented, when compared to other international initiatives, are discouraging. After three decades of integration, only around a thousand common standards are initiated. But half of the proposed regional standards were finished, and still worst, from them, only half internalized and integrated in regional and domestic norms.

Some suggestions

Mercosul is facing a dilemma – to deepen integration by regulatory convergence or to accept failure and transform Mercosul in a simple free trade area, where only tariffs and rules of origin matters.

The lead of the process must be with Brazil and Argentina. Both countries have some task to analyse and implement:

. To realize a deep study of the real costs of the non-integration of Mercosul – "the costs of non-Mercosul". This kind of study was fundamental to convince Europeans in the 70´s to accept the initiative of the "Internal Market" and the implementation of the "new approach" on standardization, fundamental to the creation of the European standardization organizations, auto-certification and market supervision with strong legal supervision.

. Concerning regulations, the mandate of Mercosul to harmonize technical regulation should be revisited and re-interpreted. The experience of the European Union should be analysed with new eyes. After more than 20 years from its creation, and trying, without success, to harmonize its standards, the EU in the 70's restarts the process with the new approach and then the global approach.

Brazil and Argentina should negotiate a new "Bilateral new approach", with a strong political initiative from the central governments to impose a strict mandate to their regulatory agencies and bodies to negotiate a "bilateral common approach" to sectorial regulations. It is easier for an expert and government official to stick to their technical position than to really construct a common approach. Their positions are too comfortable to be maintained. They have to assume their new role – Brazil and Argentina must go further on regulatory convergence.

A possible way out is to choose some less sensitive sector to start the exercise: automotive (already in its way), electrical, machinery, textile, plastic, food, cosmetics, among others.

. Concerning standards, a new strategy should be supported to convince both private sectors to leave national standards and go to internationalized ones, allowing their industries to move to accept international or globalize standards. The consequence is clear: if a standard is an international or global standard it must be accepted by the other country and by third countries. Again, some less sensitive sector could be chosen to start the exercise: automotive (already in its way), electrical, machinery, textile, plastic, food, cosmetics, among others.

. This can be a good incentive to both countries to think about the necessity of a structural regulatory reform. To Argentina, to explore its governance structure and make a reform toward the creation of regulatory agencies more independent of the central government. This is already of the recommendations proposed by OECD to other countries in acceding process. For Brazil, to modernize its agencies structure, because the present model is already old and no more functional. Agencies were included in the bargaining of political parties and lost their main independence and expertise. They have a huge stock of obsolete regulations, they introduce regulations for political reasons without any study on costs and benefits and risk analysis.

To start the process, a basic concept must be politically accepted and implemented. The experience came from the Europeans, in the 70´s, at the time of the Cassis de Dijon decision between Frenchs and Germans on a disputable content of alcohol of liquors.

The mantra between Brazil and Argentina must be: if a product does not kill an Argentinian it will not kill a Brazilian and vice versa!

Brazil and Argentina have to face reality and go further or to face failure and lose space in the international arena.

1. OVERVIEW OF BRAZIL-ARGENTINA TECHNICAL REGULATORY SYSTEMS:

MAPPING OF REGULATIONS, TECHNICAL STANDARDS, MANDATORY CONFORMITY ASSESSMENT PROCEDURES APPLICABLE TO PRIORITY SECTORS

1.1. Introduction

In the study of technical regulation, some concepts should be clarified preliminarily. The technical regulation *stricto sensu* is that rule normally produced by a public body constituted by experts and it is mandatory. It can take the form of a law approved by Congress or it can take the form of any nonstatutory normative act (for example, resolutions, decrees, ordinances). The standard is a voluntary prescription, provided it is not explicitly referred to by technical regulations. Normally, the private sector elaborates the standard, through its associations and technical experts in standardization, often centralized in a civil association divided into several committees (see ABNT, 2017 and IRAM, 2017). Such associations also contribute in the elaboration of international standards, through the participation of international standardization bodies. Procedures for assessing the application of standards are referred to as conformity assessment procedures. They are performed by specialized private organizations that have their operating authorization granted by an accreditation body. There are several conformity assessment procedures. They differ according to the purpose of the process and the type of object assessed. For tangible products, the most important of these are the product certification procedures, which are performed by impartial and reliable third parties. Many of these procedures are mandatory, such as those determined by metrology and quality assurance bodies (see INMETRO, 2017, INTI, 2017).

While technical regulations and conformity assessment procedures are important within regulatory systems, technical standards are the central item in any regulatory system. They provide the normative basis for manufacturing processes and prescribe requirements for products. They, when referred to in technical regulations, constitute the true technical prescriptions and they are the only parameters for judging conformity assessment procedures. For this reason, markets that aim a fruitful integration, economic stakeholders, especially companies, should preferably use the same technical standards. This is for example the case of the European Union, where standards are produced at the regional level, by three Community standards bodies: European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) and European Telecommunications Standards Institute (ETSI) (see EUROPEAN COMMUNITY, 2017). In the Latin American context, where the discussion has been focused for a long time only on tariff aspects, this regulatory integration presents difficulties, which has had a significant impact on the region's trade, especially in the area of manufactured goods.

The purpose of the report is to present a comparative overview between the regulation in Brazil and Argentina, especially regarding technical regulation, technical standards and conformity assessment procedures aspects. The report describes the main regulatory bodies in both countries, focusing on the role of the regulatory bodies. Additionally, the report focuses on policy and standards bodies in both countries, with the aim of assessing the level of internationalization of the standards used in the two countries, examining the

percentages of national standards as compared to international or global ones ISO, IEC, and ITU, as well as European or American standards generally accepted around the world. Finally, the report describes the main mandatory conformity assessment process.

This report covers the following sectors: a) electrical and electronic appliances and machinery (inserted in HS 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); b) vehicles and auto-parts (inserted in HS 87 -vehicles other than railway or tramway rolling-stock, and parts and accessories thereof); c) cosmetics (inserted in HS 33 - essential oils and resinoids, perfumery, cosmetic or toilet preparations); d) machinery and mechanical equipment (inserted in HS 85 - electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); e) medical devices (inserted in HS 90 - optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof); f) processed food (inserted in HS 1 to 24); g) pharmaceutical products (inserted in HS 30 - pharmaceutical products; h) plastics and plastic products (inserted in HS 39 plastic and articles thereof).

1.2. Technical Regulation System

1.2.1. Technical Regulation in Brazil

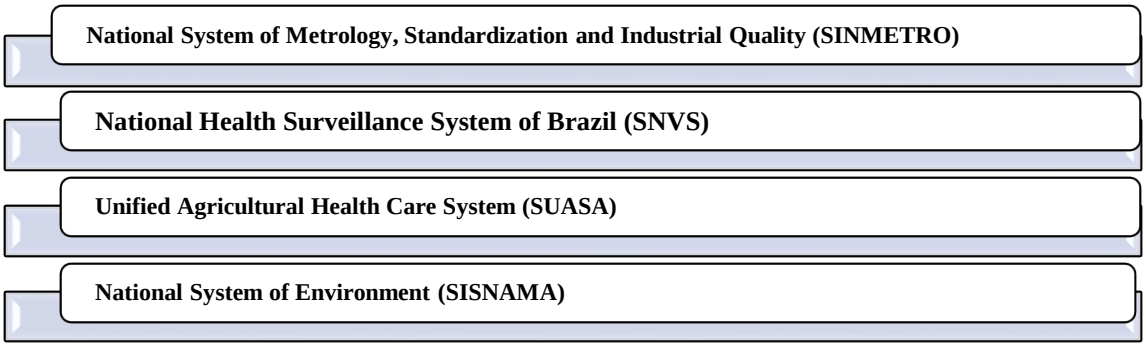
In Brazil, the policies of regulation, standardization, accreditation and certification have some important aspects that affect directly or indirectly the international trade. In each of these policies, there are different governmental and private bodies involved, many of them private actors carrying out a function of public interest. The purposes of such policies are, as a rule, the protection of public health, the environment, the consumer, as well as the guarantee of credibility of conformity assessment procedures. Currently, regulatory policies are fundamental to international trade because they can interfere positively or negatively on trade, affecting imports, exports and investment flows.

In Brazil, regulatory policies in the areas of health, phytosanitary, technical and environmental measures that impact international trade were structured by different actors. Such actors have distinct and complex interconnected relevance. In addition to the direct administration of the three Federation entities (Union, States and Municipalities), other public and private entities have important roles in the regulatory policies.

The structure of the systems derives from the political, institutional and federal organization of Brazil. The regulatory structure is the result of a decentralized policy rationality that overlaps in the distribution of competences and functional roles of the agencies. This follows a logic of institutionalization in Brazil, in which the systems are derived from legal and institutional frameworks built by the Union, with repercussion in subnational levels. In these sense, the perspective of National Regulatory Systems does not provide exhaustive analysis of the regulatory universe in Brazil, but it covers the most important and comprehensive regulation produced in the country.

There are four major national regulatory systems. These systems are composed of several bodies, many of them acting in a coordinated but functionally autonomous way.

Figure 5 - Brazilian Systems according to the respective areas



Elaborated by: CGTI – EESP/FGV.

With respect to technical regulation, the Brazilian Federal Constitution of 1988 has reserved the Union the competence to legislate on the measurement system. In this sense, the Ministry of Industry, Trade and Services (MDIC) has the obligation to manage issues related to metrology, standardization and industrial quality. The main agency responsible for such themes is the National Institute of Metrology, Quality and Technology (INMETRO)[1]. INMETRO is a federal authority, linked to MDIC, and it also perform the role of Executive Secretary of the National Council of Metrology, Standardization and Industrial Quality (CONMETRO), an inter-ministerial collegiate, which is the normative body of the National System of Metrology, Standardization and Industrial Quality (SINMETRO).

INMETRO has a central role in the import process of many goods. It maintains a computerized system called Orquestra[2] for the management of its register of items and its non-automatic import licensing activities. As at March 2016, INMETRO's register contained 32,736 items, up from 13,002 in 2013. The total number of requests for analysis of an import license rose from 197,326 in 2013 to 754,270 in 2016 (WTO, 2016).

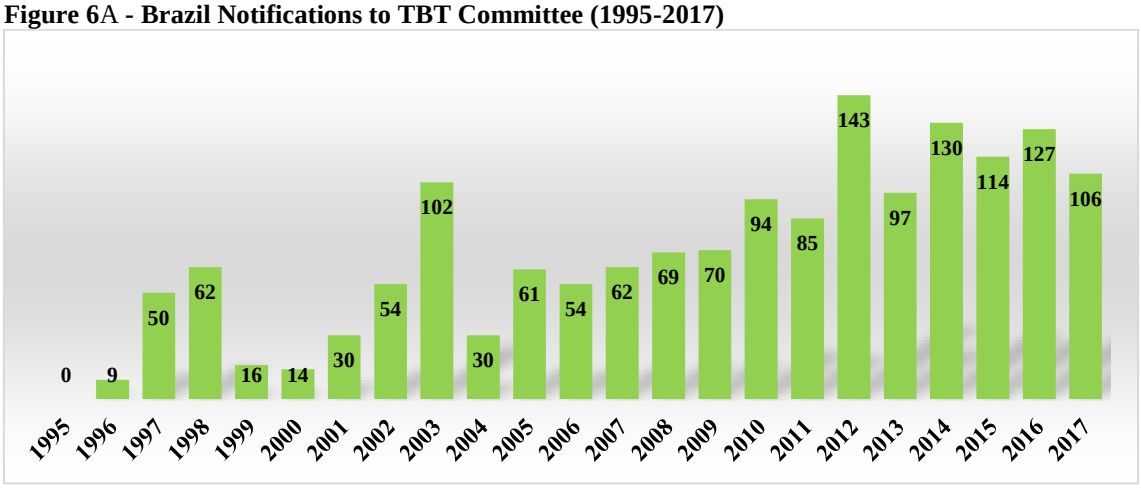
Brazil has made more than 1500 notifications to the TBT Committee. The notifications sent by INMETRO notifies public consultations or final publication of metrological and technical regulations on conformity assessment (RTCA). The INMETRO regulation set out the characteristics of a product or process and related production methods, including administrative provisions applicable to compulsory conformity assessment procedures. Such regulation concern terminology, symbols and packaging requirements, marking or labelling applicable to a product, service, goods, people, process or production method.

ANVISA and MAPA are the focal points for notifications in the area of SPS. Brazil made more than 1700 notifications to the SPS Committee. The number of notifications increased significantly since 2014, remaining on each of the last four years higher than 100.

[1] **INMETRO** issues technical regulations for all aforementioned sectors. It is possible to search by keywords, date and number of the technical regulation here.

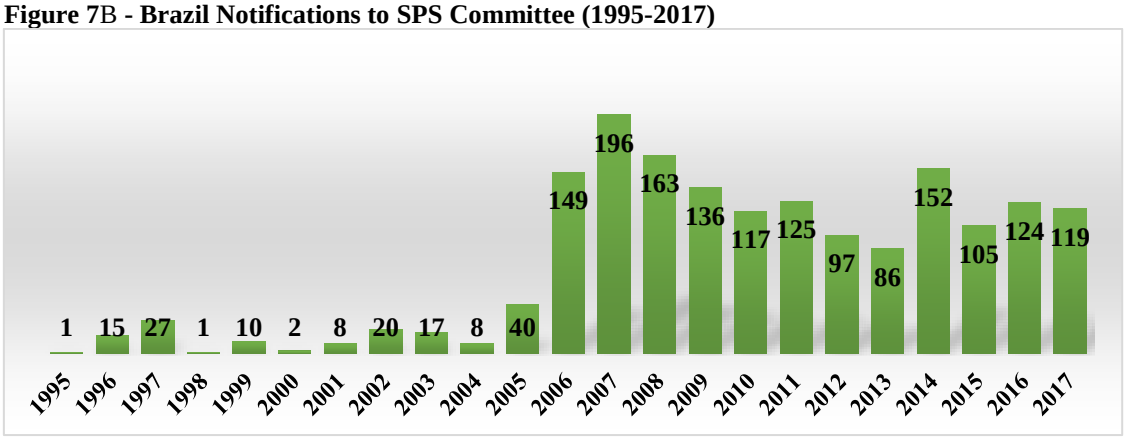
[2] More details on Orquestra System can be found in http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp

Figure 6A - **Brazil Notifications to TBT Committee (1995-2017)**



Source: WTO. Elaborated by CCGI-EESP/FGV

Figure 7B - **Brazil Notifications to SPS Committee (1995-2017)**



Source: WTO. Elaborated by CCGI-EESP/FGV

Before being approved, notifications by the regulatory authority are sent to a technical commission involving various segments of society. After a public consultation with the publication and availability of the text in the Brazil Official Journal, the stakeholders can give opinions and suggest modifications in the text. In the end, the regulation is published and made available to the public.

There is no central mechanism for publishing the drafts of technical regulation, but they are usually disseminated through the websites of the bodies adopting the technical regulations. In all cases a period of 60 days is allowed for the submission of comments. Argentina's notifications to the WTO are published on the *Punto Focal* website[3] and are also distributed through a subscription service or on request. Comments are generally discussed among the focal points of WTO Members, with intervention by the body with jurisdiction over the matter in question. The issuing body is responsible for adoption and entry into force of the measure. The measure is published in the Official Journal.

1.2.2. Technical Regulation in Argentina

Technical regulations in Argentina are frequently based on MERCOSUL standards and on the standards and recommendations of various international organizations, including

[3] *Punto Focal* online information. Viewed at: http://www.puntofocal.gov.ar.

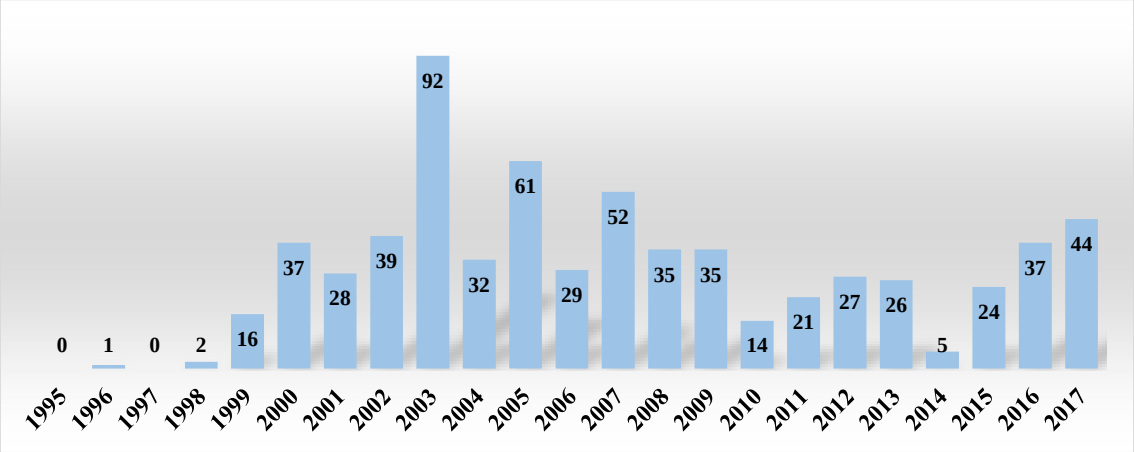
the International Organization for Standardization (ISO), the Pan American Commission on Technical Standards (COPANT), the Codex Alimentarius Commission, the International Organization of Legal Metrology (OIML), and the International Electrotechnical Commission (IEC).[4]

Various ministries and agencies are responsible for establishing technical regulations in Argentina. The following bodies may enact such regulations: the Secretariat for the Environment and Sustainable Development of the Office of the Chief of Cabinet of the National Government, the National Institute of Industrial Technology (INTI) of the Directorate-General of Domestic Trade, the National Drugs, Food and Medical Technology Administration (ANMAT), among others.

Technical regulations are usually amended or abolished on the basis of technological changes or international standards.

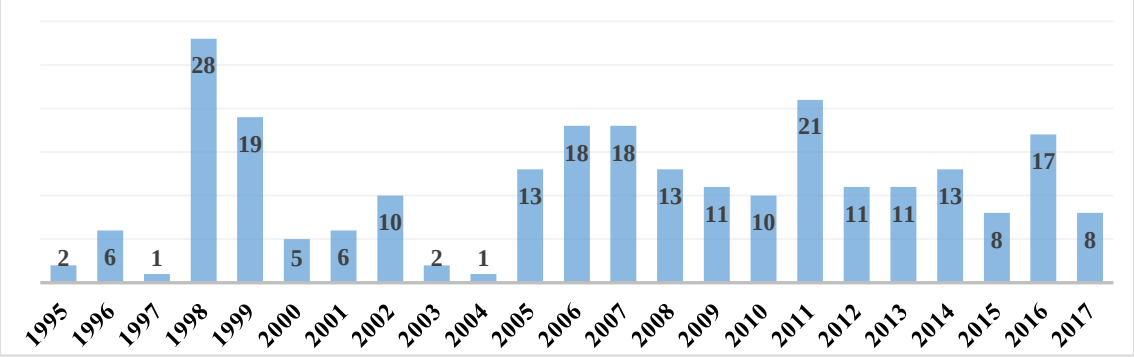
Between 1995 and October 2017, Argentina made 654 notifications to the WTO Committee on Technical Barriers to Trade. These notifications are on drafts of technical regulations (Article 2.9.2), technical regulations adopted to address urgent problems (Article 2.10.1), draft of conformity assessment procedures (Article 5.6.2), conformity assessment procedures adopted to address urgent problems (Article 5.7.1), and concerned measures under Articles 2.9 and 5.6. Moreover, Argentina made 252 notifications to the WTO Committee on Sanitary and Phytosanitary Barriers to Trade.

Figure 8A - Argentina Notifications to TBT Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV.

Figure 9B - Argentina Notifications to SPS Committee (1995-2017)

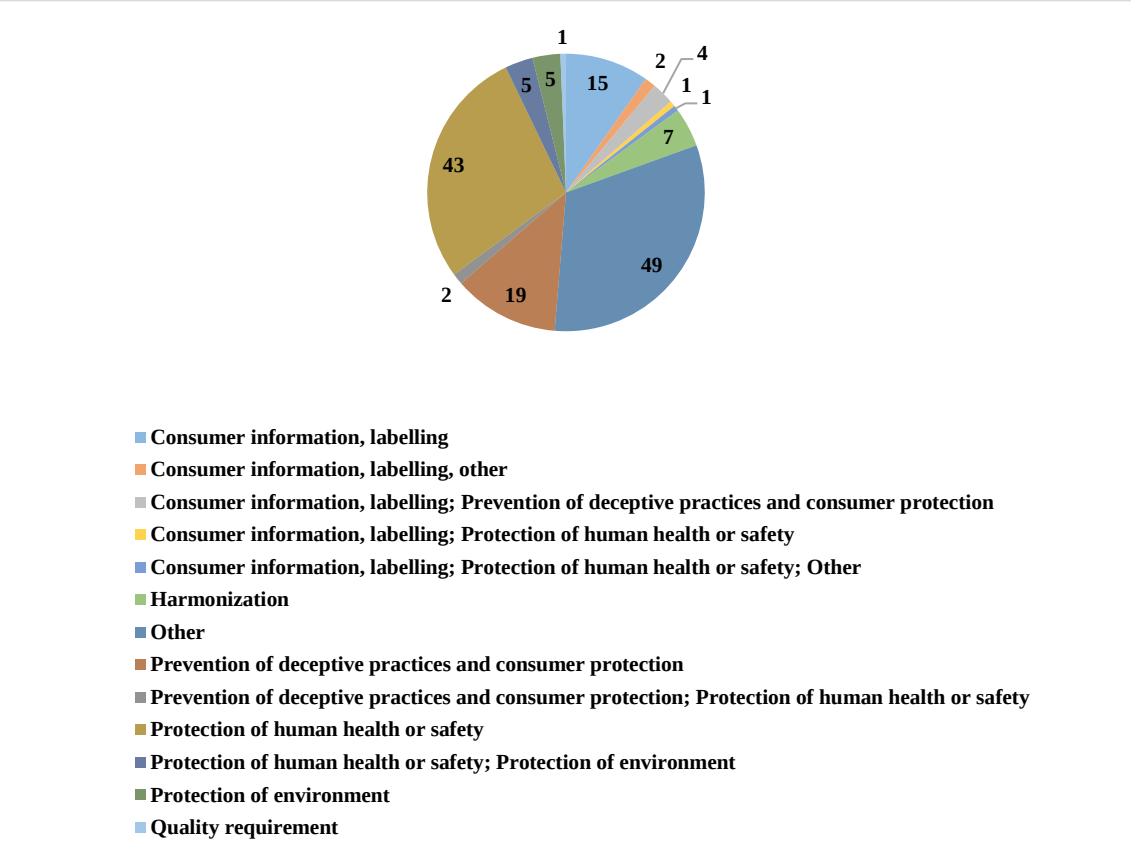


Source: WTO. Elaborated by CCGI-EESP/FGV.

[4] Information provided by the Argentine authorities.

Most notifications are regular notifications on various topics, including labelling and consumer protection. The addendums and corrigendum to previous notifications should also be highlighted. These notifications are sometimes necessary because of the economic and productive dynamics of some sectors, whose technical aspects are altered at a faster rate than the ordinary regulatory practice of the State.

Figure 10 - Scope of Notification

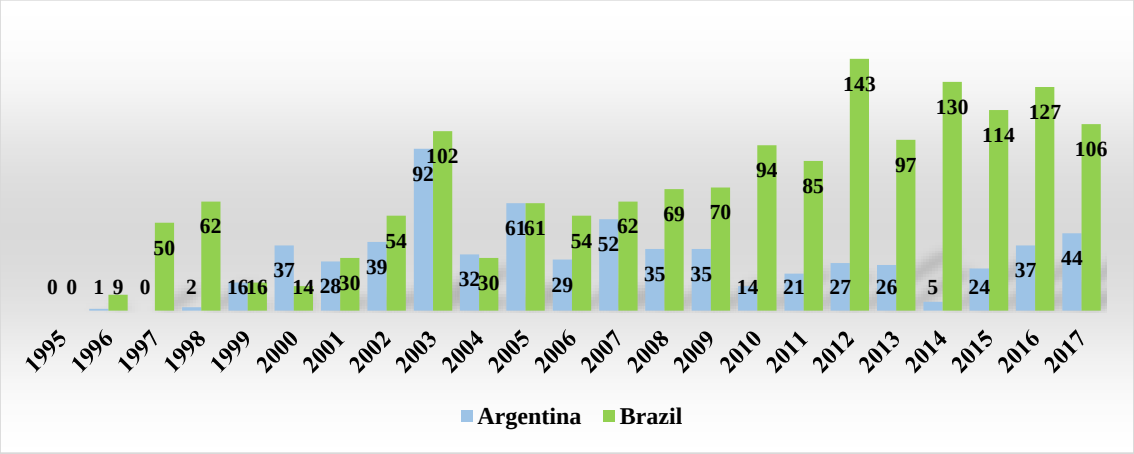


Source: WTO. Elaborated by CCGI-EESP/FGV.

1.2.3. Brazil and Argentina technical regulation: comparison based on notifications to TBT Committee

The number of Brazilian notifications to the TBT Committee is bigger to that of Argentina. This aspect reflects differences in philosophy and the intensity of regulatory activity in both countries, as well as differences in administrative and political organization. The intensity of regulatory activity can also reflect the size of the economy and international trade of the countries.

Figure 11 - Argentina and Brazil Notifications to TBT Committee (1995-2017)



Source: WTO. Elaborated by CCGI-EESP/FGV

1.3. Technical Standard Framework

1.3.1. Technical Standards in Brazil

In terms of standardization, the Brazilian Association of Technical Standards is the most important institution. ABNT is a non-governmental entity, founded in 1940. The ABNT mission is to provide to the Brazilian society systematic knowledge, producing normative documents, which allow the production, marketing and use of goods and services in a sustainable and competitive manner in domestic and foreign markets, contributing to the scientific and technological development, environmental protection and consumer protection. It is structured as a National Forum for standardization provided for in Brazilian Standardization System (SBN), under the National System of Metrology, Standardization and Industrial Quality (SINMETRO) and according to strategic guidelines of National Council of Metrology, Standardization and Industrial Quality (CONMETRO).

ABNT is recognized by international standardization bodies such as the International Organization for Standardization (ISO), International Eletrotechnical Commission (IEC) and International Telecommunications Union (ITU), the Codex Alimentarius, the *Bureau Internationale de Poids and Mesures* (BIPM), the International Organization of Legal Metrology (OIML), *International Accreditadion Forum* (IAF) and *International Laboratory Accreditation Cooperation* (ILAC).

ABNT core competence is to produce Brazilian standards (ABNT NBR), drawn up by their Brazilian Committees (ABNT/CB), sectorial standardization bodies (ABNT/ONS) and special study commissions (ABNT/EEC).

Standardization is recognized as the process of formulation and implementation of rules for the solution or the prevention of problems, with the cooperation of all concerned, and, in particular, for the promotion of the global economy. Establishing these rules refers to the technology as the instrument to establish objectively and neutrally the conditions which allow the product, project, process, system, person, good or service to meet the intended purposes, considering specifically quality and security issues.

There are different kind of supporting standards issued by ABNT that goes from a fully original standard developed under its Standardizing Committees (CB) to those based on international standards, mainly ISO and IEC. The key is to observe the number of the standard:

(i) If it is a standard identical to an international standard, it will appear, for example, as *ABNT NBR ISO nº XXX*.
(ii) If it is based on an international standard, a reference to this international standard will be in the preamble of the standard.
(iii) If it is an original standard, it will appear as *ABNT NBR nº XXX*.

The production of original standards follows a specific process: (i) the company expresses interest; (ii) a study Commission shall draw up a standard project after analysis of the industry technical Committee and inclusion in the Sectorial Normalization Plan (PNS) by consensual decision; (iii) the project is submitted to national consultation; (iv) the standard is approved, assigned a ABNT NBR and becomes available to society[5].

ABNT participates actively in various technical committees, such as ISO TC 176 (quality), ISO TC 207 (environmental) and ISO/CASCO, in addition to the ISO/TMB (Technical Management Board). ABNT signed the WTO/TBT Code of Good Practice in 1995 and follows its Annex Activities related to the accreditation and conformity assessment in SINMETRO are based on the standards and guides ABNT/ISO/IEC.

In addition to ISO, ABNT also represents the Brazil in the Copant (Panamerican Technical Standardization Commission), CMN (Mercosul Standardization Committee) and CEN/CENELEC (European Joint Standardization Organization). ABNT maintains cooperation agreement with the American National Standards Institute (ANSI) and participates, along with the INMETRO and other entities of the SINMETRO and MERCOSUL technical committees.

An overview of the standards catalog adopted by the different committees of ABNT makes it possible to verify the degree of internationalization of Brazilian standards. However, ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website[6]. Therefore, the user had to refine our keyword search in order to gather a list with relevant supporting standards for each of the economic sectors analyzed. For instance, in this report it was consulted standards discussed under ABNT Brazilian Committee nº 3 (CB 03) to find relevant supporting standards for electric-electronic and machinery sectors.

[5] The access of the content of standards issued by ABNT is not free. In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard. Therefore, going on an analysis whether such supporting standards are only based on (with some degree of modification) international standards or how different original standards issued by ABNT are in comparison with international standards is very complex task to pull through. For that matter, the report focused on the summaries of each relevant supporting standard to put together a list of them by analyzed sector and to provide a first assessment on their compatibility with international standards.
[6] ABNT Catalog with all searching tools is available here.

As at March 2017, there were 7,815 standards in force in Brazil. Between January 2013 and January 2017, Brazil adopted 2,557 new standards, some 33% of which were adoptions of international (ISO/IEC) standards.

1.3.2. Technical Standards in Argentina

The standardization system in Argentina is not centralized. There is an important standardization body, which develops most part of standards, but there are also several other sectorial bodies that produce standards for their sector.

In its capacity as the national standardizing body, IRAM develops standards in a participatory, transparent and consensual manner, using international standards as a benchmark. In Argentina, standards are prepared by standards study bodies, comprising representatives of various organizations belonging to the three sectors involved in the production of a standard: producers, consumers and those "responsible for protecting the general interest and the common good". Before a draft standard can become an IRAM standard, it must be considered by the General Committee on Standards (CGN), an independent and honorary body responsible for the comprehensive examination of all the technical documents approved by the various study bodies.

The preparation of standards begins with the production of a draft standard, either by the Executive or by representatives of the sector concerned. The draft is submitted for public discussion for a period of between 30 and 180 days (with exceptions). The draft, with the revisions considered necessary, is then submitted to the General Committee on Standards, which gives it official form and passes it on to the IRAM Directorate General for approval as a standard.

At regional level, IRAM participates in the Pan American Standards Commission (COPANT) and the MERCOSUL Standardization Association (AMN). IRAM is a member of ISO, contributing to develop international standards for different sectors.

There are other important sectorial standardization bodies in Argentina. They usually work together with IRAM, but sometimes they produce standards as single bodies. Two important sectorial standardization bodies are the Association of Automotive Engineers and Technicians (AITA) and Argentine institute of iron and steel industry (IAS).

AITA was created in 1970 with the aim of studying and issuing technical norms for the automotive industry through the agreement of technical cooperation with IRAM. AITA is a technical forum that gathers resources and efforts in order to transform the local automotive industry, the facilities of the government and the academic space in a unique context. It participates actively on the harmonization of norms inside Mercosul and is adhered to FISITA, the International Federation of Societies of Engineers in Automotive Techniques.

AITA is composed of technical commissions and/or regional nuclei, which are coordinated by professionals and specialists with vast experience and recognized trajectory. They produce works and reports that conform the recommendations and/or specifications of norms and regulations to be applied. The association publishes technical knowledge, experience and skills of engineers and technicians through a cooperative

engineering system that is useful to the State, to the industry, to educative institutions, to professionals and to the whole community.

The entity made many efforts to control the quality of safety pieces sold in the replacement market. The common user is not protected as to the possibility of accessing the technical control of what he buys for his vehicle. Resolution 91/2001 regulates the production and trade of many safety pieces. This resolution allows, among others, the agreement IRAM-AITA to certify safety auto-parts. The certification is the process in which the producer complies with the quality system established on model 5 of guide ISO/IEC 28 or IRAM standard 354 that is its equivalent. The products must also comply with the corresponding norm or normative document.

AITA integrates work and cooperation agreements with IRAM, UTN, the National Sub-Secretary of Transport, the National Commission of Traffic and Safety, the Secretary of Environment and Sustainable Development, the Brazilian Association of Automotive Engineering (AEA), the Professional Foundation of Transport (FPT), the Professional Council of Mechanical and Electric Engineering (COPIME) and the auxiliary entity of the provincial agency of transport of Buenos Aires.

Argentine Institute of Iron and Steel Industry (IAS) is an entity constituted in 1972 by Argentine iron and steel companies. IAS does activities of technological development, technical assistance, analysis, and distribution of technical information, organization of courses and conferences and normalization. These activities aim to accompany the development of the iron and steel sector, of its value chain and other industries.

The institute, on the scope of the agreement of technical cooperation subscribed with IRAM, develops the process of creation of norms relative to iron and steel products, its inputs, welding and related aspects. It participates on the study of standards on the regional level, especially with the works of MERCOSUL Standardization Association (AMN) and Pan American Commission of Technical Norms (COPANT).

The Committee of Coordination IRAM-IAS is responsible for guiding the works under the agreement. The committee is composed of representatives of each institution, considering the requirements of producers and users, of government programs and of the technical and scientific area.

The working plan is developed on first instance on IAS through specific study commissions with the participation of interested sectors: users, producers, institutions and public and private bodies. The results are turned to IRAM in order to, once done the common procedure, be approved as Argentine standards identified by the initials IRAM-IAS. This system of study of standards of products and iron and steel inputs between institutes of normalization and iron and steel institutes facilitates the advances on the standardization of the sector.

The environment working group of IAS monitors the liquid and gas effluents, the soil, underground waters and residues. Its equipment of sampling and analysis is in conformity with international standards. Since 2001, the Provincial Body for Sustainable Development oversees the environment to guarantee that corporations comply with their legal obligations. On the process area, the working group is working on the recovery of industrial residues inside an agreement with the Japanese Agency of Cooperation (JICA).

Argentina's standardization system, therefore, presents an important degree of decentralization. Although there is a main body that, in theory, should bring together the standardization activity of all associations, they continue to produce technical standards autonomously. It is also worth noting that sectoral standardization bodies also maintain relations with similar bodies in other countries, at regional and international levels. Such net of international relationships of the Argentine standardization bodies makes the system more complex.

1.3.3. Brazil and Argentina technical standards: caparison based on standards produced by the main standardization bodies

The use of international standards produced by international standardization bodies may favor the insertion of a country's exports in sophisticated foreign markets. The frequent use of international standards in domestic production processes would be indicative of the level of internationalization of production and economy.

However, all countries have their own standardization policy, coordinated by one or more national standardization body, whose work is performed directly by the domestic productive sectors. This means that countries and economic blocs are reluctant to renounce their prerogative to develop their own standards. One way to avoid incompatibilities between national and regional standards is to adopt, through simple copying or soft adaptation, international standards (eg ISO, IEC) by the national and regional standardization bodies. This is, in fact, a practice widely adopted by those bodies. Thus, a valid way of verifying the internationalization of a productive process can be by analyzing the domestically produced technical standards for different sectors. Whether these standards are replication or adaptation of international standards, the industry is technically closer to developed and demanding markets.

The table below presents the percentage of international standards that are used by the main standardization bodies in Brazil and Argentina.

Table 8 - Level of internationalization of sectorial standards

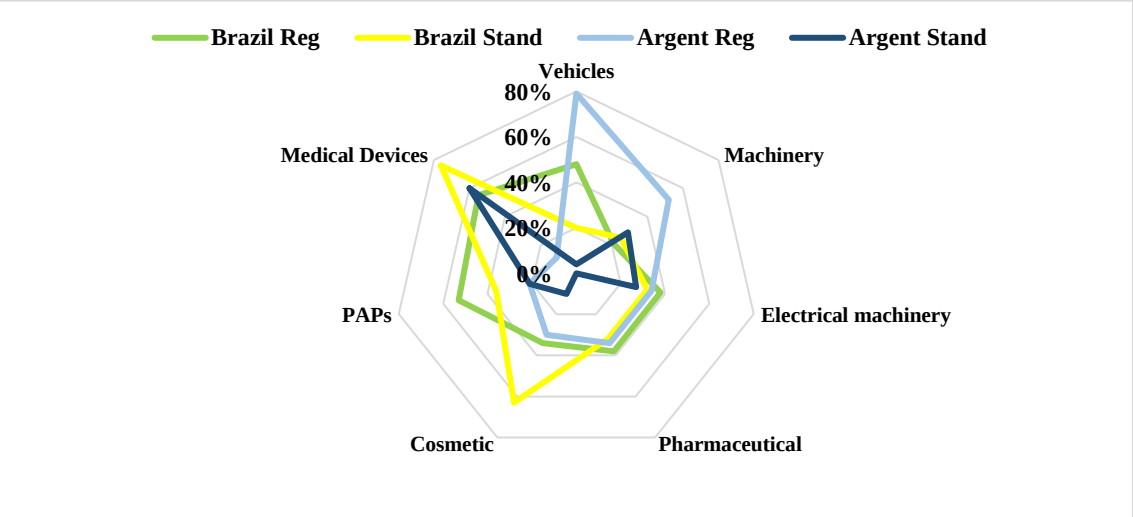
HS 87 - VEHICLES; OTHER THAN RAILWAY OR TRAMWAY ROLLING STOCK, AND PARTS AND ACCESSORIES								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		ABNT (BRAZIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	34	52%	350	80%	86	21%	80	96%
INTERNATIONAL STANDARDS	32	48%	84	20%	328	79%	4	4%
HS 84 - MACHINERY AND MECHANICAL APPLIANCES; PARTS								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		ABNT (BRAZIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	25	79%	585	75%	38	48%	71	71%
INTERNATIONAL STANDARDS	7	21%	197	25%	41	52%	29	29%
HS 85 - ELECTRICAL MACHINERY AND EQUIPMENT; SOUND RECORDERS AND REPRODUCERS; TELEVISION IMAGE AND SOUND RECORDERS AND REPRODUCERS, PARTS AND ACCESSORIES								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	80	62%	935	68%	120	66,3%	73	73%
INTERNATIONAL STANDARDS	41	38%	431	32%	61	33,7%	27	27%
HS 30 - PHARMACEUTICAL PRODUCTS								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	20	91%	3	75%	120	66,3%	19	100%
INTERNATIONAL STANDARDS	2	9%	1	25%	61	33,7%	0	0
HS 33 - PERFUMERY, COSMETIC OR TOILET PREPARATIONS								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		ABNT (BRASIL)		ARG NOTIFICATIONS TO TBT COMMITTEE		IRAM (ARGENTINA)	
	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE	TOTAL	PERCENTAGE
HOMEGROW STANDARDS	2	66%	3	37%	7	70%	9	90%

INTERNATIONAL STANDARDS	1	34%	5	63%	3	30%	1	10%
HS 16, 19, 20, 21 - PROCESSED FOOD - PAPS								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		**ABNT (BRASIL)**		**ARG NOTIFICATIONS TO TBT COMMITTEE**		**IRAM (ARGENTINA)**	
	TOTAL	**PERCENTAGE**	**TOTAL**	**PERCENTAGE**	**TOTAL**	**PERCENTAGE**	**TOTAL**	**PERCENTAGE**
HOMEGROW STANDARDS	93	47,4%	22	64%	34	79%	33	79%
INTERNATIONAL STANDARDS	103	52,6%	8	36%	9	21%	9	21%
HS 9018, 9022 - MEDICAL DEVICES								
	BRAZIL NOTIFICATIONS TO TBT COMMITEE		**ABNT (BRASIL)**		**ARG NOTIFICATIONS TO TBT COMMITTEE**		**IRAM (ARGENTINA)**	
	TOTAL	**PERCENTAGE**	**TOTAL**	**PERCENTAGE**	**TOTAL**	**PERCENTAGE**	**TOTAL**	**PERCENTAGE**
HOMEGROW STANDARDS	8	45%	35	24%	33	89%	33	89%
INTERNATIONAL STANDARDS	9	55%	111	76%	4	11%	4	11%

Source: ABNT; IRAM; European Commission. Elaborated by CGTI-EESP/FGV

The data in the table are expressed graphically in the figure below. It is clear that in some sectors where the EU had very low or no standard figures, there was a Community option to standardize products in other ways, not using the three EU standardization bodies.

Figure 12 - Level of internationalization of sectorial standards



Source: ABNT; IRAM; European Commission. Elaborated by CGTI-EESP/FGV.

The degree of internationalization of standards varies greatly according to the sector. Some sectors, such as medical devices and information technology, are heavily internationalized. Other sectors have a lower degree of internationalization, such as basic chemicals, but it suggests the irrelevance of standardization in a sector strictly ruled by compulsory technical regulations. In the comparison between countries, both Argentina and Brazil have a low degree of internationalization compared to the European Union. In fact, the production of CEN, CENELEC and ETSI standards usually reproduces international standards in their entirety and advance in product performance, environmental protection and consumer welfare requirements. In the comparison between Brazil and Argentina, Brazil has a higher degree in almost all sectors, except machinery and mechanical equipment and basic chemicals. The low level of internationalization of Argentine standards may have been partially affected by the exclusive use of the standards produced by IRAM, disregarding those produced directly by sectoral standards bodies (such as AITA). These aspects, however, would hardly change the general picture for the standardization policy in Argentina.

1.4. Conformity Assessment System

Accreditation is a process that lends credibility to a conformity assessment body or procedure. There is not only one type of conformity assessment, although the certification is the best known of them. Usually, five types of conformity assessment procedures are identified: testing, examination, verification, inspection, calibration and certification. Calibration and verification are metrological verification procedures. The inspection and the examination are procedures performed, under specified conditions, for the purpose of identifying points of interest or properties of a material in a given sample. Certification focus on products, processes, services, management systems and personnel. By definition, it is performed by a third party, that is, an independent, accredited organization to perform the conformity assessment of one or more of these objects.

Certification is one of the most important conformity assessment procedures since it covers a fairly large number of goods and services. Certification may be compulsory or voluntary, depending on the relevant legislative provision. In general, the mandatory certification is that determined by a technical regulation. The certifying bodies, in most cases, are accredited by an official accreditation body, which confers the necessary credibility to the certifying body. In general, there is only one accreditation body by country.

1.4.1. Conformity Assessment in Brazil

According to Conmetro resolution 5/95, Inmetro is competent to coordinate activities as the notification center of technical barriers, denominated Focal Point of Technical Barriers to Exportations. Under this mandate, Inmetro created a conformity assessment program.

In practice, the program operates through the collection of samples of products regulated by conformity assessment procedures and the subsequent send to accredited laboratories that belong to the Brazilian Network of Test Laboratories (*Rede Brasileira de Laboratórios de Ensaio* – RBLE). These laboratories verify the conformity of the samples with the legislation in force.

Another part of the program is the analysis of products with conformity evaluated voluntarily or compulsorily, being essential on the evaluation of the features of the product aspects directly related to safety, human health and the environment (Inmetro, 2018b). The main criteria applied on the program are listed below.

- statistical indexes of complaints on Inmetro;
- identification of the needs of organizational unities of the directorate of conformity assessment and of the general coordination of accreditation;
- priorities verified on the society through the Brazilian Committee of Conformity Assessment (*Comitê Brasileiro de Avaliação de Conformidade* – CBAC);
- requirement of regulations of conformity assessment;
- solicitation of the directorate of conformity assessment;
- expectation of the regulatory bodies;
- historic of conformity assessment programs and
- index of irregularities on oversight.

After the definition of the criteria, the systematic procedure of conformity assessment normally involves, among other actions:

- performance of tests;
- performance of inspections through the interpretation of results of tests and inspections;
- performance of audits on the management system of supplier quality through follow-up audits and the definition of systematic treatment of non-conformities identified and
- evaluation and follow-up of the product on the market (Inmetro, p. 18).

The choice among the aforementioned mechanisms is done considering different aspects. Examples of these aspects are the risk present on a possible consumption accident, the impact and the frequency of a failure, the volume of production, the speed of technological improvement on the sector, the size of the manufacturers involved,

geographical dispersion, the impact on the competitiveness of a product and the degree of difficulty in monitoring the market (Inmetro, p. 21).

The results arising from the execution of conformity assessment programs are evaluated by the directorate of conformity assessment, as foreseen on Inmetro specific norm NIE-DQUAL-145.

Another key instrument of conformity assessment is the monitoring on the market by external agents. The main objective of this activity is to amplify the necessary structure in support of the increasing demand that appeared due to the increase of products and services that underwent a conformity assessment procedure (Inmetro, 2018c). The activity also provides the follow-up of the society in relation to these products with impact on the human health and security as well as on the environment. The monitoring is justified by the increasing diffusion of a culture of certification of products and services and the expertise dissemination on conformity assessment, quality and consumer relations.

In the activity of conformity assessment of products evaluated by the external agent, Inmetro is competent to analyze the data supplied and take decisions regarding them (Inmetro, 2018c).

The conformity assessment program, thus, comprises a sequence of different moments. The initial evaluation of the conformity of the object is followed by a group of actions of follow-up and control to allow the manager of the program to be certified that the product is effectively on sale in conformity with the established rules (Inmetro, p. 18). In comparison with the initial evaluation, this later phase is more complex and requires higher systematization.

As at January 2017, 382 calibration laboratories and 1,046 testing laboratories were accredited in Brazil. There were also 879 entities with active accreditations to perform conformity assessments (certification, inspection, performance verification). Among the Brazilian-accredited entities, 10 laboratories and 4 certification bodies were located overseas.

1.4.2. Conformity Assessment in Argentina

Conformity assessment is ruled by the Laws on Consumer Protection (Law 24240/1993) and Fair Trade (Law 22802/1983). They stipulate that products must be supplied in a form such that, when used under predictable or normal conditions, pose no risk to the health or person of the consumer. The products whose use could pose a risk to the health or person of the consumer must be traded in conformity with the rules established by the national implementing authority or reasonable rules to guarantee consumer safety. The Secretariat for Domestic Trade is the national implementing authority and it is responsible for creating mandatory safety requirements.

In Argentina, accreditation is responsibility of Argentine Accreditation Agency (OAA). Accreditation means the formal recognition of competence and impartiality of laboratories, suppliers of proficiency testing, producers of reference materials and certification and/or inspection organisms. It is done through an independent evaluation based on international standards used as normative requisites. It shows that these entities

can be trusted to do tests, proficiency testing programs, production of reference materials, calibrations, inspections and certifications.

Regarding information to exporters, many countries in the world have regulations that require compulsory accreditation of certification organisms, inspection organisms and/or test laboratories that certify, inspect and test products traded on the local market. The accreditation body may have signed a multilateral agreement with ILAC, IAF or IAAC.

The accreditation bodies that signed the agreements must trust on the accreditation conceded by other signers and thus consider that the certificates, inspection or informs issued by entities accredited by the OAA have the same level of trust of the ones issued by accredited entities in each signatory country.

The main benefits derived from the accreditation process are listed on the following table.

Table 9 - Benefits derived from accreditation

ACTOR	BENEFIT
Government and regulators	OAA is an instrument of high trust to regulatory authorities in issues of health, security, food and environment. Guarantee of the compliance of requirements established to guarantee security of people and environmental protection.
Companies	Based on agreements of multilateral recognition, products and services backed up by certifications, inspections and laboratory tests duly accredited are accepted on the global market, eliminating technical barriers to trade. A contribution to improve competitiveness between companies, to increase economic growth and to generate employment. A basis to a trustworthy selection of suppliers.
People	Confidence to the public in goods and services and consumption. Reduction of failures in products. Security of people and environmental protection.

Source: OAA. Created by CCGI – FGV/EESP.

Certification is one of the responsibilities of the INTI, which also regulates and develops the metrology sector in Argentina. INTI certification organism was created by resolution of the Directive Council nº 32/2001 to certify products on the voluntary and regulated scopes. Its activities were later extended to certify processes and labor competences. The main goal of INTI certification organism is to do all the management to concede the certification. The National Directorate of Internal Trade recognized INTI as the certification organism inside the scope regulated by provision nº 775/99. OAA recognizes the competence of INTI certification organism to do the certification of products and people.

INTI acts as an independent third party regarding the compliance of standards, allowing a differentiation to transmit confidence to users and buyers. INTI has a quality policy that was implemented and kept on all the levels of the certification organism. The certification process is composed of four phases: requirement of certification, conformity assessment procedure, issuing of certificate and follow-up or oversight.

INTI and OAA signed a covenant in 2015 through which the certification organism is re-accredited to certify people that want to demonstrate their theoretical and practical knowledge on the methods of: magnetic particles, penetrant liquids, measurement of thicknesses by ultrasound. These certification processes are done according to requisites established by the standard IRAM-ISO/IEC 17024:2013.

The Secretariat for Domestic Trade established mandatory certification regimes for certain products and also must assess the technical and legal requirements of those regimes. One of the certification regimes encompasses symbols that must displayed in manufactured products. The symbols must be marked on each unit of the product, either

on the unit itself or on its packaging or labelling together with the certificate number corresponding to the product in question.

Table 10 - Mandatory certification regimes

PRODUCT	RESOLUTION NO. (UNLESS OTHERWISE INDICATED)	CERTIFICATION BODY
Domestic appliances/energy labelling	319/99 (as amended)	INTI
Devices, equipment, accessories and containers for gaseous fuels	676/99(as amended)	INTI
Safety auto parts	91/2001	INTI
New bicycles	220/03 (as amended)	INTI
Animal identification tags	Order No. 1.325/06	SENASA / INTI
Cement	130/92	INTI
Bicycle tyres and tubes	153/05 (as amended)	INTI
Low-voltage electrical equipment	92/98 (as amended)	INTI
Phthalates	583/2008	Ministry of Health / INTI
Toys	163/05 (as amended)	INTI
Anti-hail nets	Law No. 26.459	INTI
Retreads	205/2010	INTI
Paper sold packaged	653/99 (as amended)	INTI
Cells and batteries	14/2007	Secretariat for the Environment and Sustainable Development / INTI
Lead in paints, lacquers and varnishes	7/09 (as amended)	INTI
Printed graphic products	453/2010	INTI
Assembly shops for cng	2.603/2002	INTI
Dyes, lacquers and varnishes used in the printing industry, as regards their lead content	453/10, 39/11 and Order No. 26/12	INTI

Source: WTO. Elaborated by CGTI-EESP/FGV.

Resolutions set forth technical regulations and standards with which the products must comply to be certified and the procedure to obtain such certification. Some of these formalities can be suspended temporarily or definitively or for specific products.

Institutions that participate in the test and the certification of regulated products must be accredited by the OAA and recognized by the competent authority. The certifying body and the laboratory whose work involves elaborating conformity certificates and test reports must be recognized by the Secretariat for Domestic Trade. The requirement to obtain accreditation is to follow ISO/IEC guidelines.

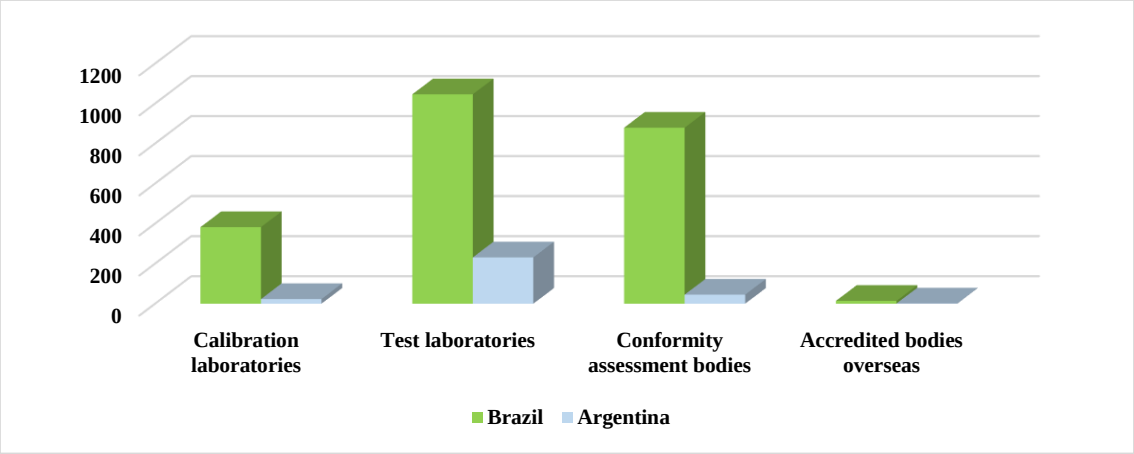
The institutions that participate in testing and certifying regulated products are IRAM and INTI. IRAM has an important role in the certification of products, processes and services over a very wide range of economic activities. The certification is done through IRAM seals and IRAM conformity marks. INTI's certifying body can certify products under the voluntary or regulated regime. OAA can accredit organizations that participate in the test and the certification of regulated products. OAA is also competent to carry out any accreditation activity incorporated in international practice or defined by the regulatory authorities.

Argentina has 23 calibration laboratories, 231 testing laboratories and 45 conformity assessment bodies. The country recognizes foreign certifying entities and laboratories of countries under two conditions: the relevant reciprocity agreements must be in effect and the entities must be accredited by the respective national accreditation body. In this aspect, OAA integrates many international organizations and is a signatory to multilateral recognition agreements (ARM) at international level.

1.4.3. Brazil and Argentina conformity assessment procedures: comparison based on certification bodies

The conformity assessment procedures are very similar in Brazil and Argentina. There is a greater number of conformity assessment bodies and laboratories in Brazil, which is explained by the existence of greater demand in the Brazilian market, which larger than Argentine´s. Brazil also has a greater presence abroad in conformity assessment services, mainly product certification.

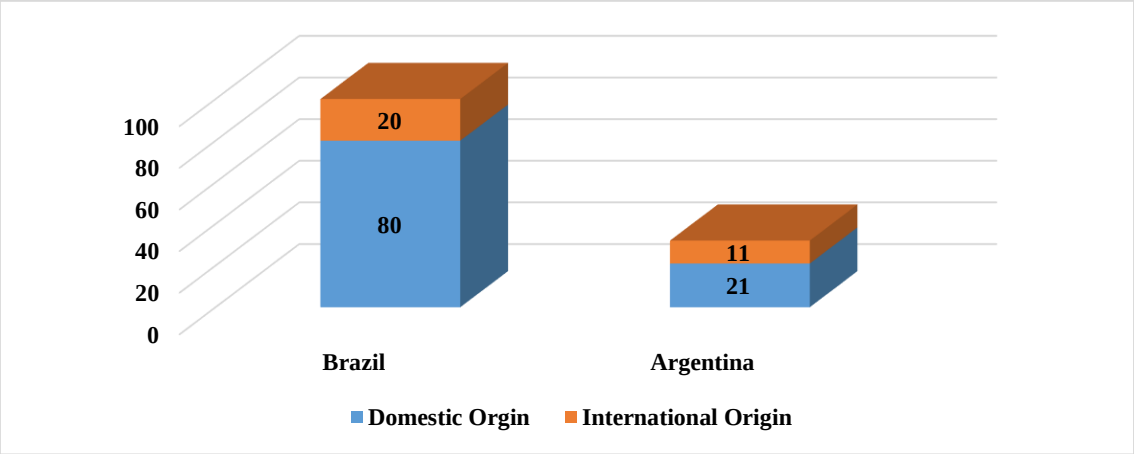
Figure 13 - Overview of accredited bodies



Source: INMETRO, INTI, OAA. Elaborated by CGTI-EESP/FGV

The participation of foreign certification bodies seems to be is higher in Argentina. This is different if one considers the total numbers of such bodies in both countries. The great number of totally Brazilian certification bodies clearly dilutes the foreign presence in the sector in Brazil. The most important international organizations (eg Intertek, TUV and UL) are present in both countries, working with the certification of various products.

Figure 14 - Origin of certification bodies (only products)



Source: INMETRO, INTI, OAA. Elaborated by CGTI-EESP/FGV.

1.5. Regional Regulatory Cooperation

Brazil and Argentina are inserted in regional initiatives for regulatory cooperation. The most important initiatives were developed in Latin American Integration Association (ALADI) and in Mercosul.

1.5.1. Regulatory Cooperation in ALADI

The theme of regulatory convergence is not central to Latin American integration. Although there are normative and policy initiatives that address the issue, it is not a priority for the Latin American Integration Association (ALADI) member states, the most comprehensive integration arrangement on the American continent.

This little importance that the theme receives in Latin America arises from two characteristics of integration projects in the subcontinent: the period in which they began and the lack of flexibility of integration structures.

Regulatory convergence is the approximation between regulatory systems of two or more autonomous customs territories, which results in the removal of non-tariff barriers to trade. The creation of a free market presupposes not only negative conduct by States, which must refrain from creating tariff and non-tariff barriers, but also positive conduct, which demands the removal of obstacles to the free transit of goods, including obstacles of a regulatory nature . One way to remove regulatory barriers is to approximate Member States' regulatory systems, particularly with regard to their technical regulation, their conformity assessment procedures and their standardization policies (creation of standards, for example, those elaborated by the Brazilian Association of Technical Standards, ABNT, and the International Standadization Organization, ISO).

There are two purposes of the de Latin American Association of Intergration (ALADI), according to provision of art. 1 of the Treaty of Montevidéu (1980) and the formation of a common market in Latin America. The members are committed to eliminating, progressively, barriers to trade, including non-tariff restrictions to regional trade (Article 13 of the Montevideu Treaty). The purpose demands regulatory cooperation between the countries of the region (Article 2 of the Montevideu Treaty).

The most important instrument for regulatory cooperation in ALADI is the Framework Agreement for the Promotion of Trade through Overcoming Technical Barriers to Trade, signed in 1997 and in force since 1998. The aim of the agreement is to ensure that the development, adoption and application of technical regulations, standards and mandatory conformity assessment procedures do not constitute unnecessary barriers to intraregional trade (art. 1 of the Framework Agreement). In line with the TBT Agreement of the WTO (see art. 2 of the TBT Agreement), States have sought to achieve this by harmonizing technical regulations that can achieve trade without reducing levels of protection animal and plant life and health, the environment, safety and the consumer (art. 3).

In the harmonization process, which is the form of regulatory cooperation explicitly adopted by ALADI members, the regulatory and standardization work developed in the region is used as the main parameter for the design of domestic technical regulations. The imminent approval of regulation or standard is considered for regulatory and standardization activity of States (Article 6). Priority shall be given to the harmonization

of technical regulations which may constitute unnecessary technical barriers to intraregional trade (Art. 7).

The idea of convergence adopted by ALADI countries was therefore to make use of international and regional regulatory and standardization parameters, in order to avoid incompatibilities between the regulatory systems of the States parties. In practice, this arrangement indicates that States should make efforts to produce technical regulations within ALADI legal framework and then internalize these regulations so that they can be applied at the domestic level, repealing earlier national rules on the same subject. In addition, voluntary standards used in production processes should be those produced by international (eg ISO, IEC) and regional standardization bodies (eg COPANT, AMN) even though they have to be submitted to nationalization process in the domestic standardization bodies.

According to art. 8 of the Framework Agreement, the establishment and strengthening of conformity assessment systems and the mutual recognition of conformity assessment systems among ALADI countries are key instruments for the regulatory cooperation. The main bases for such cooperation are recommendations from specialized international bodies such as ISO and other international forums that bring together accreditation bodies such as the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). Cooperation in this area would avoid double accreditation of conformity assessment bodies, reducing the cost of regional trade.

Besides the construction of conformity assessment systems, the art. 10 of the Framework Agreement set forth a harmonized regime regarding liability for the veracity of certificates and other documentation issued by the accredited institutions and penalties applicable in cases of fraudulent certification.

Within the framework of conformity assessment systems and the harmonized regime, the signatory countries are working to encourage the participation of their official accreditation bodies in the Inter-American Accreditation Cooperation (IAAC) and to participate in multilateral recognition agreements. Such measures are intended to enable the mutual recognition of conformity assessment structures of countries (Art. 12).

The IAAC is a regional association of accreditation bodies and other related organizations interested in conformity assessment in the Americas. Briefly, it is verified that the IAAC promotes direct cooperation between accreditation bodies in the American continent. Its overall objective is to develop conformity assessment frameworks to achieve product, process and service improvement by reducing the risk to business owners and consumers by enhancing trust in accredited certificates. Accreditation has the purpose of assuring users of the competence and impartiality of the accredited body.

The IAAC has multiple goals and carries out various functions within the American continent in regulatory matters. First, the IAAC administers the Multilateral Recognition Agreements between the accreditation bodiesof the members States. The IAAC also promotes the harmonization of accreditation programs for its members in order to eliminate the need for separate accreditations in each country. Thirdly, the entity promotes collaboration and cooperation throughout the world between accreditation bodies and between their members and other relevant bodies and groups. Fourth, the IAAC assures the representation of the Americas in international accreditation forums

and provides a wide variety of training activities. Therefore, the interaction between ALADI and IAAC is important and can facilitate the cooperation efforts in Latin American region.

In the regulation of metrology, as provided in art. 13 of the Framework Agreement, the signatory countries should adopt the international system of units and to establish the strategies, deadlines and instruments necessary to bring the national structures into line with the technological change resulting from the adoption of the international system of units.

In compliance with the principle of transparency, which is fundamental in regulatory cooperation initiatives, the signatory countries work with the General Secretariat of ALADI, the Pan American Technical Standards Commission (COPANT) and other relevant regional entities. They effort to develop and integrate information systems on draft technical regulations, technical standards and conformity assessment systems. The system shall be able to respond promptly to requests regarding the technical regulations, standards and conformity assessment procedures in force.

The permanent contacts between the national standardization, regulation and conformity assessment bodies of the signatory countries is intended to strengthen the above mentioned instruments of regulatory convergence. From the dialogue of these different institutions, signatory countries can formalize, through additional protocols, the instruments of harmonization and other concerted actions. They also can structure a conceptual framework for technical regulation and standardization, as well as conformity assessment.

In parallel to the provisions formalized under the Framework Agreement, Mercosul countries have created additional measures to strengthen regulatory cooperation.

1.5.2. Regulatory Cooperation in Mercosul

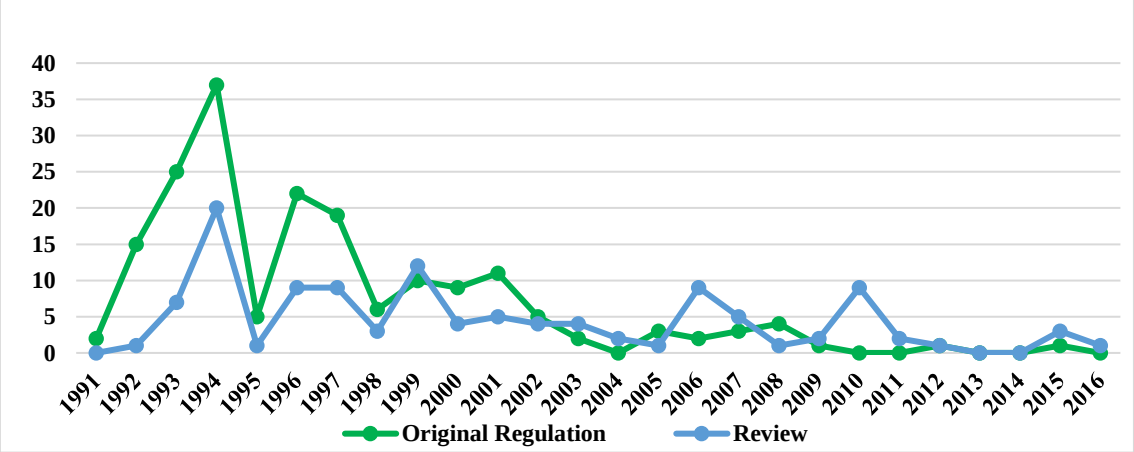
In terms of technical barriers, regulatory convergence initiatives among the Mercosul countries were adopted within the framework of the Sub-Working Group (SGT) No. 3 and the Mercosul Standardization Association. These two bodies were responsible for the production of a series of technical standards, which should be internalized by the Member States.

The SGT No. 3 is one of the eighteen subgroups of work subordinated to the Common Market Group, sharing space with subjects such as communications, institutional aspects, financial affairs, transport, environment, industry, agriculture, energy, labor, health, investment, trade electronic, productive integration, mining and geology.

Each of these subgroups is integrated and coordinated by representatives of specialized government bodies. Thus, SGT No. 3, called Technical Regulations and Conformity Assessment, has its General Coordination of International Articulation attributed to the National Institute of Metrology, Standardization and Industrial Quality (INMETRO). The other Mercosul members assign this function to higher political bodies, generally endowed with a ministerial condition. Thus, in Argentina, this function was attributed to the Sub-secretary of Consumer Defense, directly linked to the Ministry of Economy and Production (MECON); in Paraguay, the Ministry of Industry and Commerce (MIC)

operates directly in the subgroup; or Ministry of Industry, Energy and Mining (MIEM) occupies this place in Uruguay; and in Venezuela, the Ministry of People's Power for Trade carries out this technical function (see MERCOSUL, 2017).

Figure 15 - Technical regulation approved by Common Market Group

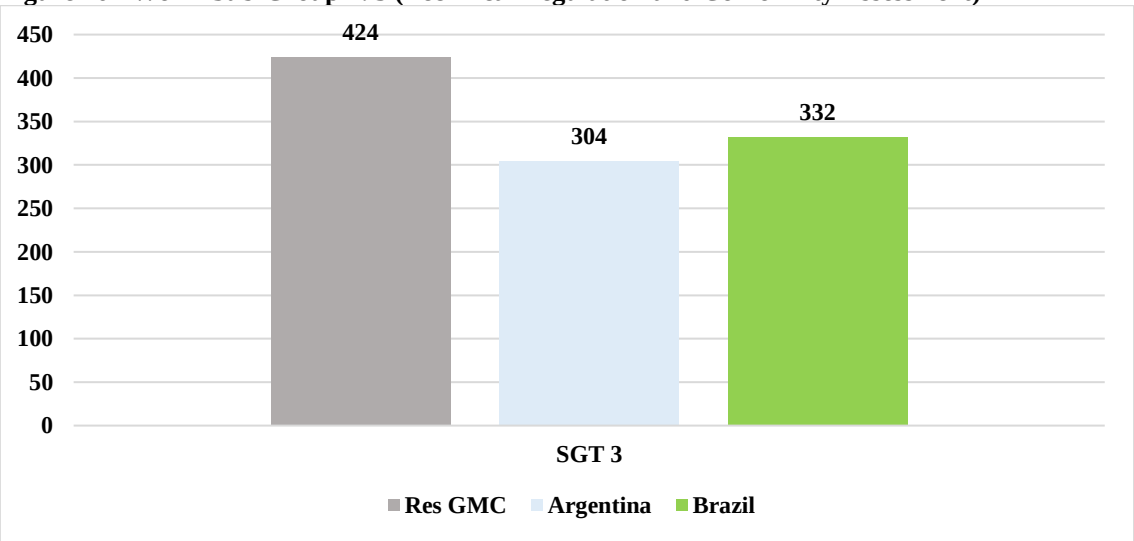


Source: Mercosul. Elaborated by CCGI-EESP/FGV.

The SGT n. 3 and the GMC works based on the principle of strong harmonization of technical regulation. Moreover, the technical regulation approved by the GMC has to be internalized by member countries. Such aspects make inefficient the Mercosul regulatory system. Several regulations are not incorporated by the member states, including Brazil and Argentina.

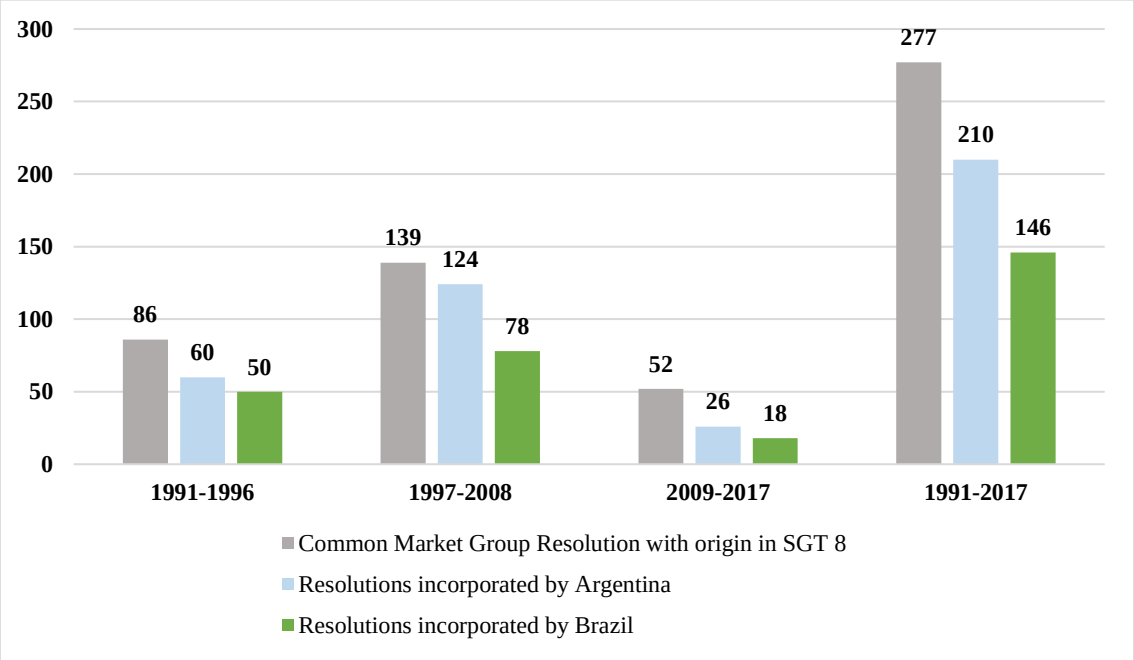
In addition to the approval of draft technical regulations produced by SGT n.3, the work of other sub-working groups should be observed. The activities of SGT n.8 and SGT n. 11.

Figure 16 - Work Sub-Group n. 3 (Technical Regulation and Conformity Assessment)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

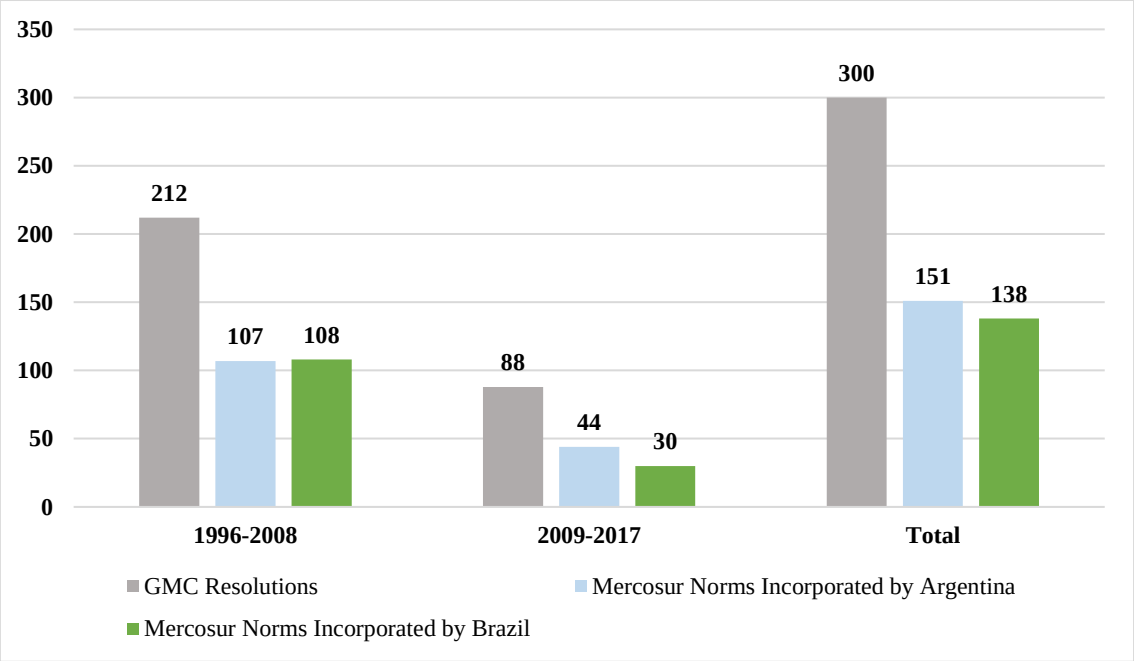
Figure 17 - Work Sub-Group n. 8 (Agriculture)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

In relation to subgroup n. 3, group 8 shows a smaller number of regulations approved by the GMC. Argentina stands out in the internalization of the rules originating from this subgroup.

Figure 18 - Work Sub-Group n. 11 (Health)



Source: Mercosur. Elaborated by CCGI-EESP/FGV.

It is worth mentioning an agreement reached with the members of the Brazilian Network of Legal Metrology and Quality. The agreement, created under SGT No. 3, aims to contribute to legal metrology being applied uniformly by the various countries of the world. It is understood that cooperation between MERCOSUL and the International Organization of Legal Metrology (OIML) should be strengthened.

In addition to the production of technical regulations, it should be noted that the Mercosul Association of Standardization, a private body that develops technical standards at the regional level. As provided in art. 4.4. of Resolution 45/2017 of the Common Market Group, the development of technical standards may be requested from AMN by the Common Market Group. These technical standards can be used to support regional technical regulation. Although the AMN is not an official body of Mercosul, it has signed an agreement with the bloc, in order to act as a standardization body responsible for the creation of Mercosul standards. The AMN participants are the main standardization bodies of Mercosul member countries.

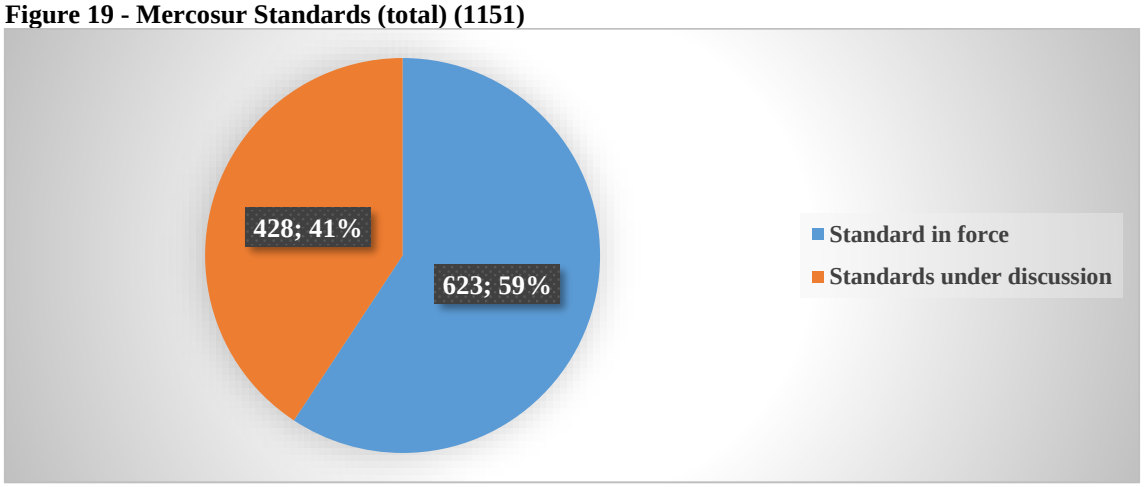
Table 11 - Mercosul Sectorial Committee

CSM	NAME	SECRETARY
01	Mercosul Sectorial Committee of Electricity	ABNT
02	Mercosul Steel Sector Committee	IRAM
03	Mercosul Sectorial Committee of Electronics and Telecommunications	ABNT
04	Mercosul Sector Committee of Toys	IRAM
05	Mercosul Sector Committee for Cement and Concrete	ABNT
06	Mercosul Sectorial Committee of Machinery and Mechanical Equipment	ABNT
07	Mercosul Automotive Sector Committee	IRAM
09	Mercosul Sectoral Committee of Plastics for Civil Construction	ABNT
12	Mercosul Sector Committee of Pulp and Paper	ABNT
13	Mercosul Sector Committee for Quality	IRAM
16	Mercosul Sectorial Committee for Environmental Management	ABNT
17	Mercosul Sectoral Committee on Accessibility	UNIT
18	Mercosul Sectorial Committee of Graphic Technology	ABNT
20	Mercosul Sectorial Committee for Clinical Analysis and In Vitro Diagnostics	ABNT
21	Mercosul Sectoral Committee of Flat Glass	ABNT
22	Mercosul Sector Committee for Conformity Assessment	IRAM
23	Mercosul Sectorial Committee of Tourism	ABNT
24	Mercosul Sector Committee for Non-Destructive Testing	IRAM
25	Mercosul Sectorial Committee for Packaging and Packaging	INTN
26	Mercosul Sectorial Committee on Food Safety	IRAM
27	Mercosul Sector Quality Committee for software	UNIT
28	Mercosul Sectoral Committee on Information Security	ABNT

Source: AMN. Elaborated by CCGI-EESP/FGV.

AMN's sector committees have so far produced few standards. The graph below shows the standards produced by AMN and establishes a comparison with other standardization bodies, including regional organizations, such as CEN and CENELEC.

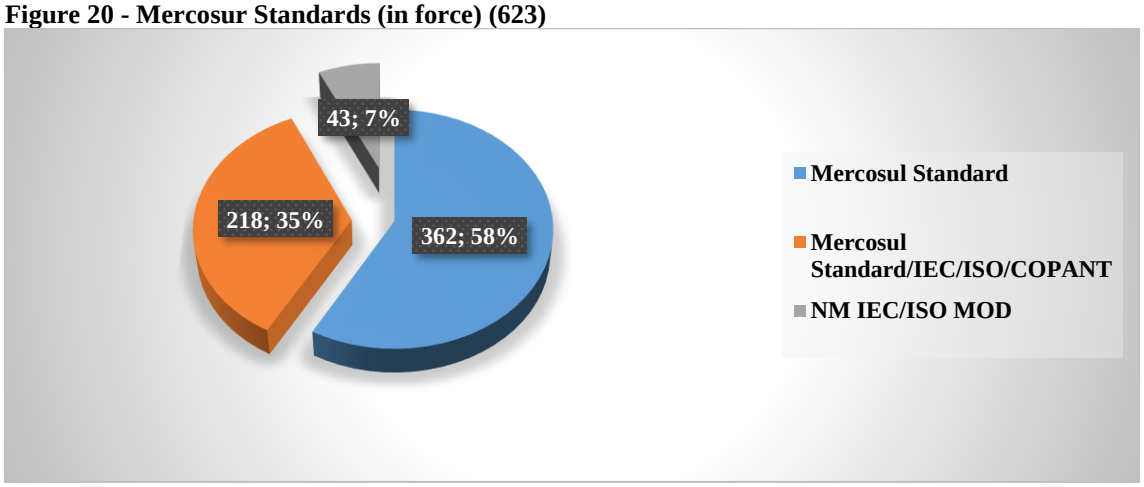
Figure 19 - Mercosur Standards (total) (1151)



Source: AMN. Elaborated by CCGI-EESP/FGV.

It is also important to highlight that, in AMN's catalog of standards, the Association's standards of origin predominate, in the detection of international and regional (continental) standards.

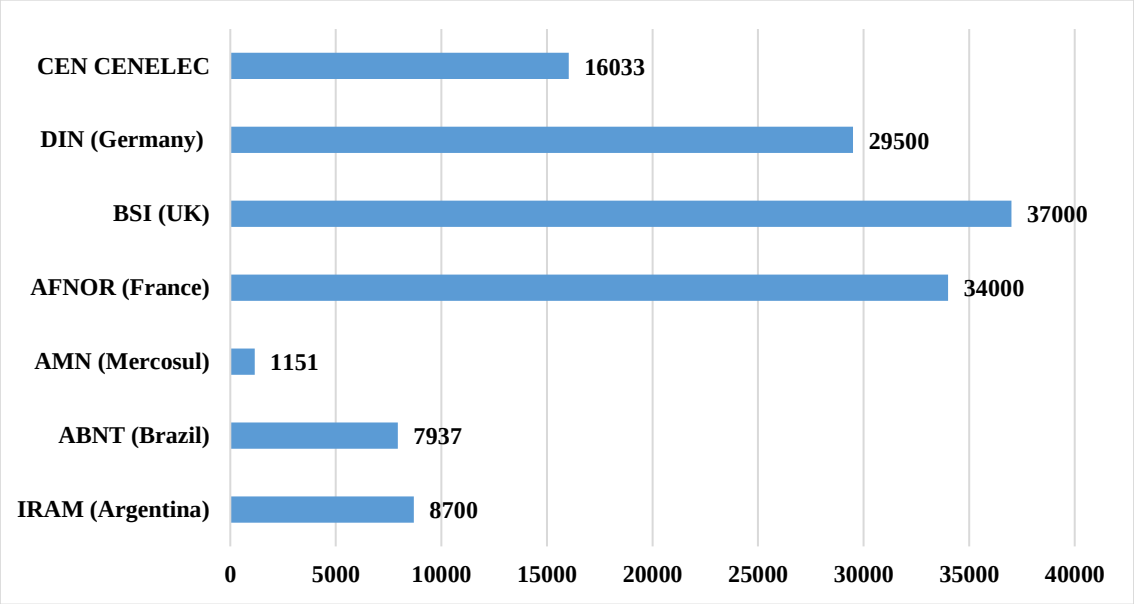
Figure 20 - Mercosur Standards (in force) (623)



Source: AMN. Elaborated by CCGI-EESP/FGV.

In addition, it is worth noting the weak standardization activity of the national standardization bodies of the two main Mercosur partners. Although the production of technical standards in Argentina and Brazil is superior to that of AMN, it is well below the production of the German standardization body.

Figure 21 - Comparison ABNT, IRAM, AMN, DIN, CEN-CENELEC



Source: AMN. Elaborated by CCGI-EESP/FGV.

Concerning standardization, is also important the agreement established with the European Union to determine the so-called ECONORMS for the convergence of technical regulations between the European Union and MERCOSUL in the fields of Metrology and Conformity Assessment (see MERCOSUL, 2017).

TBT issues were mainly debated on the negotiations for the creation of a free trade area between Mercosul and the European Union. Discussions on standards, technical regulations and conformity assessment procedures happened on the Technical Group 1 of the Committee of Biregional Negotiations (CNB). Negotiation meetings happened during the whole year of 2004, in which a consensus was reached about the redaction of section 4 of the agreement between Mercosul and EU – Norms, Technical Regulations and Conformity Assessment. The issue of free circulation of products was also debated from the acceptance of the mark CE by Mercosul on the following sectors: wood, wood furniture, machines and electrical products.

Aiming to implement the action plan on business facilitation, Mercosul and the EU created a project of technical cooperation involving the productive sectors on the value of 4 million euros. This project benefits regulation, standardization, accreditation and certification bodies and the test and calibration laboratories identified by the authorities of Mercosul State parties.

The regulatory systems of Argentina and Brazil have many similarities. Regulatory agencies have technical autonomy to regulate their respective areas of competence, even if they are sometimes subject to budget constraints and are captured by political interests. In Argentina, the production of technical standards, which is conducted by IRAM, is more decentralized than in Brazil, since many standards are published directly by the standardizing bodies of industry associations (for example, AITA, IAS). The conformity assessment system, especially the accreditation procedures for certification bodies, is similar in both countries. Brazil has a larger number of products that require compulsory certification, but this list is quite variable and usually regulated by non-statutory laws. With regard to the internationalization of the regulatory system through the use of

international standards, the two countries have a predominance of domestic standards, which may hinder the insertion of their products in the international market and even create obstacles to bilateral trade. Efforts to produce regional regulations and technical regulations, including regulatory convergence efforts within ALADI and Mercosul , have been insufficient to guarantee the free movement of goods between members and, above all, to ensure exports from the region to other markets in the world.

PART II – SECTORS[7]

2. VEHICLES AND AUTO-PARTS

2.1. Vehicles and auto parts (Brazil)

2.1.1. Overview

The domestic production of vehicles, auto-parts, agricultural machinery, and highway construction machinery, among others, is guided both to domestic and to the foreign market, making the automotive segment a strategic sector in Brazil. The goods produced in this sector are of high value added to Brazilian trade profile, contributing to the diversification of the country's export basket, concentrated in commodities.

Since the 1990s, Brazilian automotive industry has become more modern and competitive, due to the increase of foreign direct investments (FDI) supported by specific policies to the sector. Brazilian automotive industry revenue, in 2015, was USD 59.1 billion, while FDI in the sector, including the auto-part segment, were of USD 68 billion from 1994 to 2012[8].

Historically, the Brazilian automotive sector was marked by a strong presence of North American and European manufacturers; more recently South Korean, Japanese and Chinese manufacturers increased their participation in the Brazilian market, becoming relevant players in the policy arena. Such industry profile result in the technical regulation trends of the sector.

The increase of FDI from traditional and non-traditional investors was mainly a result of the increase of the domestic consumer market, but it also favored exports by the country and its integration to the global value chains of the sector. In the first decade of the 21st century, the Brazilian automotive industry had a good performance, especially in the motor vehicles sector. In 2013, the production of vehicles achieved its peak with 3.738.448 units, and Brazil was recognized as the 9th major producer of vehicles in the world. In the following years, there was a continuous decrease in those numbers, reaching in 2016 the registry of 2.175.284 units of vehicles. A synthesis of the Brazilian automotive sector trade performance with the world, from 2001 to 2016 is summarized in Table 1.

Vehicles and auto-parts segments are integrated sectors, and both segments compose the main profitable goods of Brazilian automotive industry. The agricultural machinery and

[7] The fragments referring to the Brazilian sectors were withdrawn and adapted from another research report, developed by CCGI/EESP-FGV and available at: https://ccgi.fgv.br/pt-br/eu-brazil-business-development-technical-regulations. The considerations on the sectors of Brazil and Argentina were also formulated based on research and independent and benefited by the exhibitions that took place during the event: Regulatory Dialogue Brazil-Argentina, held on June 11, 2019: https://ccgi.fgv.br/sites/ccgi.fgv.br/files/u5/Anais-Conferencia-Dialogo%20Regulatorio-BR-ARG-11-6-18.pdf

[8] Based on the numbers prepared by *Associação Nacional dos Fabricantes de Veículos Automotores*. **Brazilian Automotive Industry Yearbook.** ANFAVEA. 2017. Available at: <http://www.virapagina.com.br/anfavea2017/files/assets/common/downloads/publication.pdf>. **Yearbook.** ANFAVEA. 2017, p. 17-53. Available at: <http://www.virapagina.com.br/anfavea2017/files/assets/common/downloads/publication.pdf>. Last accesses on: Feb 23rd, 2017.

highway construction machinery segments, in which Brazil has a trade surplus, represent a smaller quota of all Brazilian trade.

Table 12 - Brazilian Automotive Industry Trade Balance

Year	Vehicles		Auto parts		Agricultural machinery		Highway construction machinery		Others		Total	
	Exp.	*Imp.*	*Exp.*	*Imp.*	*Exp.*	*Imp.*	*Exp.*	*Imp.*	*Exp.*	*Imp.*	*Exp.*	*Imp.*
2001	2.640,1	2.017,0	3.910,7	4.416,5	167,2	30,7	315,3	94,6	428,4	84,6	7.461,7	6.643,4
2002	2.633,4	1.093,5	4.163,0	4.147,3	263,8	12,1	352,2	93,0	379,4	16,5	7.791,8	5.362,4
2003	3.566,5	828,0	5.137,3	4.503,9	502,2	13,5	467,9	166,9	482,0	5,1	10.155,9	5.517,4
2004	4.950,7	880,4	6.431,5	5.824,8	810,7	65,2	954,5	149,1	648,8	21,2	13.796,2	6.940,7
2005	7.076,8	1.350,6	7.855,0	7.070,2	827,0	38,0	1.320,9	302,9	993,8	73,8	18.073,6	8.835,5
2006	7.320,7	2.633,6	9.314,6	7.236,8	701,7	35,0	1.540,4	502,5	1.129,7	28,1	20.007,1	10.436,0
2007	7.800,3	4.083,5	9.939,8	9.772,2	1.018,2	103,1	1.646,2	362,1	1.257,8	68,8	21.662,3	14.389,7
2008	8.409,6	6.865,3	10.880,5	13.557,9	1.369,6	195,6	1.870,1	931,6	1.483,8	38,4	24.013,6	21.588,8
2009	4.621,1	6.971,1	7.071,7	9.508,1	654,2	136,3	618,1	861,5	788,4	46,6	13.753,5	17.523,6
2010	6.909,6	10.869,5	10.691,7	14.855,3	948,7	177,9	1.384,6	1.144,8	1.050,7	116,5	20.985,3	27.164,0
2011	7.656,8	14.709,4	12.537,5	17.999,3	1.048,5	280,8	2.215,1	1.507,4	1.323,6	166,9	24.781,4	34.663,8
2012	6.784,6	12.701,3	11.625,5	18.129,0	906,0	483,8	2.258,2	1.658,5	1.155,4	196,2	22.729,7	33.168,9
2013	8.739,5	12.622,1	10.748,4	21.347,0	912,3	228,4	1.864,8	1.258,9	1.162,9	128,9	23.427,9	35.585,4
2014	5.531,7	10.931,3	9.185,0	19.386,8	764,3	219,2	1.956,9	907,5	1.036,5	134,9	18.474,4	31.579,7
2015	5.822,2	7.059,2	8.222,6	14.601,1	500,4	108,2	1.401,6	548,7	924,4	92,2	16.871,1	22.409,3
2016	7.639,1	4.408,2	7.315,3	12.933,9	483,8	77,6	1.432,8	244,9	985,1	107,1	17.856,1	17.771,7

Source: ANFAVEA, 2017, p. 46.

The trade balance of vehicles has floated substantially since 2013. If in 2014, the balance of trade registered a deficit of about USD 5,3 bi; in 2015, there was a lower deficit of about USD 1,2 bi; and in 2016, exports slightly grew up, inverting the trend of the last two years for a trade surplus of USD 3,2 bi.

The auto-parts segment, on the other hand, has registered a consistent deficit since 2008. In 2008, the numbers are of a deficit about USD 2,7 bi; in 2012, although exports grew, imports also increased, favoring a trade deficit of about USD 6,5 bi. More recently, in 2016, exports and imports decreased; but still with a trade deficit around USD 5,6 bi.

In the bilateral trade with the European Union, Brazil holds a trade deficit in all segments of the automotive sector, as Table 2 below:

Table 13 - Automotive Trade between Brazil and EU

Year	Vehicles		Auto parts		Agricultural machinery		Highway construction machinery		Others		Total	
	Exp	*Imp*	*Exp*	*Imp*	*Exp*	*Imp*	*Exp*	*Imp*	*Exp*	*Imp*	*Exp*	*Imp*
2001	147,7	215,9	820,7	2.101,1	3,1	6,4	37,0	24,3	9,3	23,0	1.017,8	2.370,7
2002	96,3	191,9	938,0	2.033,7	11,8	3,1	38,5	20,3	13,1	6,3	1.097,7	2.255,3
2003	120,2	232,3	1.220,3	2.210,7	17,4	3,5	49,9	28,6	22,8	3,4	1.430,6	2.478,5
2004	157,9	171,3	1.510,6	2.745,7	16,5	4,1	68,3	20,5	7,6	9,4	1.760,9	2.951,0
2005	844,2	278,2	1.752,7	3.389,6	26,9	7,4	73,8	36,7	23,5	56,0	2.721,1	3.768,0
2007	898,7	489,5	2.168,8	4.384,6	22,2	15,3	131,6	74,1	20,8	12,5	3.242,1	4.976,0
2006	767,4	517,3	1.925,4	3.198,0	18,3	10,8	100,8	117,4	8,2	12,6	2.820,1	3.856,1
2008	1.257	818,9	2.345,0	5.933,2	14,6	44,5	137,6	184,4	36,4	13,4	3.791,1	6.994,4
2009	724,1	740,6	1.347,9	3.539,1	7,9	26,3	23,1	128,5	2,8	9,2	2.105,8	4.443,7
2010	562,2	1.397,0	1.935,6	5.689,0	8,0	32,1	73,7	213,5	2,8	27,3	2.582,4	7.359,0
2011	123,8	2.074,7	2.101,9	6.844,8	19,4	35,4	152,5	292,6	5,3	39,9	2.402,9	9.287,3
2012	35,5	1.387,0	1.880,8	6.392,1	14,0	60,2	111,9	341,0	4,9	63,5	2.047,0	8.243,8
2013	63,8	1.759,5	1.947,4	7.738,8	4,1	64,6	59,4	213,5	4,5	73,7	2.079,1	9.850,1
2014	25,5	1.678,6	1.718,1	6.590,7	3,5	45,2	117,0	161,5	3,9	77,6	1.868,0	8.553,6
2015	8,6	1.073,0	1.589,5	4.444,7	1,6	32,9	32,2	53,8	4,1	39,1	1.636,1	5.643,5

Source: ANFAVEA, 2017, p. 48.

The most expressive deficit is in the vehicles segment: in 2013 and 2014, around USD 1,7 bi; and, in 2015, USD 1,1 bi. But, the trade deficit of all segments combined, for the year of 2015, is much higher, resulting in USD 4,0 bi.

It is hard to calculate the impacts of technical barriers to trade and investment inflows and outflows. However, according to the numbers above and their flotation in the last years, it seems that they had not a decisive weight at the end.

The numbers above are also driven changes in the high-level policy for the automotive sector, such as national industrial policy and regional arrangements.

2.1.2. Mapping technical regulation

The most important authorities that regulates this sector are: Brazilian National Environmental Council (CONAMA), the Brazilian Institute of the Environment and Renewable Natural Resources (IBAMA), the Brazilian National Traffic Council (CONTRAN) and the Brazilian National Institute of Metrology, Quality and Technology (INMETRO). They are responsible for regulating the automotive sector issuing technical regulations and standards related to the reduction of the emission of pollutants and car safety. The Brazilian Association on Technical Standards (ABNT) is the only private organization with an important role in promoting private and international standards in this area.

A brief analysis of the profile of technical regulations notified by the Brazilian government to the WTO under the Agreement on Technical Barriers to Trade (TBT) provides the overview of automobiles sectorial regulation in the country. The projects of technical regulations that impact international trade are notified to the TBT Committee. In addition to INMETRO, the national enquiry point to the WTO/TBT, other entities also notify under the WTO/TBT agreement, mainly IBAMA and CONTRAN (more details in Annex 2).

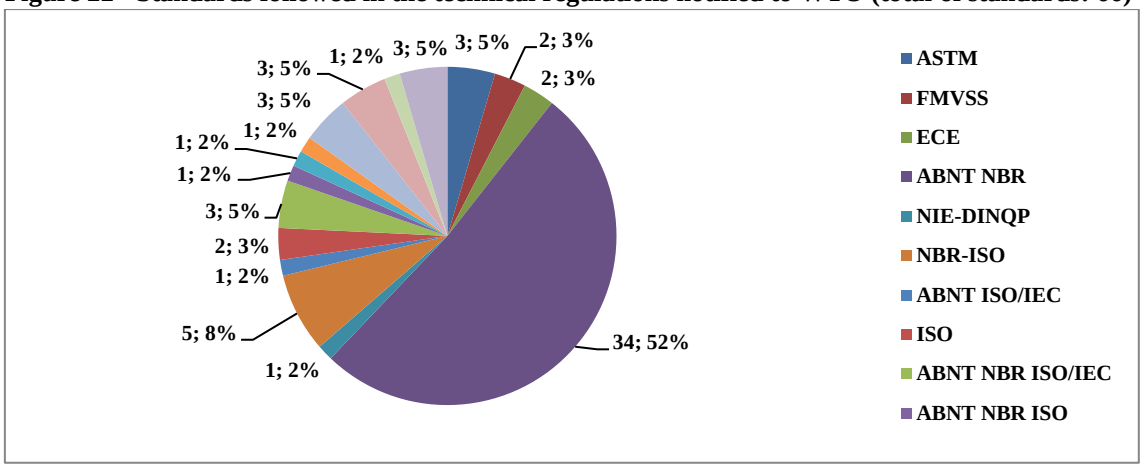
From January 1st, 1995 until March 30th, 2017, there were 29 notifications from Brazil, concerning the Automotive Sector, on TBT. In 2017, twenty of them were still in force. INMETRO[9] has traditionally been by far the main body having technical regulations notified to the WTO, but CONTRAN has been more active in the last two years.

The main objectives of the technical regulations notified to the TBT Committee deal with safety issues -i.e. human safety-, metrology, environment and other topics are of minor relevance.

The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on auto sector.

[9] INMETRO has made available to the public a searching tool in which it is possible to search by keywords, date and number of the technical regulation here.

Figure 22 - Standards followed in the technical regulations notified to WTO (total of standards: 66)



Source: WTO database. Prepared by CCGI-EESP/ FGV (March 2017).

The standards ABNT NBR correspond to fifty-two percent of the total notified. ABNT standards do not explicitly endorse any international standard[10].

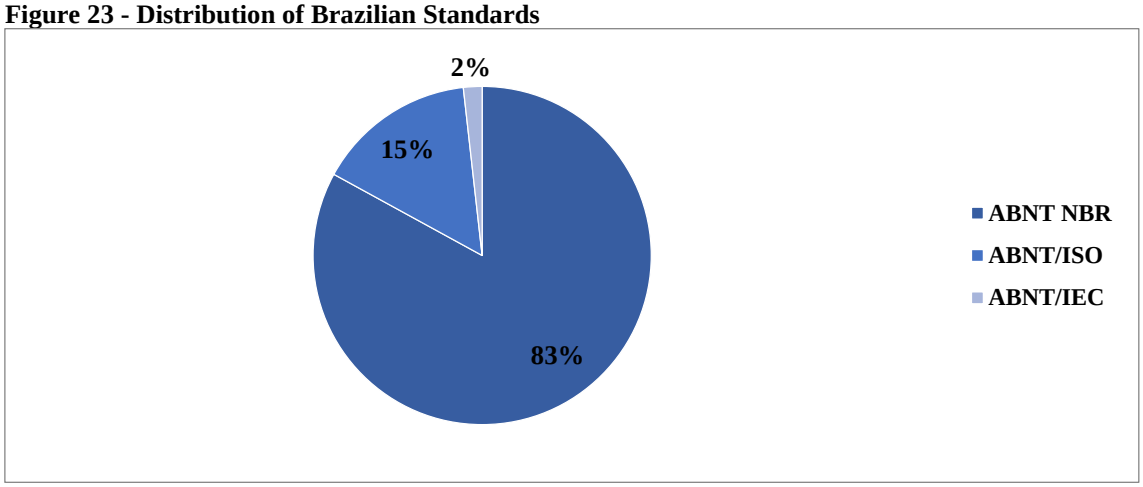
The ISO and ISO/IEC standards have also a important role, if compared to other. The ISO and ISO/IEC standards are usually adopted by certain governmental agencies or incorporated to ABNT standards. Only one notification (G/TBT/N/BRA/702, dated as of 2017) mentions expressly UNECE (ECE) and FMVSS. In such notification they were taken as alternative options by the Brazilian technical regulation. This does not mean that such standards are not important as a pattern for Brazilian regulation. As demonstrated in this report, some regulations not reported to WTO are based on European and American standards.

2.1.3. Mapping technical standards

The technical standards produced by ABNT are voluntary compliance (see Annex 2). Many of them, however, become mandatory when referred to in technical regulations. In addition, according to the Consumer Protection Code, the standards developed by ABNT are applied in a subsidiary manner as a parameter of quality of the products offered in the market.

[10] A relevant number of technical regulations (especially those on conformity assessment procedures) refer to supporting standards, usually issued by **ABNT,** a private body. There are different kinds of supporting standards issued by ABNT. These standards range from a fully original standard developed under its Standardizing Committees (CB) to a standard based on international standards, mainly ISO and IEC. Usually (i) if it is a standard identical to an international standard, it will appear, for example, as ABNT NBR ISO nº XXX; (ii) if it is based on an international standard, a reference to this international standard will be in the preamble of the standard; and, (iii) if it is an original standard, it will appear as ABNT NBR nº XXX. ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website. ABNT Catalog with all searching tools is available here. In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party has to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard.

Figure 23 - Distribution of Brazilian Standards



Source: ABNT. Prepared by CCGI-EESP/ FGV (March 2017).

2.1.4. Mandatory conformity assessment procedures

Brazil requires imported and domestic new auto-parts to be certified by accredited laboratories[11]. Brazil may accept certifications issued in other countries and tests approved by foreign institutions in the following cases: i) if the foreign certification body is accredited by INMETRO; and, ii) if the foreign accreditation body is both a member of the International Laboratory Accreditation Cooperation (ILAC) and, is signatory of the ILAC Mutual Recognition Arrangement[12].

However, there is no guarantee that specific technical regulations of auto parts will be accepted by CONTRAN if issued by a regulatory body different from INMETRO.

In the case of imported or new vehicles manufactured in Brazil, CONMETRO/INMETRO and CONAMA/IBAMA are the two ministerial councils and regulatory bodies responsible for regulating and issuing standards related to car safety and emissions homologation. The National Telecommunications Agency (ANATEL) is responsible for radio frequency devices certification. CONTRAN/DENATRAN is responsible for the whole process of national registration to new-domestic and new-imported vehicles. Therefore, at the end of the process, it concedes or not the vehicle homologation.

IBAMA accepts environmental performance tests as equivalent to domestic ones if conducted in the presence of IBAMA staff members. In this case, the new vehicle type can receive IBAMA approval. DENATRAN holds a different procedure for passive safety tests. It may exempt the importer from the requirement of conducting tests in the presence of DENATRAN/INMETRO staff members if an ILAC signatory body accredits the foreign laboratory that conducted the tests.

In what concerns other safety requirements, including active ones, the declaration of conformity with the national legislation and the statement that the company operates a management system that controls the operations of the laboratories that performed the

[11] INMETRO is the regulatory agency responsible for accrediting laboratories for certification processes.
[12] The list of signatories to ILAC Mutual Recognition Arrangement may be found at: http://ilac.org/ilac-mra-and-signatories/. Last access: April, 17, 2017.

tests may meet the need for local homologation and labelling[13]. The homologation process takes the following steps:

A) obtain the LCVM (License for use of Vehicle Configuration or Motor) issued by IBAMA. The LCVM certifies that the car complies with current environmental regulations[14]. Motorcycles and similar vehicles shall complete the same process (License to Use the Configuration of Mopeds, Motorcycles and Similar). It evaluates two aspects of the vehicle: emission and engine noise levels, which have to be within the limits established by Brazilian legislation[15].

B) request the CAT (Traffic Adequacy Certificate) by providing documents (technical tests, essays performed by a recognized laboratory) in order to obtain a registration for the vehicle in the National Registry of Automotive Vehicles (RENAVAM).

Both steps combined usually take between 40 to 90 days, according to experts and practitioners in this field. Regarding the official LCVM deadline, according to Article 9 of Ordinance n. 86/1996, IBAMA will issue the LCVM, the Declaration of Attendance and the Certificate referred to in Article 4, in a period of 60 working days, from the date of delivery of all information necessary to meet fully the requirements established in this Ordinance. The official deadline for issuing the CAT, according to Article 5 of DENATRAN Ordinance n. 190/09, is 20 working days from the receipt of the request.

2.2. Vehicles and auto parts (Argentina)

2.2.1. Overview

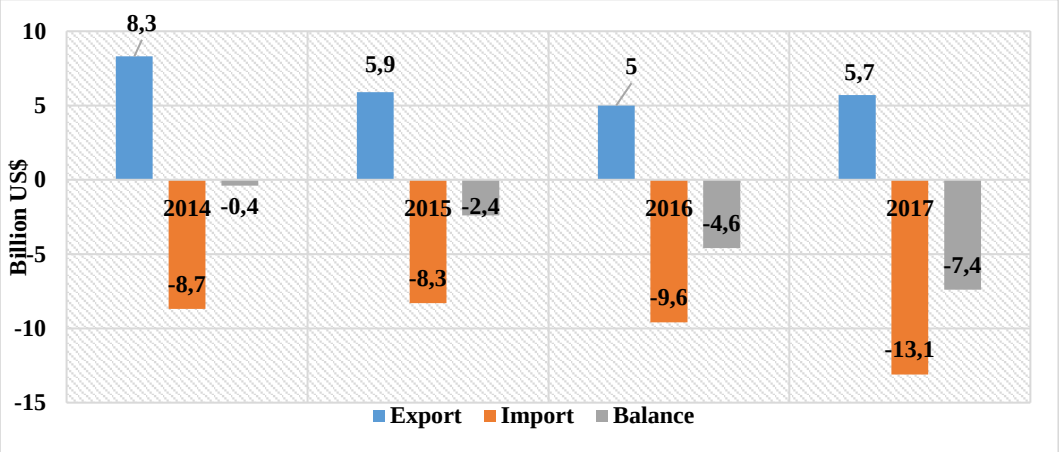
The production of vehicles is fundamental for the Argentine industrial sector and for its foreign trade in manufactured goods. The automotive production chain is quite large and generates skilled jobs in the domestic industry. For the country's foreign trade, especially the trade within Mercosul, the automotive sector is also important to diversify the exports of the country that is traditionally characterized by the predominance of commodities. Relevant part of the successful bilateral trade partnership between Brazil and Argentina results from intense flows of manufactured goods from the automotive sector. In 2017, Argentina exported almost US$ 6 billion in automotive vehicles, mainly to Brazil. Vehicles and auto-parts are the main Argentine products exported to Mercosul.

[13]See DENATRAN Ordinance n. 190/2009.

[14] IBAMA Ordinance n. 086/1996 in its Article 1, determines: imported automotive vehicles are required to meet the same pollutant emission levels and noise levels established for domestic vehicles. License for the Use of the Vehicle or Motor Configuration - LCVM, issued by IBAMA, as determined by Articles 4 and 5 of Federal Law n, 8,723/1993.

[15] The emission levels are provided for in Federal Law n. 8,723/1993. The noise levels are set out in CONAMA Resolution n. 252/1999.

Figure 24 - Argentine Vehicles Trade balance



Source: INDEC. Elaborated by CCGI/FGV-EESP

This trade, however, could be stimulated by the adoption of more active policies of regulatory convergence between Mercosul 's two main trading partners. For this convergence to materialize, there must be a progressive approximation of technical regulations, standards and regulatory authorities of the automotive sector of the two countries.

The Asociación de Fabricantes de Automotores (Adefa) has an important role in Argentine Vehicles Industry. Adefa is part of the Organisation Internationale des Constructeurs d'Automobiles (OICA), based in Paris and it was created in 1960. It includes manufacturers of automobiles, light vehicles, trucks and buses.

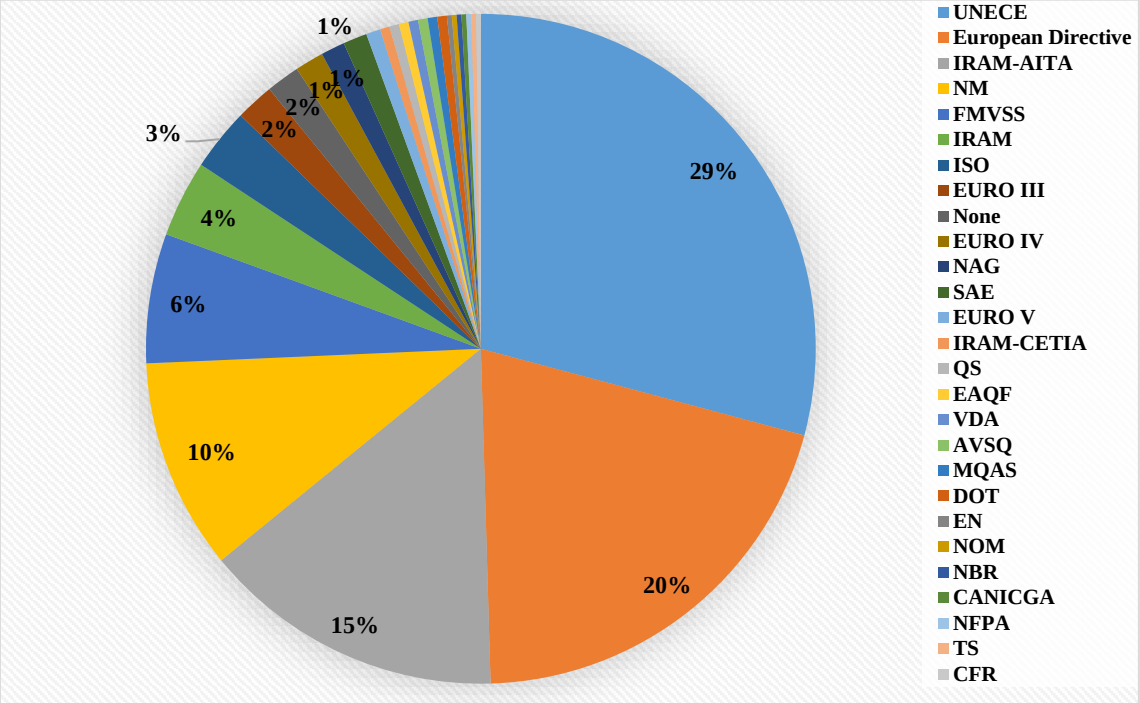
In regulatory matters, the automotive sector in Argentina is governed in two main dimensions: safety (active and passive) and environment. In the first case, the safety of the driver, the passengers and third parties in relation to the use of vehicles is sought. These are aspects related to the correct operation of the vehicle, its safety items and signs. In the second case, the aim is to mitigate the effects of fuel consumption by motor vehicles. For both cases international norms and rules are used as parameters for the design of Argentine regulation.

2.2.2. Mapping of regulations

In regulatory matters, the automotive sector in Argentina is governed in two main dimensions: safety (active and passive) and environment. In the first case, the safety of the driver, the passengers and third parties in relation to the use of vehicles is sought (see Annex 2). These are aspects related to the correct operation of the vehicle, its safety items and signs. In the second case, the aim is to mitigate the effects of fuel consumption by motor vehicles. For both cases international norms and rules are used as parameters for the design of Argentine regulation.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT on the machinery and mechanical sector.

Figure 25 - Standards in the technical regulation notified to WTO/TBT



Source: WTO. Elaborated by CCGI-EESP/FGV

There are different organizations responsible for issuing technical regulation in machinery sector in Argentina. The most important ones being:

a) **Ministry of Production (prior Ministry of Industry, Trade and Mining)**: The Argentine Ministry of Production is the government agency responsible for defining standardization and quality control of industrial production. It also designs and executes the plans related to the promotion of the country's industrial production, as well as foreign trade. Many other secretariats and organization related to this Ministry are in charge of creating technical regulation in machinery sector.

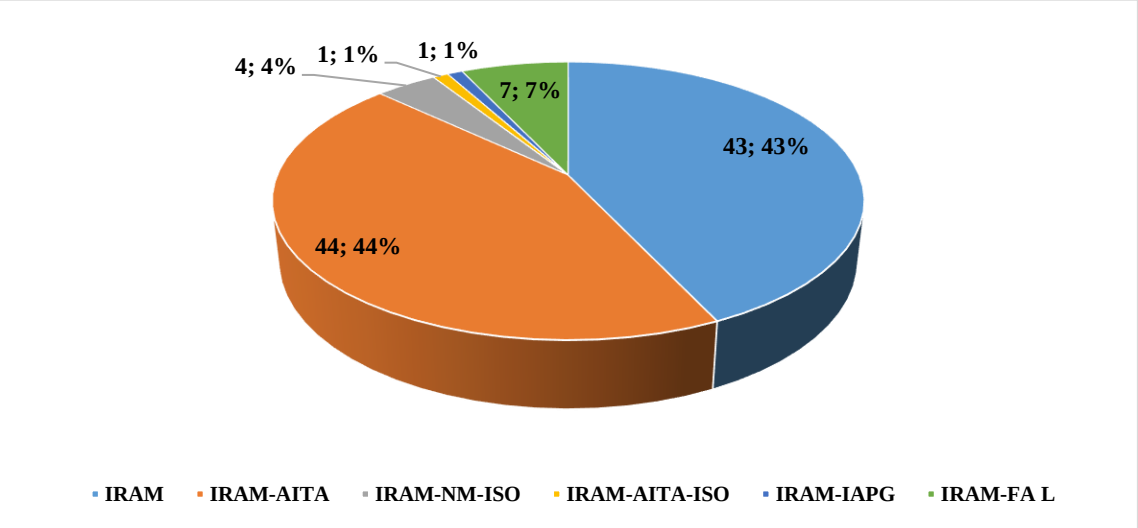
b) **Ministry of the Environment and Sustainable Development**: It is responsible for assisting the President in the formulation, implementation and execution of the environmental policy and its sustainable development as a State policy, within the framework of the provisions of article 41 of the National Constitution, in the technical aspects related to the environmental policy and the environmental management of the Nation, proposing and elaborating regulatory regimes related to the environmental order of the territory and its environmental quality.

c) **Ministry of Transport**: Responsible for everything inherent to air, rail, automotive, fluvial and maritime transport, and to the road activity.

2.2.3. Mapping Technical Standards

In Argentina, IRAM and AITA develop the most part of standards for vehicles. Some of such standards are based in international standards, but the vast majority are homegrown standards (see Annex 2).

Figure 26 - IRAM Standards



Source: IRAM. Elaborated by CCGI-EESP/FGV .

The number of international technical standards adopted by the Argentinean standardization bodies is quite low. Domestically, it must be stressed the standardization works of IRAM and AITA. IRAM is a general standardization body in Argentina. AITA is an organization specializing in the production of technical standards for automobiles.

2.2.4. Mandatory conformity assessment procedures

According to Section I of the Annex P of Decree n° 779/95, to obtain the homologation of motor vehicles, the manufacturer, importer, natural or legal person or last intervener in the manufacturing process (for armed vehicles in stages), must present the LCM application and the detailed documentation, containing information of descriptive character, technical character, on the brake system, on tires and wheels, on rearview mirrors, on safety belts, on lighting devices and signaling and on the identification of the vehicle. The interested company must submit the homologation request with a minimum of 60 days before the product commercialization.

The Law n° 24.449, together with Decree n° 779/95, designates the Ministry of Industry to establish a system of Certification for Homologation of Safety Auto parts (CHAS) for any component or part destined to spare parts of automotive vehicles, coupled or semi-coupled, that are manufactured or imported in the country for the replacement market.

The Ministry of Industry issued the Resolution n° 91/2001, which regulates the replacement market for auto parts for automotive vehicles. It seeks the least restrictive regulation for the Argentinian market of auto parts replacement compatible with protecting consumer's safety. The system generated from Resolution n° 91/2001 rules that every auto part that is commercialized in the country must demonstrate that complies with strict active and passive safety regulations. For domestic producers this implies presenting certificates of compliance with specific IRAM standards. The auto parts imported the same IRAM certificates or certificates of adaptation to the international standards of the TRANS/WP29/349 system.[16]

[16] Resolution n° 91/2001. Available at: http://servicios.infoleg.gob.ar/infolegInternet/anexos/65000-69999/68923/texact.htm

The Decree n° 779/95 and its amendments designated the former Secretariat of Natural Resources and Human Environment (*Secretaría de Recursos Naturales y Ambiente Humano*), currently Ministry of Environment and Sustainable Development (*Ministerio de Ambiente y Desarrollo Sustentable*), as the competent authority for all aspects related to the emission of pollutants, noises and parasitic radiations, coming from automotive vehicles. By the Decree n° 13/2015, the Secretariat of Environmental Control and Monitoring (*Secretaría de Control y Monitoreo Ambiental*) of the Ministry was appointed as the competent authority in the contamination control.

By virtue of this, it was possible to implement a database on emissions and fuel consumption of the different automotive vehicles commercialized in the Argentinean market in the Operative Technical Unit of Vehicle Emissions, dependent on the Pollution Monitoring Directorate of the Subsecretariat for Environmental Control and Inspection and Pollution Prevention, dependent on the aforementioned Secretariat of Environmental Control and Monitoring. The Secretariat must issue the certificates of approval related to the emission of polluting gases and sound level that the manufacturers must submit to the Secretariat of Industry and Services, to request the License of Model Configuration (LCM).

Under the limits and procedures of emissions certification, implemented by the Resolution n° 1464/2015, of the former Secretariat of Environment and Sustainable Development, for the control of emissions of light commercial and passenger vehicles (of categories M1 and N1 according to reference regulations), the European Directives n° 715/2007 and n° 692/2008 of the European Parliament and the Council for light vehicles, as well as the United Nations regulations, are taken as reference for the homologation of polluting emissions of automotive vehicles and fuel consumption. It was based on this normative framework that the IRAM-AITA 10274 standard could be adopted, establishing the procedures for the measurement of CO2 emissions and fuel consumption.

According to the Article 1 of the Resolution n° 797/2017, until January 15, 2018, all manufacturers and importers of light automotive vehicles belonging to categories M1 and N1 (defined in Annex II of Directive n° 70/156/CEE), must declare before the Operative Technical Unit of Vehicle Emissions, with respect to all models in commercialization within the national territory that have a Gaseous Emissions Approval Certificate in force (*Certificado de Aprobación de Emisiones Gaseosas* - Decree n° 779/95 and subsequent resolutions), the values of CO2 emissions and fuel consumption, according to the test procedure based on the European cycle admitted for homologation, production control or internal research and development report, specified by the IRAM-AITA 10274 standard, the ECE R.101 regulation or the European Directive n° 715/2007 and subsequent rules, as appropriate in each case. These values will only be informative and taken as a sworn statement, for this reason lacking any type of certification by third parties.[17]

As of January 15, 2018, all new gaseous pollutant emissions certification, which was presented to the Operative Technical Unit of Vehicle Emissions, of light automotive vehicles, belonging to categories M1 and N1, required to process the License of Model Configuration (LCM) of new models, must incorporate the certified values of CO2

[17] Resolution n° 797/2017. Available at: http://www.cira.org.ar/index.php?option=com_content&view=article&id=7974:resolucion-797-e-2017&catid=112&Itemid=500

emission and fuel consumption for the use of the approved fuel type(s), according to the procedure specified by the IRAM-AITA 10274 standard, the ECE R.101 regulation or the European Directive n° 715/2007 and subsequent rules, as appropriate in each case.

Thus, in Argentina the Euro V norm for auto vehicles should already be in force and this means that the maximum that diesel cars can emit is 0.18 g/km of nitrogen oxides and 0,50 g/km of carbon monoxide. While for a naphtero, these values are 0.06 g/km of NOx and 1 g/km of monoxide. [18]

[18] RUSSO,Victor. En la Argentina, por ahora, la norma es menos exigente. Clarín, 22 Sep. 2015. Available at: https://www.clarin.com/mundo/volkswagen-escandalo-falsificacion_de_datos-ecologia_0_H1pcjfKvQe.html

3. MACHINERY

3.1. Machinery (Brazil)

3.1.1. Overview

The machinery and mechanical equipment sector in Brazil is a traditional sector of Brazilian industry. Its origins go back to the period of import substitution, which also explains its strong concentration in the southeast region of the country, the core of the state-induced industrialization process. The sector is made up of different types of companies, most notably transnational companies, which, with an intense outsourcing policy, feed a large number of medium and small enterprises with national capital. In terms of international trade, Brazil is a net importer of machinery and mechanical equipment, although Latin America, especially the Mercosul partners, are important destinations for Brazilian exports of this type of product.

The machinery and mechanical equipment sector has had an important role in the recent economic growth of Brazilian economy and in international trade. In the last four years, the values of trade in machinery and equipment varied between US $ 30 and US $ 50 billion, narrowing substantially between 2013 and 2016.

Table 14 - Trade of Machinery and Equipment (US$ billions)

Year	Brazil-World	
	Exports	Imports
2013	12,9	35,7
2014	12,7	31,9
2015	11,4	24,8
2016	11,6	21,1

Source: MDIC/AliceWeb. Prepared by CCGI-EESP/ FGV (May 2017).

3.1.2. Mapping Technical Regulation

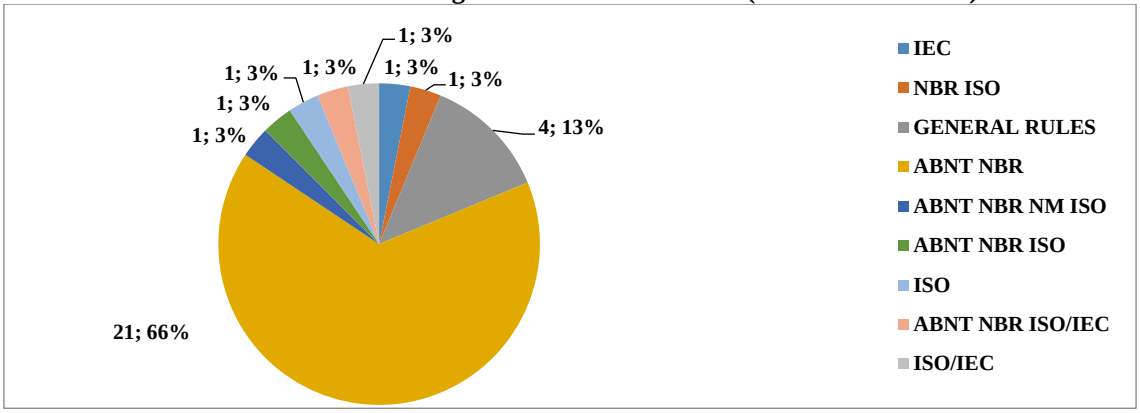
The Brazilian main regulation for machinery deals with worker safety, machine safety and consumer safety (see Annex 4). The Brazilian National Institute of Metrology Quality and Technology (INMETRO) regulates machinery appliances in the perspective of the final consumer. INMETRO normally notifies in detail its regulation to the TBT Committee of the WTO.

A brief analysis of the profile of technical regulations notified by the Brazilian government to the WTO under the Agreement on Technical Barriers to Trade (TBT) provides an overview of machinery and mechanical appliances sectorial regulation in the country. INMETRO notifies projects of technical regulations that impact international trade. Besides INMETRO, the national enquiry point to the WTO/TBT, other entities also notify under the WTO/TBT agreement, mainly Ministry of Mines and Energy (MME).

From January 1st, 1995 until March 30th, 2017, there were 45 notifications from Brazil, concerning the Machinery and Mechanical Sector, on TBT. INMETRO has traditionally by far been the main body having technical regulations notified to the WTO, however, as we may notice from the following Figure, MME has been more active in the last two years.

The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on the machinery sector.

Table 15 - Standards in the technical regulation notified to WTO (total: 32 standards)



Source: WTO database. Prepared by CCGI-EESP/ FGV (March 2017).

The standards ABNT NBR correspond to 66 per cent (21 standards) percent of the total notified (32 standards). Such standards are issued by the Brazilian organization ABNT, without explicitly endorsing any international standard.

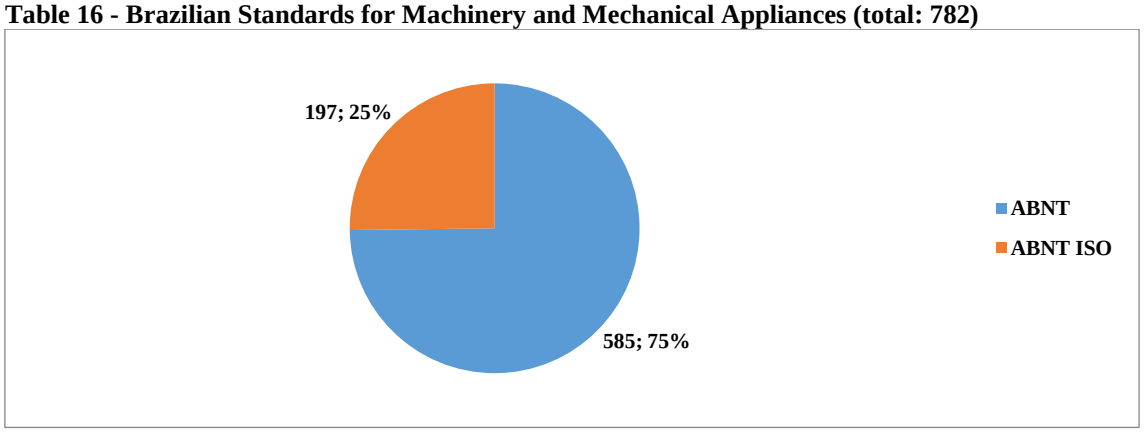
3.1.3. Mapping Technical Standards

In general, the ABNT uses ISO standards as a basis for elaborating its own standards (see Annex 4)[19]. ISO standards are also a basis for many INMETRO technical regulations and they are even mentioned in the MTE's regulations. Usually, ABNT standards are voluntary but when referred to in a technical regulation they become mandatory standards. In the absence of a technical standard, ABNT standards become a reference of product quality to the market.

A quarter of the standards (there are 197 ISO NBR standards and 585 pure ABNT NBR standards) used by Brazilian manufacturers derives from ISO standards. This number is due in part to the maintenance of some longstanding ABNT NBR standards, elaborated in a period in which there was no obligation or incentives to follow and adopt international standards. After the WTO Agreements entered into force, standards developed in Brazil started adopting international standards. This percentage of ISO standards have grown in recent years.

[19] A significant number of technical regulations refer to supporting standards, usually developed by technical committees of ABNT, the main standardization body in Brazil. There are different types of standards issued by ABNT. These standards can be fully developed by the technical of the Standardization Committees (CB) or can be based on international standards, mainly ISO and IEC, but also ASTM and AMN. A Brazilian standard identical to an international standard, will appear, for example, as ABNT NBR ISO No. XXX; (ii) If it is based on an international standard, a reference to this international standard shall be included in the foreword to the Brazilian standard; and (iii) if it is an original standard, it will appear as ABNT NBR No. XXX. ABNT has no organized information on all international standards adopted wholly or modified by any of its committees, although it has general figures on the use of those standards. The available research tool is based on me research by keywords or in the enumeration of the norms produced by a given committee. In the same way as CEN, CENELEC, ASTM, IRAM and other standardizing entities, the interested party must pay a fee to have full access to the content of the standards issued by ABNT.

Table 16 - Brazilian Standards for Machinery and Mechanical Appliances (total: 782)



Source: ABNT. Prepared by CCGI-EESP/ FGV (March 2017).

The increasing application of international standards by ABNT is shown on the following graphic.

3.1.4. Mandatory conformity assessment procedures

In Brazil, the certification consists on a series of acts done by a third party body (an independent body) to confirm and declare that a good, service, person or system is in conformity with specified technical requirements, whether domestic, foreign or international. In other words, the certification process starts with the awareness that getting a certificate is necessary to show the quality of a product and to keep the level of competitiveness in a given market, involving the use of technical standards. It also involves the diffusion of the concept of quality through all the sectors of a company, including its internal operative aspects and the relationship with the society and the environment[20].

Third party bodies normally receive the name of certification organisms (OC) or accredited certification bodies (OCC). In Brazil, the National Institute of Metrology (INMETRO)[21] is responsible for the accreditation. The certification can be voluntary, whose decision is exclusive of the company that manufactures the product or supplies the service; or compulsory, established by the government to the trade of goods and services[22]. The following table contains the machines with compulsory certification.

[20] ABIMAQ. *Avaliação de conformidade*. Available at: <http://www.abimaq.org.br/site.aspx/Avaliacao-da-Conformidade> (accessed on 27 February 2018).
[21] INMETRO has made available to the general public a searching tool in which it is possible to search by keywords, date and number of the technical regulation here.
[22] ABIMAQ. *Avaliação de conformidade*. Available at: <http://www.abimaq.org.br/site.aspx/Avaliacao-da-Conformidade> (accessed on 27 February 2018).

3.2. Machinery (Argentina)

3.2.1. Overview

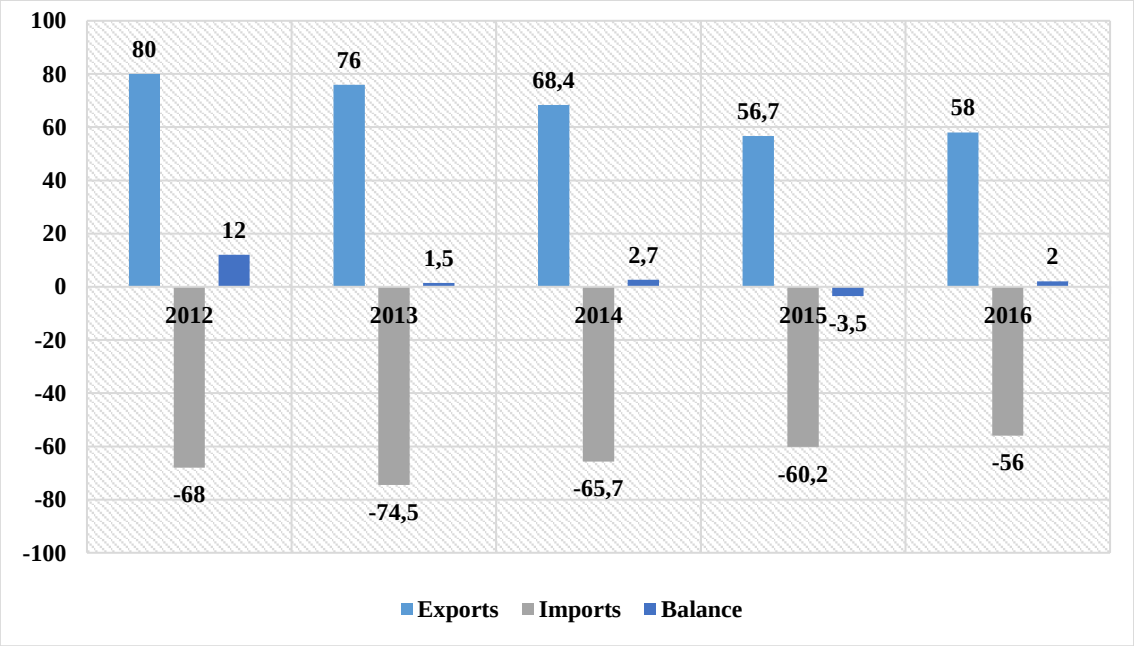
The machinery sector formation in Argentina dates back the second phase of the 1930s' import substitution policy and in the following decades, especially in Perón and Frondizi governments, production in this field was intensified. More recently government demands have forced equipment manufacturers to incorporate more local content, with multinationals using more than 50 percent of local components. [23]

Farm machinery counts on approximately 730 companies, 10% of which have been operating for over 50 years in the country. It accounts for around 60 percent of the total sector and includes: seeders, sprayers, and tools.[24]

The direct foreign investments of large transnational corporations were important for this development. They were mostly directed to Buenos Aires city, the largest industrial cluster in the country, where many machinery industries, like other industries of capital goods, were located. Other cities such as Córdoba, Rosario, Tucumán, Mendoza also host them.

In general, the foreign trade in Argentina is relatively balanced. Over the last five years, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods. However, Argentina is heavily deficient in the trade of machinery and other industrial equipment.

Figure 27 - Argentine Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV.

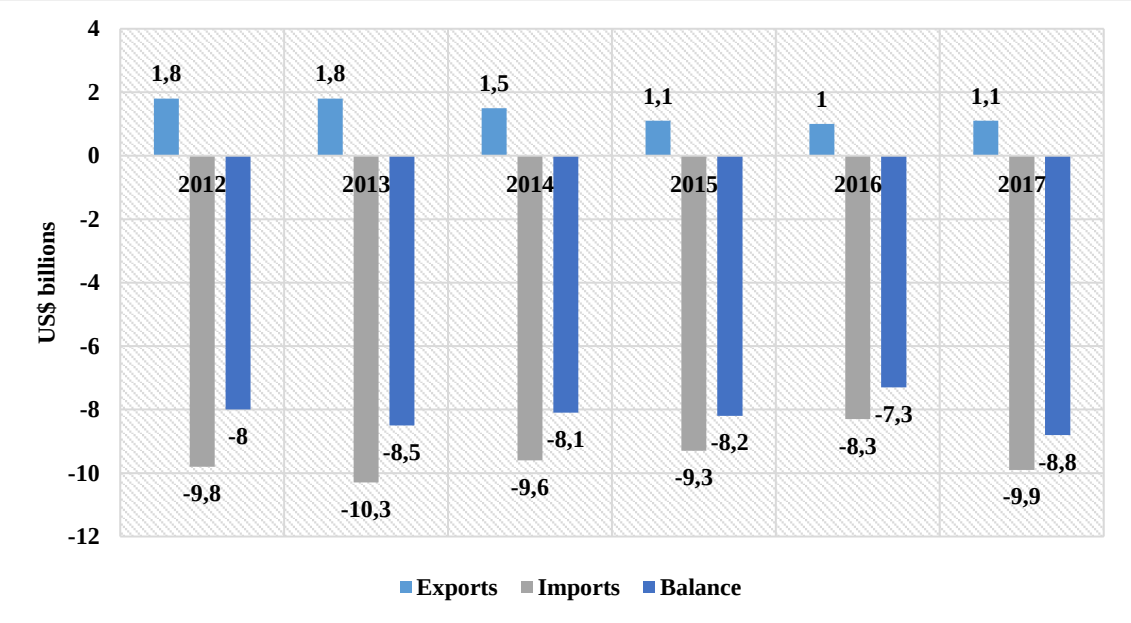
[23] Information gathered at the Doing Business in Argentina: 2015. Available at https://www.pwc.com.ar/es/doing-business/assets/doing-business-arg-2015.pdf Visited on April, 18, 2018.

[24] Information gathered at the Doing Business in Argentina: 2015. Available at https://www.pwc.com.ar/es/doing-business/assets/doing-business-arg-2015.pdf Visited on April, 18, 2018.

However, as any other sector that has its origin in protectionist development policies, the machinery sector always had problems competing with similar products in the international market and, more recently, this sector lost space in domestic market as well. Such problem became more evident in the last decades with the strong process of de-industrialization that the country faces.

Argentina is heavily deficient in the trade of machinery and other industrial equipment and is considered an importer of machines. The weight of these products in exports is of little relevance, although the sector has strategic importance as provider of capital goods for other industrial sectors.

Figure 28 - Argentine Trade Balance for Machinery and Mechanical Goods



Source: INDEC. Elaborated by CCGI-EESP/FGV.

Thus, is the total amount of Argentine imports of machinery and mechanical products between 50 and 80 billion negatively affects the country balance of trade, as shown at the above figure.

5.2.2. Mapping Technical Regulation and Main Regulatory Authorities

There are many organizations responsible for issuing technical regulation in machinery sector in Argentina (see Annex 4). The most important ones being:

a) **Ministry of Production**[25]: The Argentine Ministry of Production is the government agency responsible for defining standardization and quality control of industrial production. It also designs and executes the plans related to the promotion of the country's industrial production, as well as foreign trade. Many other secretariats and organization related to this Ministry are in charge of creating technical regulation in machinery sector.

b) **National Institute of Industrial Technology (INTI)**[26]: The INTU is an Argentine body created by Decree Law 17.138 of December 27, 1957 to focus on science and

[25] Further information in https://www.argentina.gob.ar/produccion.
[26] Further information in https://www.inti.gob.ar

technology matters. It is an autarchic entity that operates under the Ministry of Production, whose mission is to accompany and promote the growth of Argentine small companies, promoting federal industrial development through innovation and technology transfer. Nowadays, INTI has six thematic areas in its headquarters in Buenos Aires, each with two or more INTI Centers and each with one or more fields of action and services.

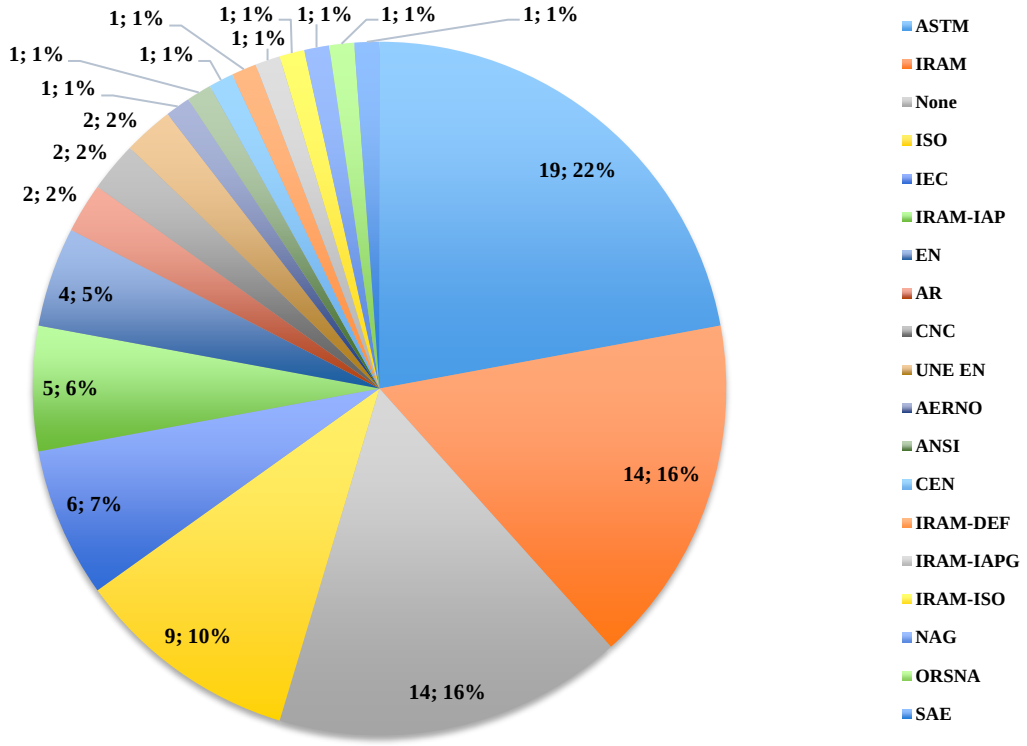
c) **Ente Nacional Regulador del Gas - ENARGAS**[27]: ENARGAS is an autarchic organism created by Law No. 24,076 - Regulatory Framework of the Gas Industry - in 1992. It is within the scope of the Ministry of Energy and Mining and is responsible for fulfilling the functions of regulation, control, inspection and resolution of disputes, which are inherent to the public transport and gas distribution service. Besides regulating the transport and distribution of natural gas it also issues regulations to adjust other laws in terms of safety, standards and technical procedures, measurement and billing of consumption and control and use of meters, besides other responsibilities related to specific machines.

d) **Ente Nacional Regulador de la Electricidad – ENRE**[28]: While the Ministry of Energy is responsible for setting policies regarding electrical issues, the Ente Nacional Regulador de la Electricidad (ENRE), an autarchic organism created by the Ley N° 24,065- Regulatory Framework of the Energy Sector - in 1992, is responsible for the regulation and general supervision of the sector under federal control. So ENRE and provincial regulators set technical regulations regarding the compliance of safety, quality, technical and environmental standards in machinery sector. Its competencies are clear: to issue regulations to which the producers, transporters, distributors and users of electricity must conform with in terms of safety, standards and technical procedures, measurement and billing of consumption, control and use of meters, interruption and reconnection of supplies, access to third-party properties and quality of services provided.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT on the machinery and mechanical sector.

[27] Further information in https://www.enargas.gob.ar
[28] Further information in https://www.argentina.gob.ar/enre

Figure 29 - Standards in the technical regulation notified to WTO/TBT



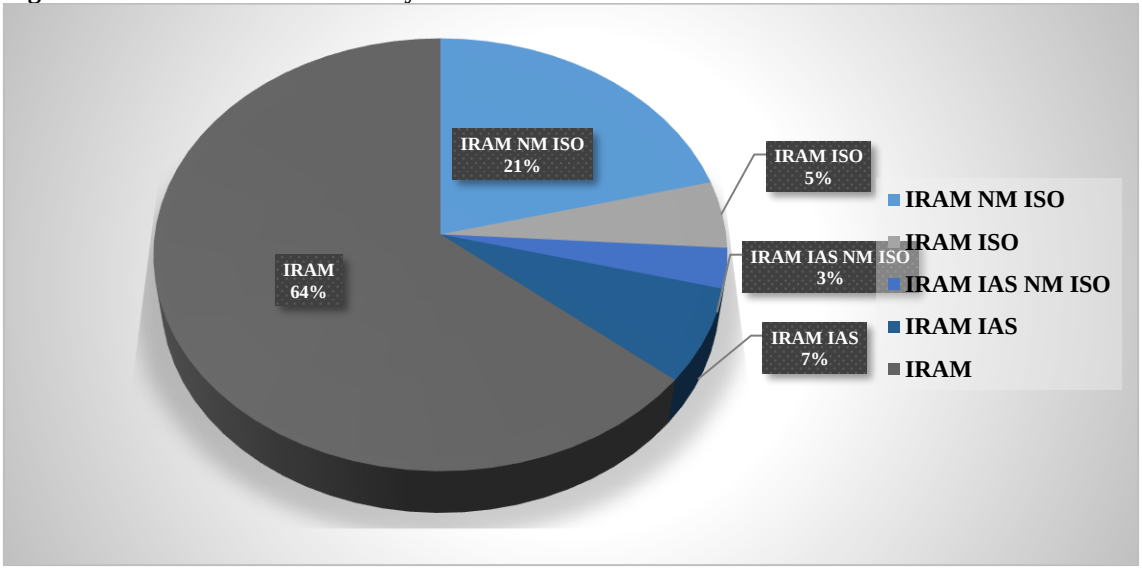
Source: WTO database. Prepared by CCGI -EESP/ FGV (March 2018).

The American Society for Testing and Materials (ASTM) standards correspond to 22 percent of the total notified, most of them by ENARGAS, which applied 14 different ASTM standards in one regulation. ASTM is an American association, created in 1898, but named, since 2001, ASTM International. Currently, the organization is responsible for more than 12,000 technical standards and has more than 30,000 members distributed in 140 countries. ASTM develops standards for various industrial sectors and in its directory there are 325 accredited laboratories for the compliance evaluation with standards developed by ASTM.

3.2.3. Mapping Technical Standards

The Argentine technical standards are produced by the Argentine Institute for Standardization and Certification (IRAM) (see Annex 4). Many of these standards are based on international standards, such as standards produced by the International Standardization Organization (ISO). Argentine standards that are mirrored in subregional standards (Mercosul) and industry standards (e.g. ASTM, UL) should also be highlighted.

Figure 30 - Standards on Machinery



Source: IRAM. Elaborated by CCGI -EESP/FGV.

In the machinery sector, standards produced by Mercosul Standardization Association (AMN) are relevant. It is interesting to note that almost all Mercosul standards on machinery and mechanical equipment are replicas of ISO standards.

3.2.4. Mandatory conformity assessment procedures

Resolution 595/99 regulates the intervention of the Argentine Association of Producers of Machines, Accessories and Similar Goods on the assessment of goods. The association, as an observer, will accompany the customs officers on the assessment practiced on the destinations of imports to consumption. A red signal of selectivity must have been attributed to the imports. The association must intervene on goods of the following tariff positions: 8456 to 8463, 8465, 8466, 85152100, 85152900, 85153100, 85153900, 85158010, 85158090, 85159000, 84122110, 84122190, 84122900, 84123110, 84123190, 84135010, 84135090, 84136011, 84136019, 84136090, 84811000, 84812090, 84813000, 84814000 and 84819090.

The association will indicate the names of technical personnel authorized for the task. The absence of the representatives on the assessment will not block the execution. The requiring association will arbitrate the necessary means to know the assessments to be done. The customs of Buenos Aires, Ezeiza and of the Interior will provide the necessary information to the performance of the assessment.

In general terms, the machinery sector has also to comply with Resolución SC N° 404/2015, according to which every certification and inspection bodies and any laboratory whose work is intended for the issuance of certificates of conformity and test protocols for compliance with mandatory certification schemes for products and services, established by the secretariat of commerce of the Ministry of economy and public finance, must have be duly registered.

The following requirements must be met:

- Comply with the guidelines established in the IRAM ISO / IEC 17065: 2013 Standard;
- Have legal status in the country;
- Have been accredited by the Argentine Accreditation Body belonging to the National System of Standards, Quality and Certification, created by Decree No. 1,474 dated August 23, 1994;
- Have a staff of personnel based in the country that evidences background with a seniority and minimum experience of five (5) years in product certification by conformity mark and of three (3) years in the sector of activity for which aspires to be recognized;
- Have a decision-making certification committee with a seat in the country;
- No operation as a testing laboratory or inspection body;
- Assume civil, commercial, administrative and criminal liability arising from the certification functions, and the commitment to hire, in addition, civil liability insurance.

4. ELECTRICAL APPLIANCES

4.1. Electrical Appliances (Brazil)

4.1.1. Overview

Electrical goods are all goods and their parts that are powered by eletricity. Electrical goods can be divided into three subsector: major appliances or white goods; small appliances; and consumer goods or brown goods.

Majors appliances encompasses refrigeration equipment such as freezers, refrigerators and water coolers; cooking equipements such as cookers (range, stoves, ovens, cooking plates and cooktops) and microwave ovens; washing and drying equipment such as washing machines, clothes dryers and drying cabinets, and dishwashers; and air conditioners and air heaters, and water filters.

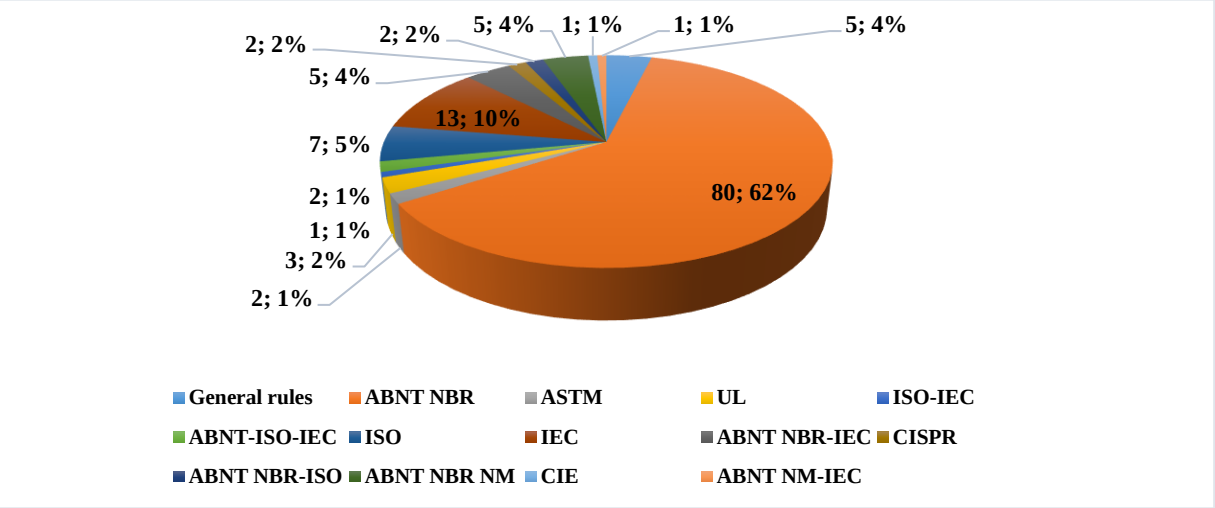
Small appliances includes lighbulbs and light fixtures, fans (table, ceiling and others), portable wineries, water jet washers, sewing machines, drills, vacuum cleaners, blenders, mixers, juice centrifuges, food processors, floor waxers, shaving appliances, hair cutting machine, depilatory devices, electric heating appliances, electric iron, grills, coffee or tea makers, toasters, deep fryers and other household equipment.

Consumer goods, small appliances or home electricals, are electrical or digital equipment for daily use. They are entertainment goods such as: musical instruments, flatscreen TVs, DVD players, DVD movies, iPods, video games and consoles, remote control cars, radio and audio devices, home theaters, cameras; communication and telecommunication goods: telephones, cell phones, smartphones, tablets, e-mail-capable devices and laptops, and home and office goods such as: laptops, desktop comupters, printers, scanners, paper shredders.

4.1.2. Mapping of technical regulation

In Brazil Federal government, many ministries and numerous agencies have jurisdiction for establishing regulations to this sector, ensuring safety of goods, energy efficiency and regulating imports of such goods. The Ministry of Mines and Energy (MME), Ministry of Science, Technology and Innovation (MCTI), and Ministry of Industry, Trade and Services (MDIC), through its interministerial committee, the Energy Efficiency Indicators Management Committee (CGIEE), regulate the National Policy on Conservation and Rational Use of Energy. The Ministry of Labour and Employment (MTE) regulates safety in labour environment and production, as well as sectorial agreements between labour associations of a specific product or section and its employees. The National Institute of Metrology, Quality and Technology (INMETRO) and the National Agency of Telecommunication (ANATEL) are the primary regulators of electrical goods. In any case, the Brazilian Law requires all regulatory documents to be available online. The list of main regulation on electrical and electronic appliances is on Annex 1.

Figure 31 - Standards in the technical regulation notified to TBT Committee of WTO (total: 124)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

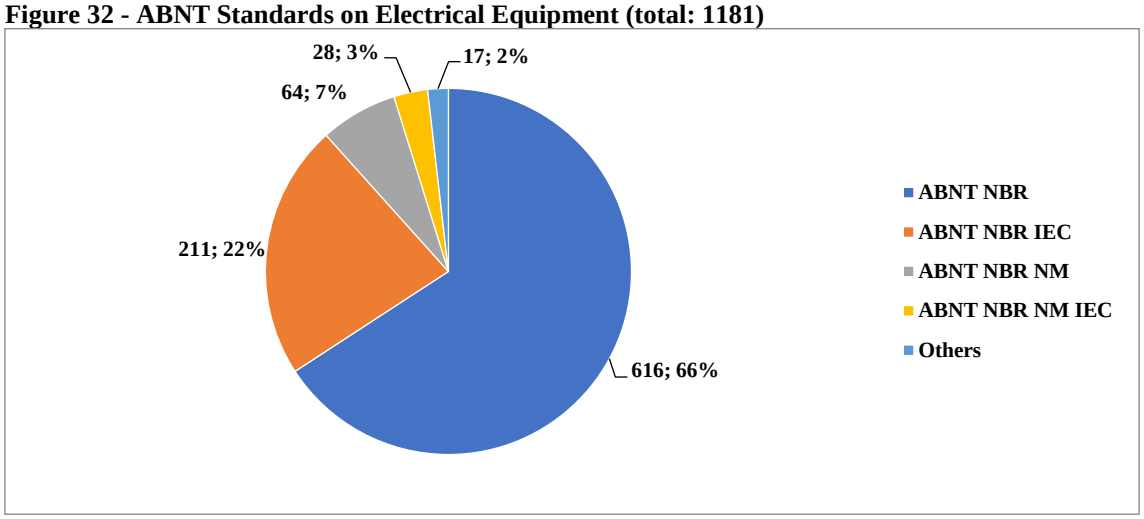
Figure 3 above demonstrates that 62 percent of all notified regulation is based on standards issued by ABNT. The other 38 percent is divided into ASTM, UL, ISO, IEC, ISO-IEC, CISPR, CIE and general rules, which means standards or regulation borrowed from other sector.

4.1.3. Mapping of technical standards

ABNT[29] issued about 1181 standards for electronic products or parts (Annex 1). The Committee on Electricity (ABNT/CB-003) has 936 norms, while the Committee on Computers and Data Processors (ABNT/CB21) has 51 norms. Committee on Air Refrigerators and Heaters (ABNT/CB55) has 42 norms, the Comission on Digital Television (ABNT/CEE-85) has 146 norms. Comission on Energy Management (ABNT/CEE-116), has 5 norms all of them ISO-based, and the Comission for Mitigation of Electric Interferences (ABNT/CEE-212) has only one standard. The following graphic illustrates the different types of ABNT standards on electrical equipment.

[29] A relevant number of technical regulations (especially those on conformity assessment procedures) refers to supporting standards, usually issued by **ABNT,** a private body. There are different kind of supporting standards issued by ABNT that goes from a fully original standard developed under its Standardizing Committees (CB) to those based on international standards, mainly ISO and IEC. Usually, (i) If it is a standard identical to an international standard, it will appear, for example, as *ABNT NBR ISO nº XXX;* (ii) If it is based on an international standard, a reference to this international standard will be in the preamble of the standard; and (iii) If it is an original standard, it will appear as *ABNT NBR nº XXX*. ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website. ABNT Catalog with all searching tools is available here. In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard.

Figure 32 - ABNT Standards on Electrical Equipment (total: 1181)



Source: ABNT. Prepared by CCGI -EESP/FGV.

4.1.4. Mandatory conformity assessment procedures

Before a electronic product can be placed on the Brazilian market, it shall be registered with INMETRO and receive a registration number which shall be placed on the label of the product. Therefore, INMETRO is responsible for the compliance and registration of any electronic processing facility established in Brazil. Brazil does not have any policy for pre-market notification process. Each company registration or authorization to sell is the first step to have access to INMETRO services. There are, then, two registry and conformity assessment paths. The first is the Brazilian Labeling Program (*Programa Brasileiro de Etiquetagem* - PBE). PBE relates to energy efficiency and is part of the implementation of the National Plan for Energy Efficiency (*Plano Nacional de Eficiência Energética* (PNEf)), as regulated by the CGIEE. The current National Energy Plan (PNE2030) sets goals and establishes the PBE new requirements. All products at free zones establishments where electro- electronics are manufactured and packaged are under the PBE program. The second path is through Ordinance 371/2009, which establishes basic compulsory standards for all electronic products that does not fall under Inmetro's PBEs.

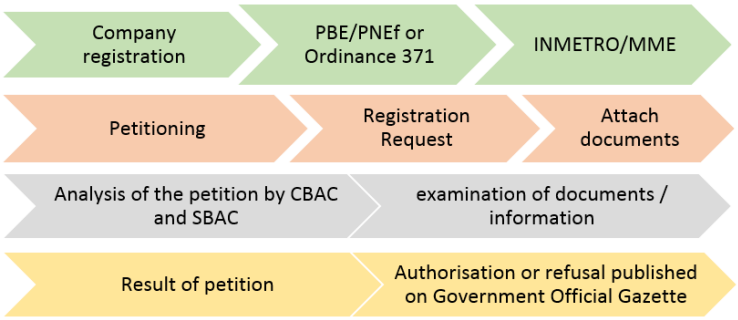
The conformity assessment procedure is compulsory for various electrical and electronic products. In certain cases, certification may be replaced by a supplier's declaration. Conformity assessment procedures are determined in INMETRO ordinances. These procedures often adopt international standards, especially those issued by the IEC, which is frequently mentioned in Brazilian technical regulations. The following table summarizes by products the conformity assessment mechanism, the issuing regulatory agency, the ordinance number and standards and other regulation mentioned. In total, 28 percent of all Brazilian Technical Regulation use Brazilian standards, while 72 percent are based on international standards.

Moreover, the Good Manufacturing Practices (GMPs) include a set of measures that should be adopted by the electro-electronic companies, in order to ensure the quality of the products. Each type of product has its own specifications, but all shall comply with the Ministry of Labor regulations. The certification procedure consists of official certification bodies, or officially recognized certification bodies ensure, recognizing that the electro-eletronic products or parts, or their control systems, are in conformity with the

requirements of a standard. Where possible, alternative measures are considered for certification, such as, special inspection systems or equivalent requirements of trade partners are alternative measures considered when possible.

This registration flow is ilustrated bellow:

Figure 33 - Brazilian Electronic and Electric Goods Registration Flow



Source: INMETRO, 2017.

Bilateral or multilateral treaties such as mutual recognition agreements may be stipulated. INMETRO, the only acredutation body in Brazil, usually negotiates such agrrements. The Conformity Assessment Brazilian System (SBAC) and Conformity Assessment Brazilian Committee (CBAC) are regulated by CONMETRO Resolution 4/2002. Importers and like producers of electro-electronic goods under the compulsory list shall register their products and pay fees, which vary according to the type of product and the size of the company. The competent public body for dealing with imports and their conformity with domestic regulations is the Department for Foreing Trade Operations (*Departamento de Operações de Comércio Exterior* – DECEX). All products shall have an Import Lincense (*Licença de Importação* – LI) previous to its shipping at the Integrated System of Foreing Trade (Sistema Integrado de Comércio Exterior – SISCOMEX). If it is a good exclusive for industrial use, or if it is a like product to those listed at Ordinance 371/2009 of INMETRO or even if they are just samples, INMETRO can issue a Declaration of Import Liberation (*Delcaração de Liberação de Importação*), in accordance with terms set at Ordinance 199/2011.

4.2. Electrical Appliances (Argentina)

4.2.1. Overview

The Argentine electrical sector results from import substitution industrialization, which began in the 1930s and deepened in the following decades, especially in the governments of Perón and Frondizi. The direct foreign investments of large transnational corporations were also important for the sector development. Most of them located in the Buenos Aires, the largest industrial cluster in the country, and in cities such as Córdoba, Rosario, Tucumán, Mendoza, and Tierra del Fuego.

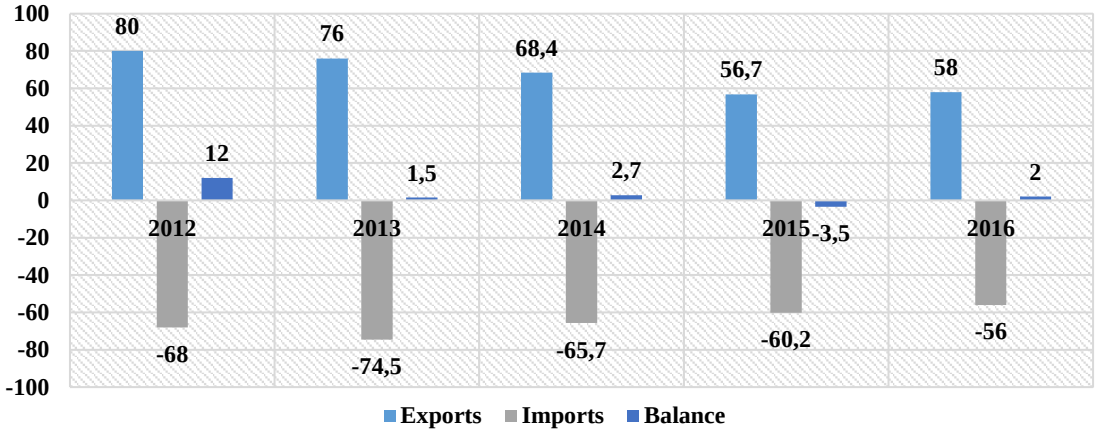
Like other sectors resulting from protectionist development policies, the electrical sector in Argentina always had problems in competing with similar products in the international

market and, more recently, lost space in domestic market. This problem became more evident in the last decades when the global economy became more connected and interdependent, while Argentina had to cope with a strong process of de-industrialization.

Nowadays, Argentina is an importer of electrical and electronic products, although the sector has some expression in the assembly of electrical and electronic products, including telecommunications, based on imported components. The weight of these products in the Argentine exports is also of little relevance, although the sector has strategic importance in manufacturing chain of some products, such as vehicles and building sector.

As it can be seen in its trade balance the foreign trade in Argentina is relatively stable. Over the last five years, according to data collected on INDEC, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods.

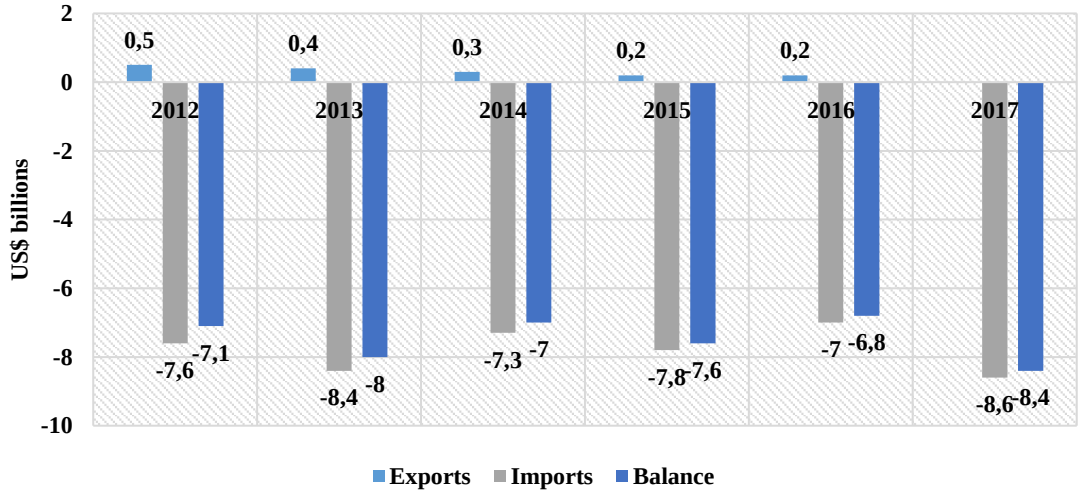
Figure 34 - Argentine Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV.

Regarding the electrical trade balance, in the last five years, Argentina has presented a significant deficit. This characteristic indicates a strong dependence on imports of this type of product, which total between 50 and 80 billion.

Figure 35 - Argentine Trade Balance for Electrical Products



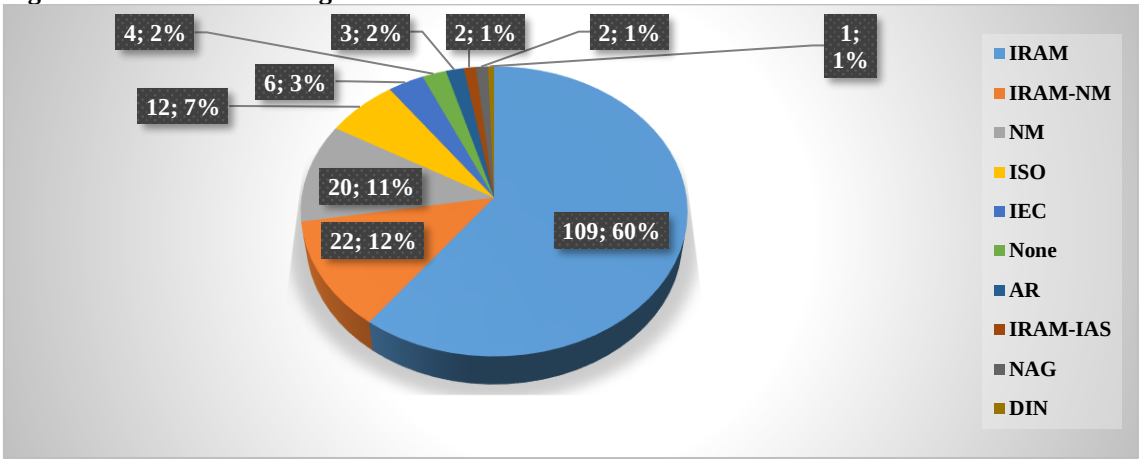
Source: INDEC. Elaborated by CCGI-EESP/FGV.

Argentina develops domestically an important part of the technical standards used in the production process of electrical and electronic appliances, although it also uses sporadically international standards produced mainly by the International Standardization Organization (ISO) and International Electrotechnical Commission (IEC). The technical regulation derives mostly from the activity of *Asociación Electrotécnica Argentina* (AEA). The AEA is a private non-profit entity that performs an important normalization function and, through state delegation, specific regulatory activity. The standards are developed by the *Instituto Argentino de Normalización y Certificación* (IRAM).

4.2.2. Mapping of technical regulations

Technical regulations notified by the Argentine government to the WTO under the Agreement on Technical Barriers to Trade (TBT) may also elucidate the big picture of electrical sectorial regulation in the country. All projects of technical regulations that impact international trade, have to be notified to the WTO. From January 1st, 1995 until March 8th, 2018, there were twenty-two notifications. The provisions of technical regulation usually use standards produced by international or Argentine standardization bodies.

Figure 36 - Standards in Regulation notified to TBT Committee of WTO



Source: WTO. Elaborated by CCGI-EESP/FGV.

As stated before the main subject contained in such technical regulation notified to TBT Committee is the user's safety of electrical products.

There are many organizations responsible for issuing technical regulation in electrical sector in Argentina. Most of them, such as Secretariat of Trade, National Directorate of Domestic Trade and Ministry of Competition, Deregulation, National Directorate of Domestic Trade, and Consumer Protection are part of the Ministry of Production. Other ones are the Ministry of Energy and Mining, the National Regulatory Agency for Gas (ENARGAS) and the National Regulatory Entity for Electricity (ENRE).

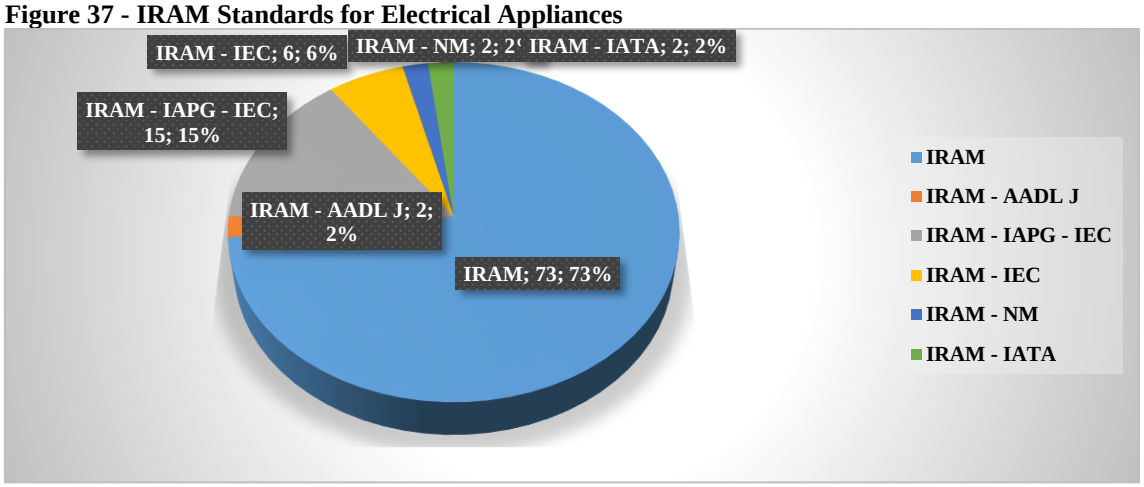
Most of the technical regulations concerning electrical equipment concern the safety of workers who operate the electrical appliance. With regard to the correct functioning of the apparatus, the most important are the voluntary standards produced mainly by *Instituto Argentino de Normalización y Certificación* (IRAM), *Asociación Electrotécnica Argentina* (AEA) and international standardization bodies. More regulation in Annex 1.

4.2.3. Technical Standards

The technical standards used by the sector are usually domestically produced by IRAM and *Instituto Argentino del Petroleo y del Gas* (IAPG) (see Annex 1). Some of them are based on technical standards produced by international standardization bodies such as ISO and IEC. These standards are voluntary but are compulsory if specifically referred to by a technical regulation. They must be used in conjunction with the mandatory requirements of the AEA.

Most of the standards used in the electrical sector are homegrown standards. Considering as international the IEC standards and those produced by some Committee of the Mercosul Standardization Association (AMN), it is observed that they correspond to a little more than 20% of the IRAM standards, which may indicate a low degree of internationalization of the sector.

Figure 37 - IRAM Standards for Electrical Appliances



Source: IRAM. Elaborated by CCGI-FGV/EESP.

As electrical appliances are used in productive processes in various sectors of the economy, many technical standards are designed by standardization bodies apparently unconnected to the electricity sector. For example, the standards produced by *Instituto Argentino del Petroleo y del Gas* (IAPG) and *Asociación de Ingenieros y Técnicos del Automotor* (AITA) can be highlighted as important standards for the correct use of electrical appliances.

4.2.4. Mandatory conformity assessment procedures

In terms of conformity assessment, it should be highlighted the *Resolución* (Resolution) 171/2016, which contains important definitions of technical expressions and prescribes the necessity of certification of low voltage electrical products.

In the *Resolución*, it is clear the importance of IRAM, which acts as the main normalizing body and as an important certification body (articles 4 and 5). The conformity assessment models are provided in art. 5 and may be divided in three models: terms of type, conformity mark and batch. These modalities are provided in detail in Article 1 of *Resolución* No. 197 of December 29, 2004 of the former SECRETARIAT OF

TECHNICAL COORDINATION of the former MINISTRY OF ECONOMY AND PRODUCTION.

The way certification is done is based on standards produced by IRAM, which confers an advantage to Argentine conformity assessment bodies. The Argentine network of conformity assessment bodies is made up of organizations originally from Argentina and other international bodies.

5. MEDICAL DEVICES

5.1. Medical Devices (Brazil)

5.1.1. Overview

The proliferation of medical devices in the world symbolizes technological advances for diagnostic and treatment purposes. However, it can also represent risks to patients and users of these products. Thus, it requires both control and protection, including a "regulation of health risk" approach, instead of a mere general market regulation rationale.

Brazil is the largest medical device market in Latin America. This industry is capable of supplying 90% of the internal market needs and exports to more than 180 countries generating around 60,000 jobs in the country[30]. According to the Brazilian Association of Medical, Dental, Hospital and Laboratory Equipment (*Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratórios* - ABIMO), Brazil has 418 companies related to health products, including manufacturers, importers and distributors.

The Brazilian medical devices sector is segmented into: Dentistry (equipment, consumer and instrumental material), Laboratory (equipment, reagents and consumer products), Radiology (apparatus, accessories and consumables), Medical and hospital equipment (non-electrical, electro-medical, surgical instruments, physiotherapy and general equipment), Implants (orthopedic, neurological, cardiac and others) and Consumer materials (hypodermic, textile, adhesives and others).

In Brazil, the Federal Law 6,360/1976 is the main regulatory legal norm controlling this sector. It establishes that medical devices may be solely manufactured or imported for use or for sale exhibitions, after the Ministry of Health (MS) has announced whether or not registration is mandatory. In addition, certificate of conformity can be required for some medical devices, especially for electro-medical equipment.

Nowadays, the competence to guarantee the sanitary safety of medical devices is under the Brazilian Health Regulatory Agency (ANVISA) responsibilities, even though product certification remains under the Brazilian National Institute of Metrology, Quality and Technology (INMETRO) obligation.

5.1.2. Mapping Technical Regulation

The main agencies dealing with technical regulations from medical devices sector are ANVISA and INMETRO (see Annex 5). There is only one non-governmental body with a relevant role in promoting private and international standards, which is the Brazilian Association on Technical Standards (ABNT)[31]. The role and standards published by this association are also covered in this report.

[30] Data available at Brazilian Health Devices web site in http://brazilianhealthdevices.com.br/market 5/4/2017.

[31] All acronyms will be used in its Portuguese version, simplifying the references to national regulation applying such acronyms.

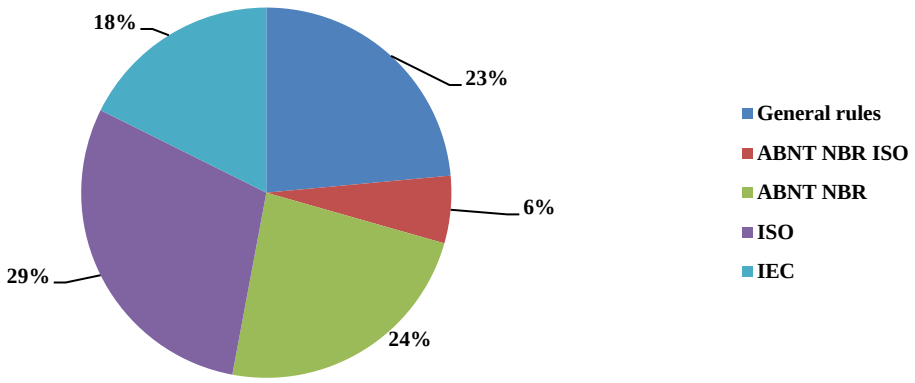
While ANVISA[32] determines that all suppliers of medical products shall obtain its approval prior to selling them in Brazil and after classifying them by the risk-level they represent to the health of consumers, patients, operators, or third parties involved, INMETRO maintains the national measurement standards in the country, evaluates compliance requirements for products manufactured in or imported into Brazil and implements the national policies on metrology and quality[33].

Projects of technical regulations that impact international trade are to be notified to the Committee on Technical Barriers of the World Trade Organization (WTO). In addition to INMETRO, the national enquiry point to the WTO/TBT, other entities also notify under the WTO/TBT agreement, mainly Ministry of Mines and Energy.

From January 1st, 1995 until March 30th, 2017, there were 23 notifications from Brazil on TBT. In May 3rd, 2017, 13 of them were still in force. INMETRO has traditionally by far been the main body having technical regulations notified before the WTO.

The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on the sector.

Figure 38 - Standards in technical regulations notified to WTO (%) (total: 13)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

The standards ABNT NBR correspond to sixty-two percent of the total notified. Such standards are issued by the Brazilian organization ABNT, without explicitly endorsing any international standard. The ISO and ISO/IEC standards have also a relevant role, in comparison to other. The ISO and ISO/IEC standards are frequently adopted by certain governmental agencies or incorporated do ABNT's standards.

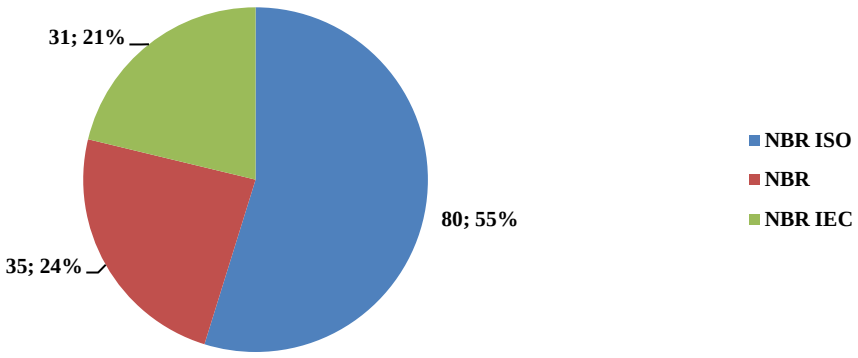
5.1.3. Mapping Technical Standards

The Brazilian Association of Technical Standards (ABNT) develops Brazilian standards and adopts international ones into Brazilian regulatory scheme characteristics. Specifically, for medical devices, currently ABNT has 146 standards, of which 35 are

[32] Resolution 59/2000.
[33] Information available at: http://inmetro.gov.br/english/institucional/index.asp.

elaborated in Brazil (NBR), 31 are a translation from standards developed by the International Electrotechnical Commission (NBR IEC) and 80 are a translation from standards developed by the International Organization for Standardization (NBR ISO) (see Annex 5). As technical standards, they are not compulsory in isolation, but ANVISA Resolution no. 444/1999 makes them compulsory for certification of conformity and requires registration before the release in the market.

Figure 39 - Standards and supporting standards of ABNT (%) (total: 146)



Source: ABNT. Prepared by CCGI-EESP/ FGV (May 2017).

With respect to the use of technologies involving ionizing radiation, since 1988, the Brazilian National Commission for Nuclear Energy (CNEN) has defined technical requirements for radioprotection through the CNEN-NE-3.01 standard, establishing Radioprotection and Safety Requirements specifically for Medical Services Nuclear and Radiotherapy respectively in 1989 and 1990 through standards CNEN-NN-3.05 and CNEN-NE-3.06.

However, legislation regarding radiological protection in medical and dental radiodiagnosis was only established in June 1998 by the Ministry of Health and the Secretariat of Sanitary Surveillance through Ordinance No. 453, which also contains technical requirements for the implementation of metrological reliability of these devices.

5.1.4. Mandatory conformity assessment procedures

Concerning ANVISA's registration process[34], first, these instruments have to be listed in one of the four classes in ascending risks: classes I, II, III and IV representing low-, medium-, high- and very-high-risk devices. If it is listed as Class I or Class II it is not required registration, unless it has potential risk involved. Class III and Class IV devices require listing and registration and in the registration process it shall be specified all parameters and specifications of the device[35].

[34] According with Resolution 185/2006.
[35] Medical products submitted to clinical research are hereby exempt from registration, provided that they comply with the legal provisions of the competent health surveillance authority on the performance of this activity, prohibiting such products to be commercialized and used for other purposes.

ANVISA medical device approval process involves the following steps: **Step 1:** Determine device classification using ANVISA's rules (Annex 2: ANVISA: Products Classification); **Step 2:** For all classes: Appoint a company that holds a Company Working Allowance permit from ANVISA as the Brazil Registration Holder (BRH); **Step 3:** For all classes: Provide Letter of Authorization to the BRH, who will submit the registration application to ANVISA. The BRH maintains control of the device registration and Brazil Good Manufacturing Practice (BGMP) certification; **Step 4:** For all classes: Certain devices[36] require INMETRO Certification. Testing for electro-medical products performed outside Brazil is usually accepted, if performed by an ILAC-certified lab (CB Scheme is not accepted). Third edition of IEC 60601 testing is mandatory. All tests performed outside of Brazil must be less than two years old when they are submitted to INMETRO Certifier; **Step 5:** For Class I and II (*Cadastro*): Class I and II device manufacturers must comply with BGMP requirements. However, ANVISA will not conduct an audit. For Class III and IV (*Registro*): Class III and IV manufacturers must be audited for BGMP compliance by ANVISA as outlined in RDC 16/2013. BGMP fees are due every two years; **Step 6:** For Class I and II (*Cadastro*): Prepare Technical Dossier and application for registration. Send legal documents, as well as proposed RDC 185/2001-compliant labeling (IFU and labels) to BRH. These files are maintained by the BRH in case of ANVISA on-site inspections. For Class III and IV (*Registro*): Prepare Technical File, including clinical data, clinical studies (if applicable), information on the device in accordance with Annex III, Part A, B, and C in RDC 185/2001, and proposed labeling (IFU and labels) per Annex III Part B; **Step 7:** For all classes: BRH prepares and submits the application to ANVISA. All documents must be submitted in Brazilian Portuguese; **Step 8:** For all classes: ANVISA reviews registration application. Upon approval, ANVISA will publish registration number in the Diário Oficial da União (DOU); **Step 9:** Class I and II registrations do not expire. Class III and IV registrations are valid for 5 years. Registration renewals must be initiated one year, and no later than six months, prior to expiration; **Step 10:** For all classes: Appoint a qualified importer/distributor to bring the device into Brazil.

Besides those health products must have proven safety and effectiveness. It shall be submitted a specific clinical testing with the product to be registered by ANVISA in the following situations:

- Innovative health products, regardless of their risk class (innovation in design, raw material, indications for use, among others);
- Health products of risk class III and IV that require safety and effectiveness verification using specific clinical data of the product submitted, due to their unique nature and performance linked to the material design and manufacturing process.

The Resolution RDC no. 56/2001 establishes the need of compliance with essential requirements of safety and effectiveness of health products. It determines that these requirements must be based on clinical data, especially for health products of risk class III or IV, as follows:

[36] Includes a variety of devices, such as breast implants, sterile hypodermic syringes, sterile needles, examination/surgical gloves, condoms, certain mattresses, blood bags, intrauterine devices, protective (laser) glasses, and those electro-medical devices outlined in IN 4/2015.

- compilation of scientific bibliography of indexed publications related to clinical researches on the product's intended use and, if applicable, related to written reports containing a critical review of this bibliography; or
- results and conclusions of a clinical research specifically conducted on the product.

The Resolution RDC no. 40/2015 determines the requirements of registration of medical products, established in Article 4, Paragraph 1, ANVISA may request the submission of additional documentation and information for "technical reasons, in order to prove the safety and effectiveness of products due to potential public health risks, and for those products considered strategic by the Ministry of Health."

In these cases, a clinical assessment report must be submitted at the time of application for listing and registering, contemplating clinical trial(s) that provides valid and sufficient scientific evidence for verification and confirmation of the safety and effectiveness. Several methodologies and study designs can be used to prove the safety and effectiveness of a medical product.

"The specificities of the product and risks associated with its use shall be taken into account, thus contemplating randomized clinical trials with control group" and well-documented series of case studies. "The selected methodology must be appropriate to provide valid safety measures and clinical performance" and the "level of evidence required to approve the product will depend on its indication for use, characteristics of the device, its level of innovation, among other aspects"[37].

In general, the clinical development of a health product is divided into the following phases: pilot and pivotal. "The purpose of the pilot or feasibility phase, which begins with the first clinical use of the product, is to establish the safety of the product, initial parameters of effectiveness, and assist in the development of the subsequent pivotal study". The pivotal study confirms that the product is safe and effective for its target population. "Pivotal studies are usually well-controlled experimental studies using either control or partially controlled groups. Pivotal clinical studies with confirmatory methodological characteristics of safety and effectiveness will be requested." Non-pivotal studies may be accepted in some cases, depending on the specificity of the product, as previously clarified (e.g. health products indicated to treat a rare clinical condition). [38]

Clinical trials must include clinical condition(s) and target population for the medical products. The duration of the clinical study shall be adjusted to assess the expected effectiveness of the product as well as the occurrence of events and acute and late side effects. Robust outcomes shall be used, preferably clinical endpoints or the combination of clinical and surrogate or imaging endpoints, and the study design shall contain the methodology that allows a direct relation between the findings and the performance of the product tested. The rationale shall be demonstrated in order to determine the sample size of the study (number of participants), and the same must be obtained through statistical grounds and adjusted to the clinical development stage of the product.

The results of clinical trial(s) shall be submitted to ANVISA in the form of report, as well as publications in scientific journals related to these trials, if already available in the

[37] Technical note no. 004/2016/GGTPS/DIREG/ANVISA
[38] Technical note NO. 004/2016/GGTPS/DIREG/ANVISA

scientific literature. The following information must be contained in the documentation, when applicable:

- Objectives of the research;
- Description of the study design;
- Inclusion and exclusion criteria;
- Hypothesis of the study;
- Definition of primary and secondary outcomes (safety and effectiveness endpoints);
- Criteria for the study success;
- Allocation of type I error (alpha) for the hypothesis evaluated;
- Type II error;
- Demonstration of the statistical analysis plan;
- Rationale to determine the sample size;
- Statistical methods used;
- Submission of results and data evaluation;
- Safety and effectiveness evaluation plan for the ITT population (intention-to-treat) or PP population (per protocol);
- Method, in case of blinding;
- Evaluation of adverse events.

Finally, the studies submitted to ANVISA must comply with ethical and Good Clinical Practices principles. Clinical trials performed in Brazil shall comply with RDC no. 10/2015 or with standards that preceded it[39].

ANVISA suspends the registration of medical devices in the following cases:

a) when the validity of any document is suspended for safety reasons and is duly justified;
b) when the non-compliance with any requirement has been proven;
c) when the product is being investigated by the competent health surveillance authority due to irregularities or defects found in the product or in its manufacturing process, representing a risk to the health of consumers, patients, operators, or third parties involved.

ANVISA cancels the registration of medical products in the following cases:

a) when there is proof that the information in any document has been forged or when any of these documents has been cancelled by ANVISA;
b) when the product or its manufacturing process has been proven by Anvisa to be a risk to the health of consumers, patients, operators, or third parties involved.

To investigate this cases ANVISA counts on a surveillance system for adverse events and technical complaints related to health products in post-marketing phase, aiming to recommend the adoption of measures to ensure people's health protection and promotion. This is called technovigilance whose requirements are determined by the RDC no. 67/2009.

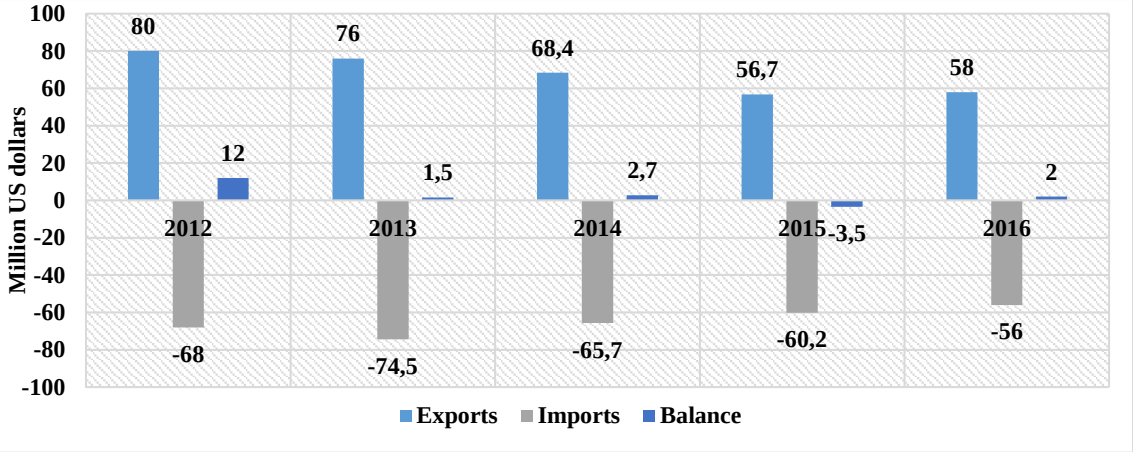
[39] For details on Good Manufacturing Practices see Annex 3.

5.2. Medical Devices (Argentina)

5.2.1. Overview

The foreign trade in Argentina is relatively balanced. Over the last five years, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods. However, Argentina is heavily deficient in the trade of electrical materials and equipment.

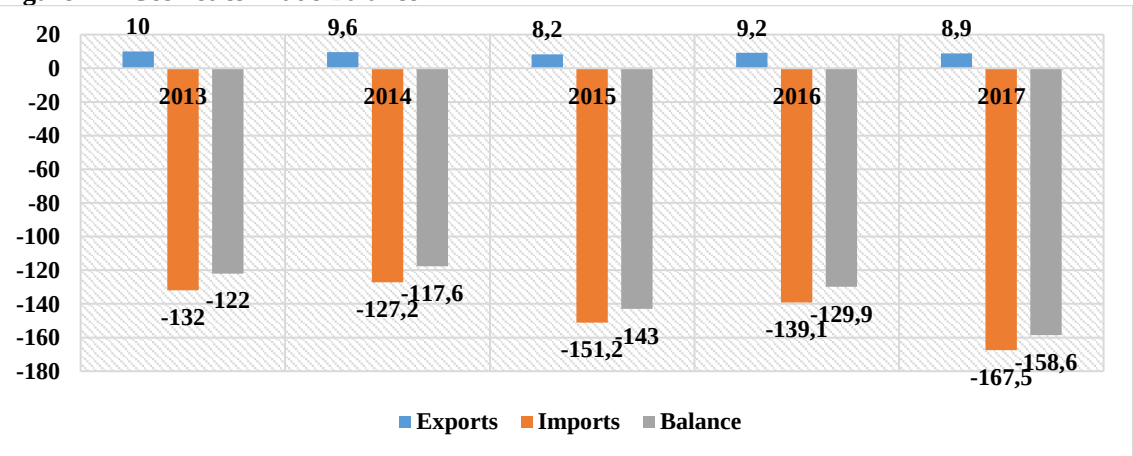
Figure 40 - Argentine Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV.

The medical devices sector presents significant deficits. Despite the production of some types of medical devices on the country, health services are heavily dependent on imported equipment. During the last five years, trade deficits have been higher than US$ 115 million. Exports oscillated around U$$ 8,2 million and US$ 10 million. Imports, on their turn, oscillated around US$ 127,2 million and US$ 167,5 million.

Figure 41 - Cosmetics Trade Balance



Source: INDEC. Elaborated by CCGI-EESP/FGV

5.2.2. Mapping Technical Regulation and Authorities

Argentine laws and regulations aim to provide access to qualified and efficient health services and to define criteria of use of existing technologies (see Annex 5). The main

issues regulated by national laws are the importation of medical devices and the conditions for the use of medical devices.

Law 21908/1978 establishes the rights of importation of equipment of medical use. The systems, equipment and apparel of medical use of advanced technology are exempted of payment of importation taxes and the value added tax when they satisfy the following requisites:

- they constitute a relevant improvement of the existent techniques about medical research, diagnosis or any step of the process of medical attention;
- they are considered of high cost;
- their production is not on the country and
- they are conceded at no cost in favor of the State to be used in no less than 20% of useful time or of the complete and integral benefits of such systems, apparel or equipment during their useful life.

The State Secretariat of Public Health has a relevant role as it will extend, on each case, a certificate of necessity aiming to guarantee a rational distribution and exploitation of the resources. It will formalize an agreement that will regulate the concessions at no cost in favor of the State to be used in no less than 20% of useful time or of the complete and integral benefits of such systems, apparel or equipment during their useful life. The State Secretariat of Public Health, the respective sanitary authority and the entity that provides the service will be part of the agreement. Such agreement, legally formalized, will be the previous condition that will allow the ministerial resolution of franchising importation.

Resolution 30/1997 updates norms that regulate the importation of products considered medical apparel and equipment subject to the intervention of ANMAT. In order to regulate the importation of medical apparel and equipment, the procedure foreseen on the resolution will be applied to the tariff positions of the Common Nomenclature of Mercosul (*Nomenclatura Común del Mercosul* , NCM) foreseen on the following positions: chapter 28 (only diagnosis reagents), chapter 29 (only diagnosis reagents), 3002.90.10, 3005.10.20, 3005.10.30, 3005.10.40, 3005.10.50, 3005.10.90, 3005.90.11, 3005.90.12, 3005.90.19, 3005.90.20, 3005.90.90, 3006.10, 3006.40, 3822.00.00 (only diagnosis reagents), 3926.20 (only for medical use), 3926.90.30, 4015.11, 4015.19 (only for medical use), 9004.90.10, 9018.11, 9018.12, 9018.13, 9018.14, 9018.19, 9018.20, 9018.31, 9018.32, 9018.39, 9018.41, 9018.49, 9018.50, 9018.90, 9019.10, 9019.20, 9021.11, 9021.19, 9021.21, 9021.29, 9021.30, 9021.40, 9021.50, 9021.90, 9022.12, 9022.13, 9022.14 and 9022.21.

Decree law 2469/58 establishes conditions for the use of every medical instrument or equipment with diagnosis or therapeutic goals. Every element, material, instrument or equipment of medical use that is applied with diagnosis or therapeutic goals must be used by enabled professional and under its responsibility.

Law 14583/2013 is the main provincial law that regulates medical equipment. It establishes a regulation and oversight regime of medical equipment in use in relation with its technical fitness in terms of security and efficacy on public and private health institutions on the province of Buenos Aires. Every following reference to the regime will be done under the simplified denomination VATEM (Verification of Technical Fitness of Medical Equipment).

The adopted definition of medical equipment is the one created by the National Administration of Medicine, Food and Medical Technology foreseen on disposition ANMAT 2318/2002. The medical equipment is categorized according to the intrinsic risk they represent to the health of the consumer, patient, operator or interested third parties. The categorization norms established by the application authority must be applied to categorize medical equipment.

The law also creates the Provincial Registry of Medical Equipment in Use and of Lenders. The health institutions must annually present an official declaration to the corresponding sanitary region that includes the name of medical equipment in use on each establishment. The main institutions that regulate the use of medical instruments or equipment with diagnosis or therapeutic goals are the Ministry of Social Assistance and Public Health, the Coordinating Unity of Evaluation and Execution of Health Technologies, the Medical Argentine Association and the Executive Power.

Inside the Medical Argentine Association, the Directive Commissions of the Medical Argentine Association (*Asociación Médica Argentina*, AMA) and the Society of Ethics in Medicine created the Code of Ethics of the Argentine Medical Association for Health Equipment. The main goal of the code is to serve as a guide for the performance of AMA's associates and for all other members that wish to adhere to the code.

Chapter 21 of the code regulates conditions of sale and use of medical equipment. The companies that produce or trade medical equipment must guarantee the quality of the offered product, comply the term conceded by the guarantee, train, if necessary, the personnel involved on its use, offer the reparation or substitution of the damaged elements and install the equipment according to norms in force about labor safety.

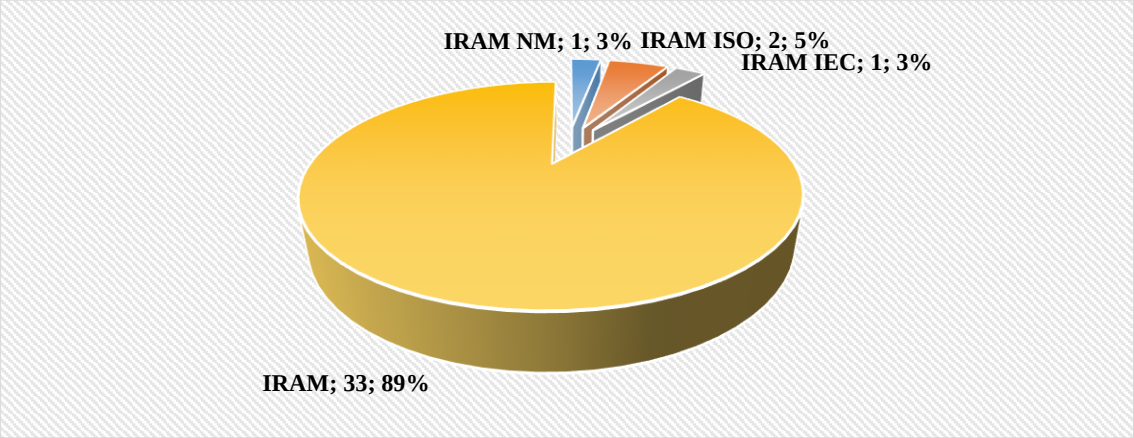
The companies involved on the provision of medical equipment must respect the norms foreseen on the national legislation about the issue. The conduct that can induce mistake, error, confusion or obscurity about the secondary effects of medical equipment will be considered a violation of ethics. The intermediates that trade medical equipment are also responsible for the quality of such products.

Considering the current technological developments to the practice of invasive methods, the companies that produce and trade them and the people that work on them must guarantee the safety of patients and of the doctors.

5.2.3. Mapping Technical Standards

In Argentina, there are several standards applicable to medical equipment. The vast majority of standards consist of standards originally produced by IRAM (see Annex 5). A small minority of standards consist of the adoption of international standards.

Figure 42 - Medical Devices Standards: IRAM and others



Source: IRAM. Elaborated by CCGI-EESP/FGV.

5.2.4. Mandatory conformity assessment procedures

The medical equipment in use, established by the application authority, must be object of technical verification, test or calibration according to the applicable norm or standard and/or indication of the producer according to the periodicity established by the application authority. The technical verification, test or calibration must be done by laboratories accredited by the Argentine Accreditation Organism (O.A.A.), belonging to national universities on the province of Buenos Aires, the National Institute of Industrial Technology (I.N.T.I.) and other agents authorized by the application authority, being obliged to comply with norms established on the issue for the territory of the province of Buenos Aires.

The application authority must extend a certificate of assessment of medical equipment in use for cases in which the parameters obtained in the technical assessment, test or calibration are adjusted to the corresponding norm/standard. The authority must also determine the period of enforcement of the document that must be updated on equal periods.

The certificate can be without effect at any moment if it is proved that the equipment does not comply totally or partially the requisites foreseen on the law. When there is a drop of an indispensable equipment for the specialty and there is no other equipment to continue the supply of the service, the establishment must interrupt the internment of patients of this specialty.

The application authority will register and archive the informs in which there is a technical protocol of assessment under norm/standard, the result of the inform, the date of emission, the norms applied, the observations and the responsible person. The application authority must also, on a regular and systematic form, do inspections conformity assessment of medical equipment in use.

6. PHARMACEUTICALS

6.1. Pharmaceuticals (Brazil)

6.1.1. Overview

The medicines and pharmaceutical sector is a relevant sector for Brazil. The exports and imports of pharmaceutical products have contributed to strengthen the Brazilian economy and to foster international trade. In the last four years, the values of trade in pharmaceutical products oscillated between US$ 7,5 and US$ 9 billion and went down from 2013 until 2016 (MICS, 2017). It can be observed in the table below:

Table 17 - Trade of Pharmaceutical Products (US$ billions)

Year	Brazil-World	
	Exports	Imports
2013	1,5	7,4
2014	1,6	7,4
2015	1,3	6,5
2016	1,2	6,4

Source: MDIC/AliceWeb. Prepared by CCGI-EESP/ FGV.

Moreover, the number of medicines, biological products and active pharmaceutical ingredients registered in National Health Surveillance Agency (ANVISA) raised significantly from 2014 to 2016. Considering innovation and technology applied to health, 15 goods applied in the treatment of cancer were registered in 2016 in the category of new medicines, new biological products and radiopharmaceuticals. Still in the field of innovation, it is worth mentioning that 28 of the goods registered in the category of generic drugs were produced with new active substances, 5 with new pharmaceutical forms and 2 with new concentrations. The register of generic drugs helps to promote the access to medicines by the population, considering its lower price in relation to the reference product (Anvisa, 2017, p. 21).

The participation of ANVISA in the evaluation of requirements of priority of analysis was also relevant. The priority of analysis is a regulatory instrument that allows the drastic reduction of the queue time and reduces the necessary term to the evaluation of petitions of public interest (Anvisa, 2017). In 2016, 428 requirements of priority of analysis were evaluated and more than 60% of them were deferred by ANVISA.

A panel created by ANVISA with data and comparisons with previous years reveals moreover the increasing number of clinical trials authorized in Brazil and of consent on patent. In 2016, ANVISA conceded 882 registers against 773 in 2015 and 366 in 2014. It reveals a more than double increase.

The variants of registered medicines are encompassed by biologics, energized, specific, Phytotherapeutic medicine, generic, active pharmaceutical ingredient, new medicines, radiopharmacology or similar. The increase is highlighted in the generic sub-sector. It took off from 146 in 2014 to 343 in 2015 and 404 in 2016. Similar medicines are also in a high level, 299 in 2015 and 317 in 2016.

Moreover, it can be inferred that the pharmaceutical industry has shown significant progress in the last years. From 2007 to 2011, the retail drug sales increased 82,2%, from R$ 23,6 billion to R$ 43 billion and the prospection is that from 2016 to 2026,

three main submarkets will grow: (i) Patented therapies - original brands of prescription drugs; (ii) Generic pharmaceuticals (generics) and (iii) OTC medicines - over-the-counter treatments.

6.1.2. Mapping Technical Regulation (see Annex VII)

(i) Constitution: The Brazilian Constitution, enacted in 1988, guarantees the right to universal, equal access to actions of promotion, protection and recovery of health (art. 196). It is competence of the Union, the States and the Federal District to legislate concurrently on health (art. 24, XII) and according to art. 30, I and VII, it is competence of the Municipal government to legislate about issues of local interest (including health) and health actions and public health services.

(ii) Main Regulations: There are several basic laws enacted that cover health, and are related to medicines and pharmaceutical products. The Law n° 5.991/73 provides the sanitary control of drugs, medicines, pharmaceutical and correlated inputs.
According to the Law n° 6.360/76 (amended from time to time, with the last amendment by Law 13.411/2016), the medicines, drugs, pharmaceutical inputs and correlated in the Law n°. 5.991/73 (Law of Sanitary Control) as well as other hygienic products, cosmetics, among others will be subjects to the Health Surveillance (*Vigilância Sanitária*).

Moreover, the Law n° 9.787/99 provides about the generic medicine. For this law, generic medicine is a drug similar to a reference or innovative product, intended to be interchangeable, usually produced after the expiration or waiver of patent protection or other exclusive rights, proven to be effective, safe and Brazilian Common Denomination (*Denominação Comum Brasileira* – DCB) or, in its absence, International Common Denomination (*Denominação Comum Internacional* – DCI). In accordance with the Decree n° 3.181/99, the DCB and DCI are required to packaging, labels, package inserts, leaflets, texts, or any other type of dissemination material and medical information relating to medicinal products and, the generic name of the medicinal product must be in the same printing field and below the trade name or brand name. The criteria of the DCB are regulated by ANVISA. The internal norms of ANVISA that regulate the Package leaflet and labeling are: Ordinance 344/1998, Ordinance 6/1999, Resolution n° 510/1999, RDC 92/2000, RDC 168/2002, RDC 137/2003, RDC 333/2003, RDC 297/2004, RDC47/2009, RDC 71/2009, RDC 50/2009, RDC 26/2011, RDC 21/2012, RDC 60/2012, RDC 61/2012, RDC 59/2014 and Resolution 572/2002[40].

[40] BRASIL. *Lei n° 6.360, de 23 de Setembro de 1976. Dispõe sobre a Vigilância Sanitária a que ficam sujeitos os Medicamentos, as Drogas, os Insumos Farmacêuticos e Correlatos, Cosméticos, Saneantes e Outros Produtos, e dá outras Providências.* ***Diário Oficial [da] República Federativa do Brasil****, Brasília, 24 de Setembro de 1976. Acesso em: <http://www.planalto.gov.br/ccivil_03/leis/L6360.htm>. Acesso em: 15 mai.2017; BRASIL. Lei n° 5.991, de 17 de Dezembro de 1973. Dispõe sobre o Controle Sanitário do Comércio de Drogas, Medicamentos, Insumos Farmacêuticos e Correlatos, e dá outras Providências.* ***Diário Oficial [da] República Federativa do Brasil****, Brasília, 19 de dezembro de 1973. Disponível em: <http://www.planalto.gov.br/ccivil_03/leis/L5991.htm>. Acesso em: 15 mai. 2017; BRASIL. Lei nº 9.787, de 10 de Fevereiro de 1999. Altera a Lei no 6.360, de 23 de setembro de 1976, que dispõe sobre a vigilância sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. Disponível em: <http://www.planalto.gov.br/ccivil_03/leis/L9787.htm>. Acesso em: 15 mai. 2017; BRASIL. Decreto n° 3.181, de 23 de Setembro de 1999. Regulamenta a Lei no 9.787, de 10 de fevereiro de 1999, que dispõe sobre a Vigilância Sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. Disponível em: <http://www.planalto.gov.br/ccivil_03/decreto/d3181.htm>. Acesso em: 15 mai. 2017.*

The Law n° 9279/96 provides that medicines and pharmaceutical products are target by the Law of Industrial Property Rights. Art. 230 infers that a patent application for substances, materials or products obtained by chemical means or processes and substances, materials, mixtures or food products, chemical or pharmaceutical products, as well as the respective processes of obtaining or modifying them may be filed by whom has protection guaranteed in the treaty or convention in force in Brazil.

It is important to highlight that the Law n° 8.080/90, enacted to regulate art. 196 of Brazilian Constitution, creates the Unified Health System ("SUS"), which is financed by the Federal, State and Municipal Governments and the Federal District, among other sources.

(iii) Regulatory Authority: Within the Health Surveillance, the regulatory initiatives are several, all promoted by National Agency of Health Survaillance (*Agência Nacional de Vigilância Sanitária* – ANVISA), an autarchy with special regime bind to the Ministry of Health. The law that creates ANVISA is the Law n° 9.782/99.

The register is in the Law n° 6360/76, which provided that the product will be register only after scientific evidence and analysis, recognizing the product as safe and effective for the use. In the case of a new product, extensive information should be provided on its composition and its use, in order to evaluate its nature and determine the degree of safety and efficacy. More specific rules are available in the RDCs 60/2014, 124/2004, 37/2014, 31/2014, 134/2003, 210/2004, 250/2004, 98/2016, 5/2014 and the Normative Instruction 5/2014 and 2/2011[41].

For the operation of companies that intend to carry out activities of extracting, producing, manufacturing, transforming, synthesizing, packaging, repackaging, importing, exporting, storing, dispatching, distributing, contained in Laws n° 6.360/76, Decree n° 79.094/77 and Law n° 9.782/99, Decree n°. 3.029/ 99, correlated to the Medicines, Drugs and Pharmaceutical Supplies is required the Authorization of ANVISA.

The management and administration of the Agency shall be exercised by a Collegiate Board of Directors, composed of up to five members, one of whom shall be its Chief Executive Officer. The Executive Officers shall be Brazilian, nominated and appointed by the President of the Republic after prior approval by the Federal Senate, for a three-year term of office, with a single renewal. It is also forbidden for managers to have a direct or indirect interest in a company related to the Health Surveillance area provided for the Law n° 9.782/99 as provided in the regulations.

The Law n°10.742/03 encompasses the regulation to the pharmaceutical sector and creates the Regulatory Chamber of Medicines Market (*Câmara de Regulação do Mercado de Medicamentos* – CMED, see Annex IV). The producers of medicines must observe, for the adjustment and determination of their prices, the rules defined in this Law. Drug pricing will be based on a ceiling price model calculated on the basis of an

[41] *BRASIL. Lei n° 6.360, de 23 de Setembro de 1976. Dispõe sobre a Vigilância Sanitária a que ficam sujeitos os Medicamentos, as Drogas, os Insumos Farmacêuticos e Correlatos, Cosméticos, Saneantes e Outros Produtos, e dá outras Providências.* ***Diário Oficial [da] República Federativa do Brasil****, Brasília, 24 de Setembro de 1976. Available at: <http://www.planalto.gov.br/ccivil_03/leis/L6360.htm>. Accessed on: May 15th, 2017*

index, a factor of productivity, and an intra-sector and cross-sector relative price adjustment factor.

(iv) Programs and Supports: In May 2004, the Brazilian National Bank of Economic and Social Development ("BNDES") launched the Programme for Supporting the Development of the Pharmaceutical Productive Chain (*Programa de Apoio ao Desenvolvimento da Cadeia Produtiva Farmacêutica - PROFARMA), as an instrument of the Industrial, Technological and Foreign Trade* (PITCE), valid from 2004 to 2007. The result achieved was 49 projects supported and the supportive amount of R$ 1.03 billion. The main purposes of the programme was: (i) encourage the increase of the medicine production and its inputs in the country; (ii) improve the quality of medicines standards; (iii) reduce the commercial risks of the pharmaceutical production chain; (iv) stimulate research, development and innovation in the country; and (v) strengthen the economic, financial, commercial and technological position of the national industry.

(v) Transport of Pharmaceutical Products: The transport of medicines is regulated by private and public rules. The Resolution n° 433/05 from the National Council of Pharmacy provided that it is competence of the pharmaceutical professional in a medicine transport company to watch over the compliance with sanitary regulations, to allow only the transport of registered medicines and authorized companies, to install a good practices manual for the transport of medicines, pharmaceutical products and products for health, to train the human resources involved, to elaborate cleaning procedures to register and control the temperature of the vehicles, to clean the vehicles and deposit terminals and to inspect the loading and unloading activities, among others. In addition, the Ministry of Health in the Ordinance 1.052/MS/SVS/99 provided that it is necessary firstly an authorization for the functioning of an enterprise that aims to transport medicines and pharmaceutical products and the same Ministry enacted also the Resolution n° 329/99 enabling a Form of Inspection to Transport Medicines, Drugs and Pharmaceutical Inputs indispensable for the transportation of this kind of products[42].

(vi) Exports and Imports: The ANVISA controls also the regime of exports and imports of medicines and pharmaceutical products. The RDC 60/2004 provided that the company authorized by ANVISA, whom registers the respective product for the need for control and quality of these services until the availability in the market, must adopt appropriate measures to avoid or prevent health prejudices to population. Other regulations are also important such as RDC n° 11/2007 and n° 81/2008[43].

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[42] *CONSELHO FEDERAL DE FARMÁCIA. Resolução nº 433 de 26 de Abril de 2005. Regula a atuação do farmacêutico em empresa de transporte terrestre, aéreo, ferroviário ou fluvial, de produtos farmacêuticos, farmoquímicos e produtos para saúde Available at: <http://www.cff.org.br/userfiles/file/resolucoes/433.pdf>. Acesso em: May 15th, 2017; BRASIL. Ministério da Saúde: Secretaria de Vigilância Sanitária. Portaria nº 1.052, de 29 de Dezembro de 1998. Available at: <http://bvsms.saude.gov.br/bvs/saudelegis/svs1/1998/prt1052_29_12_1998.html>. Acessed on: 15 mai. 2017; BRASIL. Ministério da Saúde: Agência Nacional de Vigilância Sanitária. Resolução nº 329, de 22 de Julho de 1999. Institui o Roteiro de Inspeção para transportadoras de medicamentos, drogas* e insumos farmacêuticos. Available at: <http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/1999/res0329_22_07_1999.html>.Acessed on: May 15th, 2017.

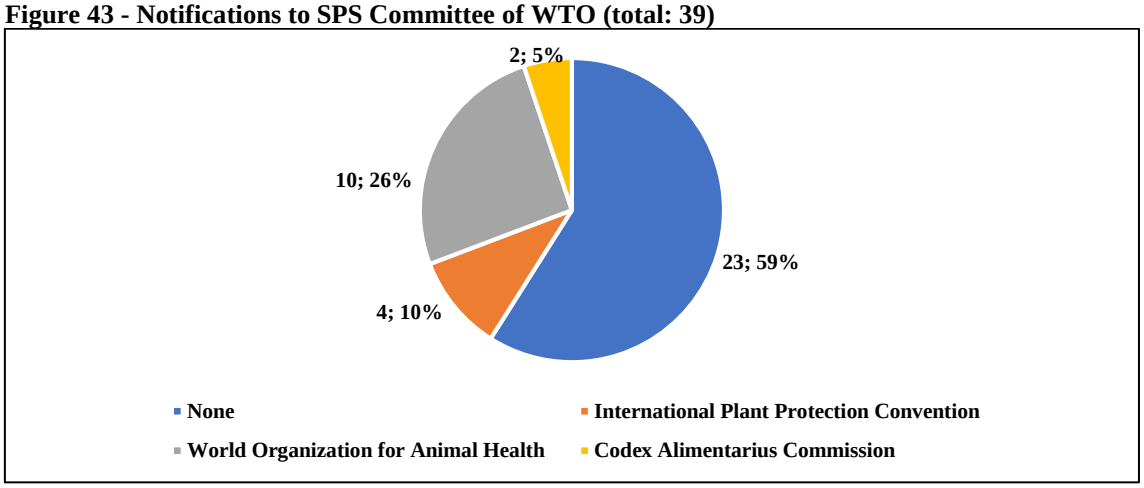
[43] *BRASIL. Ministério da Saúde Agência Nacional de Vigilância Sanitária Diretoria Colegiada Resolução-RDC nº 61, de 19 de Março de 2004. Available at: <http://www.codigoslex.com.br/doc_360114_RESOLUCAO_N_61_DE_19_DE_MARCO_DE_2004.aspx>.Acessed on: May 15th, 2017.*

(vii) Good Practices: There is also the requirement of a certificate of good practices, provided in the RDC n°39/2013, n° RDC 15/2014, RDC n°56/2014 and Ordinance n° 4/2008, attesting that a particular establishment complies with Good Distribution and Storage Practices or Good Storage Practices.

(viii) Labeling: The Ordinance n° 510/99 of the Ministry of Health, the RDC n° 92/00, RDC n° 168/02, RDC n° 137/03, RDC n° 47/09, RDC n° 60/2012, RDC n° 71/09, RDC n° 61/2012, Ordinance n° 572/02 and n°230/04 of the Ministry of Health provides regulation concerning the labeling of medicines and the content of the package inserts.

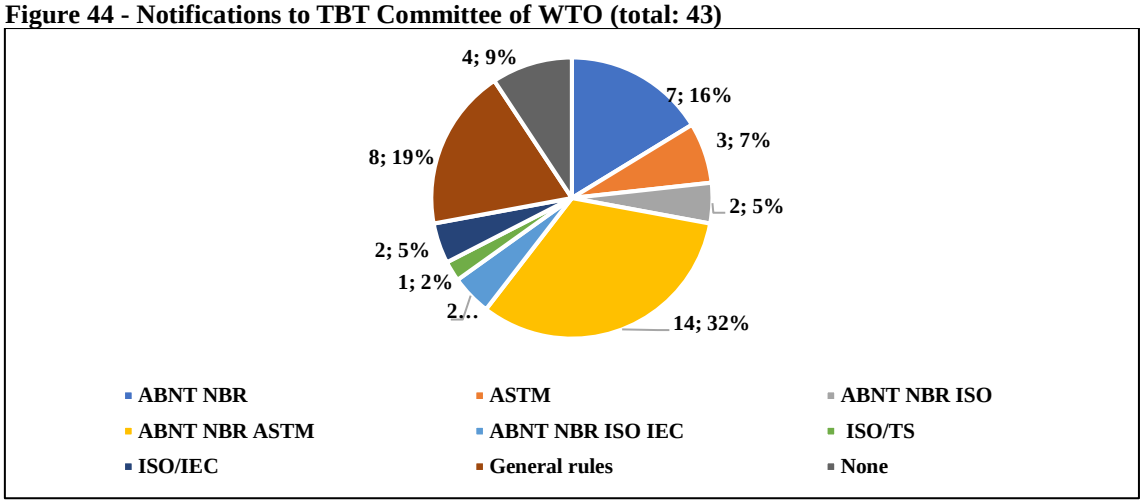
The following figure shows picture general framework of the international standards adopted by the Brazilian technical regulation on chemical sector. To the SPS Committee, Brazil notified 39 times; to the TBT Committee, another 43 times diverse regulations on chemical sector.

Figure 43 - Notifications to SPS Committee of WTO (total: 39)



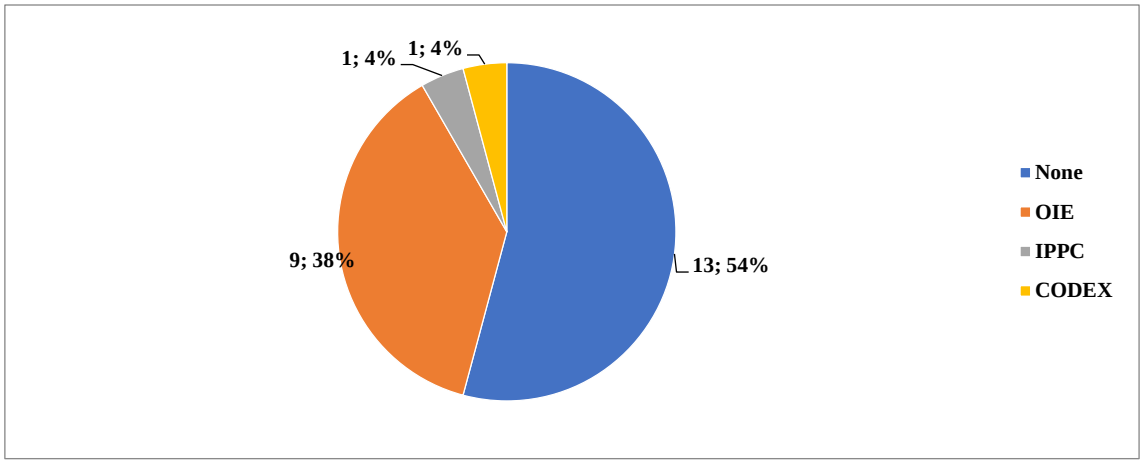
Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

Figure 44 - Notifications to TBT Committee of WTO (total: 43)



Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

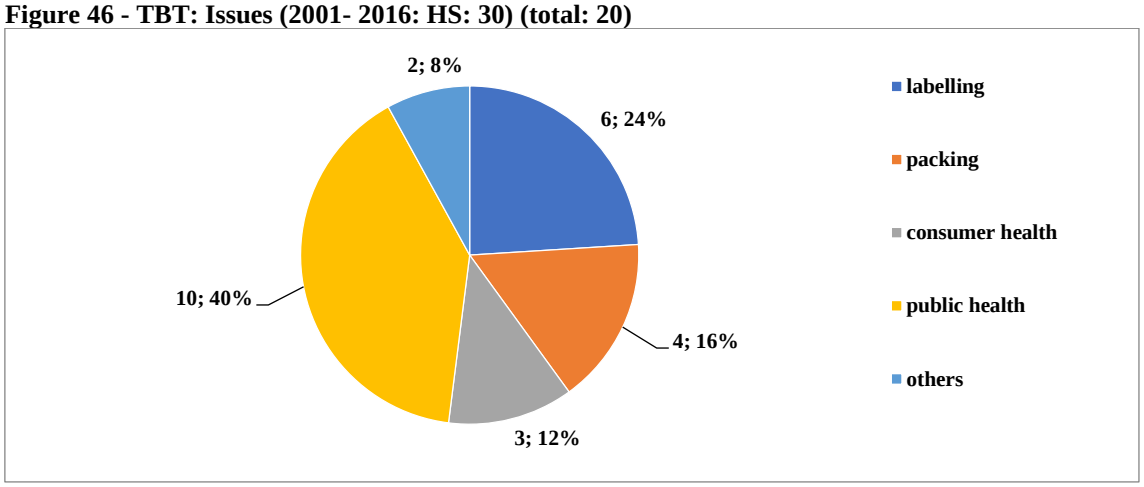
Figure 45 - SPS: Issues (2001- 2016: HS: 30) (total: 23)



Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

The most frequent issue in the notifications to the TBT Committee is the protection of the environment. Other important topics are consumer protection, labels with nutritional information and human health. No international standardization organization is explicitly mentioned in the notifications.

Figure 46 - TBT: Issues (2001- 2016: HS: 30) (total: 20)



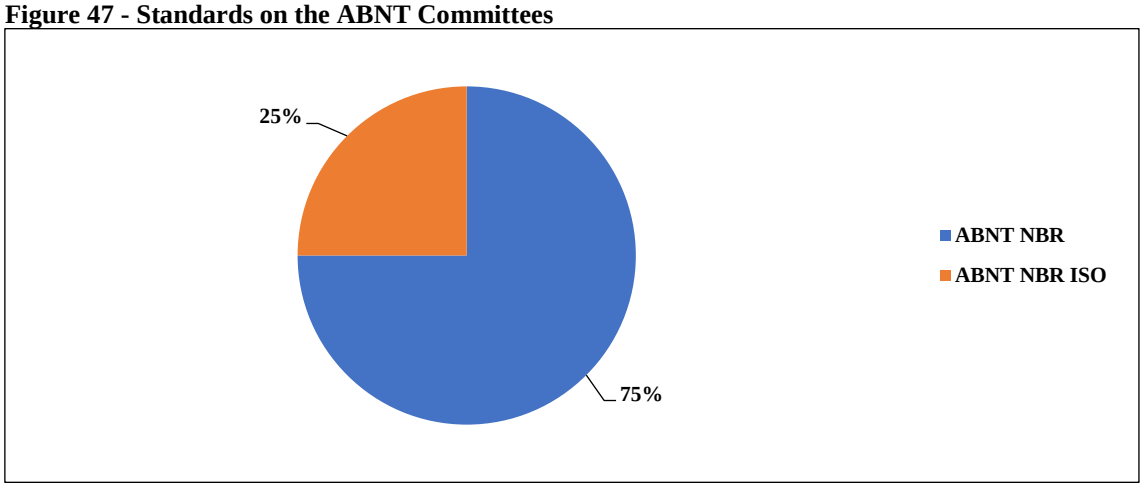
Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

6.1.3. Mapping Technical Standards

Brazil adopts some standards concerning pharmaceutical products. ABNT is liable for the creation of Brazilian Standards. Prepared by its Committees, there are only 4 standards related to medicines or pharmaceutical products at ABNT (see Annex VII). The standards can be found in the waste from health services committee, medical-hospital committee and safety in articles for babies and children committee. The following table shows the ABNT standards.

The only ABNT standard which follows ISO is the ABNT NBR ISO 14708-4:2016, located in the Medical-Hospital Committee representing 25 per cent of all the standards found in the present analysis. The other 75 per cent of the standards follows the ABNT NBR, manufactured by the own ABNT. The following graphic illustrates the percentage of each type of standard.

Figure 47 - Standards on the ABNT Committees



Source: ABNT. Prepared by CCGI-EESP/FGV.

6.1.4. Mandatory conformity assessment procedures

The Brazilian Health Surveillance Agency (ANVISA) is linked to the Ministry of Health and it is responsible for approving products and services subject to sanitary surveillance for both industry and commerce. The RDC 60/2014 provides the criteria for grant renewal of registration of drugs with active principles Synthetic and semi-synthetic, classified as new, generic and similar, and gives other measures[44].

The **company registration** is the first stage to have access to ANVISA services. In this context, companies that provide products or services that may be regulated, supervised or sanitary inspected by ANVISA and/or by the State and Municipal Visas must register with ANVISA.

For this the company should access the www.anvisa.gov.br <Regulated Sector <Company Registration <Registration System <Access the System. Fill out and click on "Register New Company".

In addition to allowing the registration of the company, the System of Registration of Companies also requests the registration of users linked to the company, who will be responsible for access to other ANVISA systems. These users can be registered in the following profiles: legal responsible, technical responsible, legal representative and security manager.

Next, the Authorization of Operation of the Company (***Autorização de Funcionamento da Empresa*** **- AFE**) is the act of competence of ANVISA that allows the operation of companies or establishments, by complying with the technical and administrative requirements contained in the RDC No. 16/2014.

The AFE is required of companies that carry out activities of storage, distribution, packaging, shipping, export, extraction, manufacture, fractionation, import, production,

[44] BRASIL. Ministério da Saúde Agência Nacional de Vigilância Sanitária Diretoria Colegiada Resolução-RDC nº 60, de 10 de outubro de 2014. Available at: <http://www.poderesaude.com.br/novosite/images/publicacoes_13.10.2014-III.pdf>. Accessed on: May 15th,2017.

purification, repackaging, synthesis, transformation and transportation of medicines and pharmaceutical products for human use, products for health, cosmetics, personal hygiene products, perfumes, sanitizers and filling of medicinal gases.

The interested company through the Petitioning System must make the AFE request. In addition, the **Certificate of Good Manufacturing Practices** (*Certificado de Boas Práticas de Fabricação* - CBPF), the document issued by ANVISA certifying that the establishment complies with Good Manufacturing Practices is also required. CBPF is issued per plant, covering the production lines, pharmaceutical forms and special classes of drug products for which the company has been inspected.

The **authorization** is granted exclusively by the health department of the state or local government to authorize establishments carrying out any business activities subject to sanitary surveillance to operate. It must be issued to each establishment separately (an independent, specific authorization). If the establishment aims to manufacture, industrialize or import products subject to sanitary laws, it must operate under the assistance and responsibility of a technician (this is the why companies must keep in their business a sufficient number of technically responsible professionals with proper skills, so that all different activities are covered.

Then comes the **drug registration**, which is the act by means of which ANVISA authorizes the commercialization of the product, through evaluation of the legal-administrative and technical-scientific compliance related to the efficacy, safety and quality of the products. The registration, or market approval, issued by ANVISA is the effective authorization for the manufacturing and marketing of a drug in Brazil.

The application for drug registration must be individualized by pharmaceutical form. If the drug is imported and labeled in Brazil, both CBPFs issued by the manufacturer and the local labeling site must be submitted.

The activity of drug registration is the responsibility of the Board of Authorization and Registration Sanitary (*Diretoria de Autorização e Registro Sanitários* - Diare) of Anvisa. Moreover, within Diare, it is the responsibility of the General Management of Medicines and Biological Products (*Gerência-Geral de Medicamentos e Produtos Biológicos* - GGMED) to coordinate activities and propose the granting or rejection of registration, renewal and post-registration of medicines, among other matters.

6.2. Pharmaceuticals (Argentina)

6.2.1. Overview

Pharmaceutical products are among the most important goods of the chemical industry, as it has to ensure the highest possible level of public health and patient confidence in safe, effective and high-quality health.

Also, pharmaceuticals are the 8th most exported and imported global product. In pharmaceuticals import export business, six types of products are included and come under following HS code – 3004, 3002, 3006, 3005, 3003 and 3001. The product under HS code 3004 (Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses) are the most exported and imported pharmaceutical products. Besides,

Packaged Medicaments are the 399th most complex product according to the Product Complexity Index (PCI).[45]

In Argentina, the pharmaceutical industry is strongly dependent on import of basic chemicals. More complex pharmaceutical products are usually imported by the country.

6.1.3. Mapping Technical Regulation (see Annex VII)

In Argentina, in 1964, through the enactment of Law No. 16.463, the National Institute for the Regulation of Drugs was created, later the National Institute of Pharmacology and Bromatology (*Instituto Nacional de Farmacología y Bromatología* - INFyB), and later the National Institute of Drugs (*Instituto Nacional de Medicamentos* - INAME).

And in 1992, the National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* - ANMAT) was created by Decree No. 1.490/92, incorporating the INAME into its structure.

The main objectives of the ANMAT are the registration, inspection, control and monitoring of medicines, food and medical technology material whose purpose is to guarantee the population the efficacy, safety and quality of the products.

The INAME is a National Control Laboratory for quality control testing of medicines. Samples are collected by government inspectors for undertaking post-marketing surveillance testing.

Having a nationwide jurisdiction, ANMAT was created to fulfill the process of registration, authorization, standardization, vigilance and monitoring of the products used in the human medicine, food and cosmetic fields. Granted with an economic and financial autarky, in the technical and scientific field it is under the authority of the Ministry of Health.

Likewise, the National System of Pharmacovigilance was created in 1993 by the Ministry of Health and Social Action, through the Resolution No. 706/93. Its functions are collecting, assessing and organizing the information on adverse reactions to drugs after authorization and commercialization. For the functioning of this entity, a Central Enforcer was established in ANMAT headquarters, and Peripheral Enforcers, institutions with relevant experience such as hospitals or university departments, were added later.

Peripheral Enforcers are private and public institutions, of recognized academic or clinic experience. Some of them are the provincial health ministries, professional societies, public and private hospitals, universities and social security organizations.

With the objective of strengthening ANMAT's institutional capacity, as well as fostering coordination with other health authorities, Memoranda of Cooperation and Confidentiality Agreements have been signed with international organizations and strategic foreign regulatory authorities to facilitate regulatory decision-making, such as:

[45] The PCI is the measure of the relative knowledge intensity of a product by considering the knowledge intensity of its exporters (see https://atlas.media.mit.edu/en/rankings/product/hs07/?year_range=2011-2015)

- ANVISA and ANMAT Technical and scientific cooperation in Health Technology Assessment (2005)
- ANVISA and ANMAT Exchange of inspection reports (2006)
- ANVISA and ANMAT Cooperation in pharmacopoeia (2007)
- ANVISA and ANMAT Joint work on reference substances (2009)
- ANVISA and ANMAT - Joint work on reference substances (2009)

And here you will find ANMAT latest regulations published in the Argentine Official Gazette: http://www.anmat.gov.ar/boletin_anmat/BOindex.asp.

Also, under the scope of the National Ministry of Health, the Superintendence of Health Services (*Superintendencia de Servicios de Salud* - SSS) has monitoring, control and enforcement capacities over insurers of the National Health Insurance System.

And the Secretariat for Programming Drug Abuse Prevention and the Fight against Drug Trafficking (*Secretaría de Programación para la Prevención de la Drogadicción y la Lucha contra el Narcotráfico* -SEDRONAR), is the national agency acting on behalf of the Executive Branch that controls all operations with certain chemical substances capable of being used in the illicit manufacture of narcotic drugs and psychotropic substances.

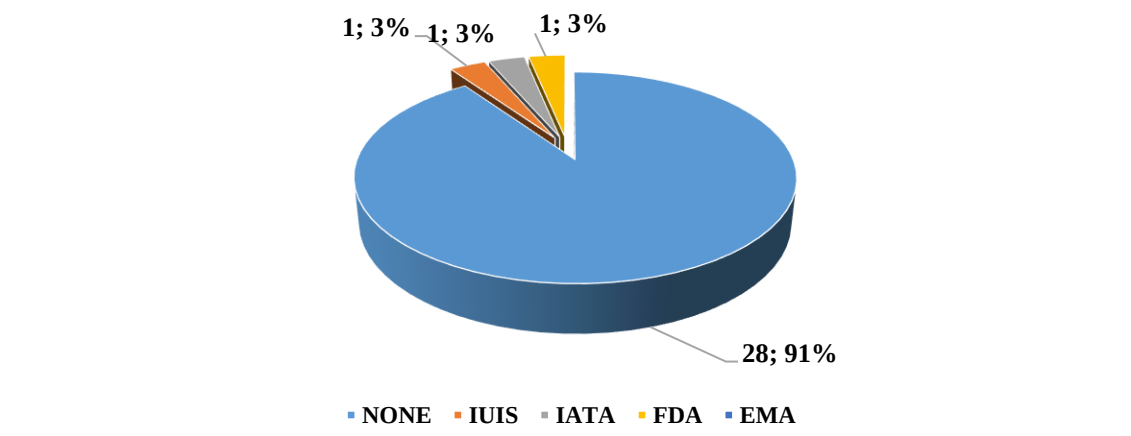
In Argentina, legal provisions require registration and marketing authorization for all pharmaceutical products on the market. The list of registered pharmaceutical products is publicly available regularly by ANMAT.

The main pharmaceutical products regulation in Argentina is the Law 16.463/64, supplemented by Decrees 9.763/64.

Law 16.463 and Decree 9.763/64 regulate all matters related to the import, export, manufacturing, fractionation, commercialization or storage in Argentine jurisdiction or intended to interprovincial commerce, of drugs, chemical products, reagents, dosage forms, medicines, diagnostic elements, and any other product to be used and applied to human medicine, as well as the physical or legal persons participating in such activities.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT on the pharmaceutical sector.

Figure 48 - Standards in the technical regulation notified to WTO/TBT



Source: WTO. Elaborated by CCGI-EESP/FGV.

So although all standards produced by IRAM which are voluntary, technical regulations notified to WTO/TBT seem to not follow them or any other international standards.

6.1.3. Mapping Technical Standards

In Argentina, considering that the standards are voluntary, the buyer and seller share responsibility in determining what product standard is applicable. For the pharmaceutical sector, all the standards identified in IRAM catalogue are homegrown standards. (see Annex VII, for the full list).

6.1.4. Mandatory conformity assessment procedures

Entities that engage in certification for regulated products must be accredited by the Argentine Accreditation Organization (*Organismo Argentino de Acreditación*, OAA) and recognized by the Argentine Government. Testing laboratories must similarly be accredited and recognized.

The OAA is a non-profit Civil Entity, created within the framework of the National System of Standards, Quality and Certification, to develop the functions established in accordance with the provisions of Decree No. 1474 of the National Executive of August 23, 1994, Resolution No. 90 of the Ministry of Economy and Public Works and Services of September 26, 1995, Resolution No. 330 of the Ministry of Industry, Commerce and Mining of May 19, 1999, Decree No. 73 of the National Executive Power of January 13, 2003, the Statute of the Organization and the principles described in its Policy Manual.

The OAA in the status of sole accreditation body is responsible for: testing laboratories; calibration laboratories; clinical laboratories; fitness test providers.

(OECD), OAA is responsible for:

- Monitor Good Laboratory Practices applicable to non-clinical studies in Pesticides and Biocides and industrial chemical products for registration or marketing authorization purposes under the Mutual Data Acceptance Agreement (MAD).
- All other monitoring of the compliance of Good Laboratory Practices (GLP) that is required.

7. COSMETICS

7.1. Cosmetics (Brazil)

7.1.1. Overview

The cosmetics industry in Brazil is economically very important. Brazil is a major consumer and producer of this type of product. The technical regulation of this sector is almost entirely harmonized within Mercosul.

Cosmetics items are enclosed on Chapters 33 and 34 of the Harmonized System. From 1996 to 2015, the liquid superavit in the sector increased an average of 11,4% (deflated) per year in the last two decades, reaching U$ 13,0 billion in 2015 (ABIHPEC, 2016). According to Euromonitor, Brazil is the fourth biggest consumer of PHPC products in the world (Euromonitor, 2016).

7.1.2. Mapping Technical Regulation

Law 6.360/76 regulates the PHPC sector. Apart from the law and two decrees that regulate it, there are several ANVISA resolutions and ordinances, INMETRO resolutions and MERCOSUL resolutions (see Annex 3).

The law regulates the parameters for sanitary surveillance to medicine and the requirements for the products to be sold in the Brazilian market. Article 3 of Law 6.360/76 presents the concepts of perfumery, cosmetics and hygiene products, raw materials, labelling, packaging, batch or lot of a product and establishes their registry number and product quality control.

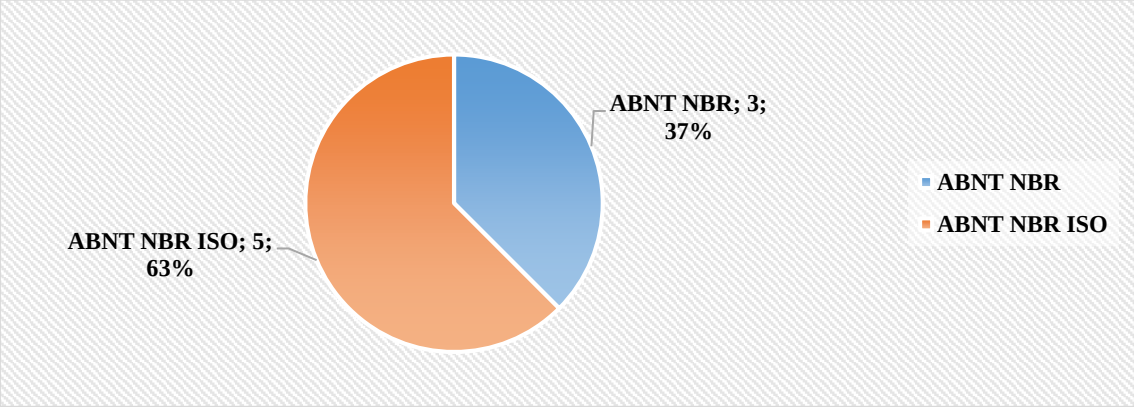
As PHPC are intended to be used externally or through topic application, these products do not need to go through the same drugs and medicine quality procedures, restrictions and surveillance requirements. Regardless of this fact, PHPC products must all be authorized and registered by National Sanitary Surveillance Agency (ANVISA). Article 26 determines which products can be registered as PHPC, while article 27 determines that PHPC must only be composed of innocuous substances, as determined and allowed by ANVISA.

Currently Law 6.360/76 is regulated by Decree 8.077/13. The Decree regulates the conditions for the operation of companies subject to sanitary licensing, and the registration, control and monitoring, within the scope of health surveillance, of all the products referred to in Law nº. 6.360, including PHPC products. It determines the registry, control and monitoring requirements at ANVISA and stipulates that for products that will not harm or risk harming human health, the registry can be simplified and pre-regulated by the agency.

7.1.3. Mapping Technical Standards

There are a few standards on cosmetics and similar products issued by ABNT. Moreover, ABNT has based its standards for detection of microorganisms on ISO standards (see Annex 3).

Figure 49 - ABNT Standards on Personal Hygiene, Perfumery and Cosmetics based on ISO



Source: ABNT. Prepared by CCGI-EESP/ FGV (May 2017).

7.1.4. Mandatory conformity assessment procedures

The registration by ANVISA creates a presumption that the product is adequate to be commercialized domestically. The product has to meet the criteria set forth in laws and the specific rules established by health surveillance authorities. Such rules aim to minimize potential risks associated with the product. The Resolution ANVISA, RDC n. 07/2015 establishes technical requirements for the regularization of toiletries, cosmetics and perfumes.

The registration shall comply with the following steps: i) registry of the user or the company registration, ii) petition or identification of the code of subject related to the petition, iii) taxes including a payment bill (GRU) for the payment of the supervision fee of sanitary surveillance (TFVS) related to the subject chosen, iv) the protocol with all the documentation required by the sanitary authority.

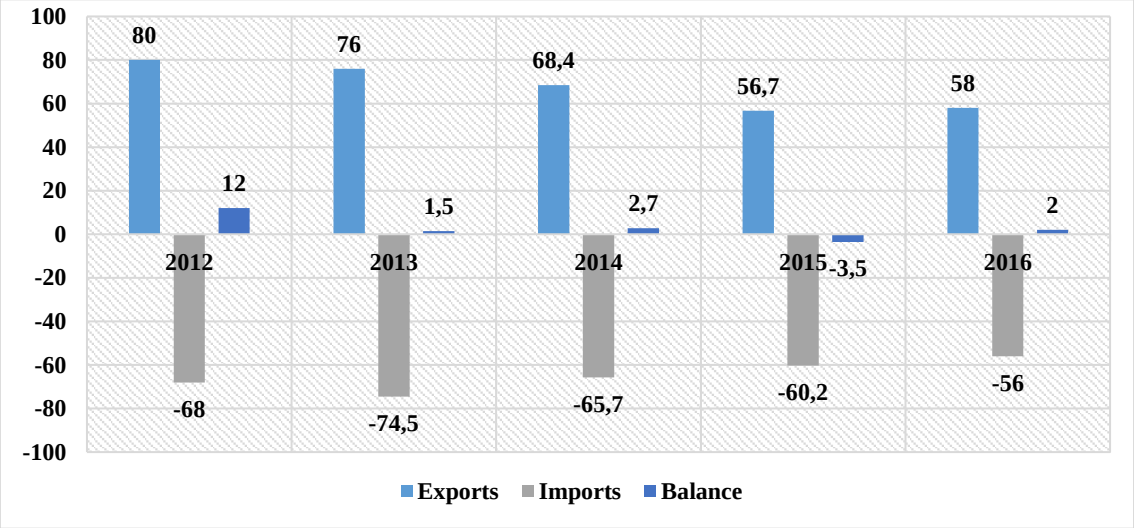
ANVISA shall publish the results in Brazil's Official Gazette (DOU), which serves as proof to the applicant of the given registry. After that, the product has clearance to be commercialized throughout the country for five years, when it expires. This procedure is receiving some criticism because, allegedly, it can have an impact on shipping costs as well as a time-consuming activity because of several deadlines set forth in order to register a given PHPC good.

7.2. Cosmetics (Argentina)

7.2.1. Overview

The foreign trade in Argentina is relatively balanced. Over the last five years, trade surpluses have predominated in Argentina, mainly due to the export of agricultural goods. However, Argentina is heavily deficient in the trade of electrical materials and equipment.

Figure 50 - Argentine Trade Balance

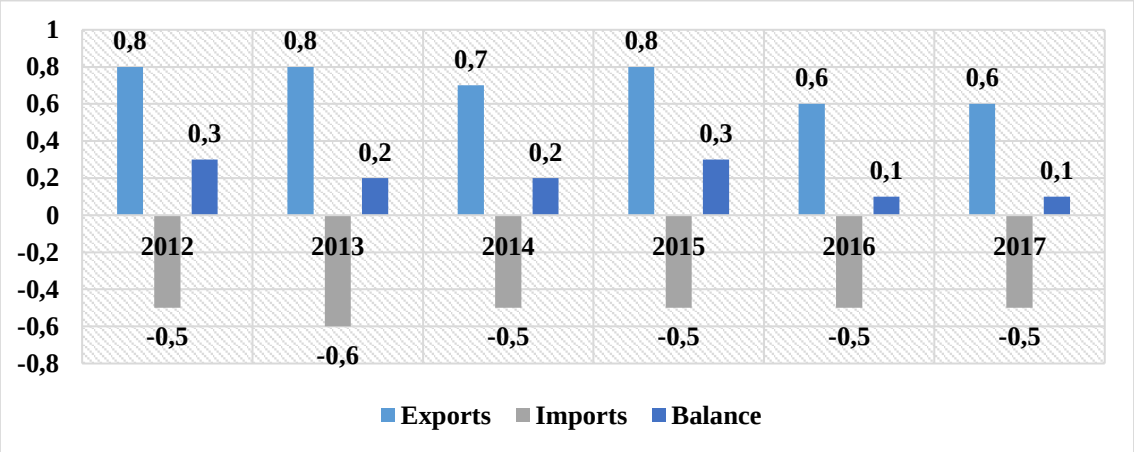


Source: INDEC. Elaborated by CGTI-EESP/FGV.

The analysis of the history of Argentinean industrialization can provide a useful explanation for the main characteristics of the sector of chemical products in Argentina. Although important, the chemicals sector presents structural problems stemming from the incomplete industrialization of the country. Thus, the basic chemical goods industry is underdeveloped and dependent in Argentina. The downstream sectors, therefore, are heavily dependent on imports of basic chemicals, since these are inputs for the production of medicines, cosmetics and other fine chemical by-products.

As the basic chemicals sector weighs heavily on the trade balance, this deficiency of the Argentine chemical industry generates constant deficits in the country's external accounts, as verified in the general figures of the international flow of chemical goods in Argentina.

Figure 51 - Chemical Products Trade Flow

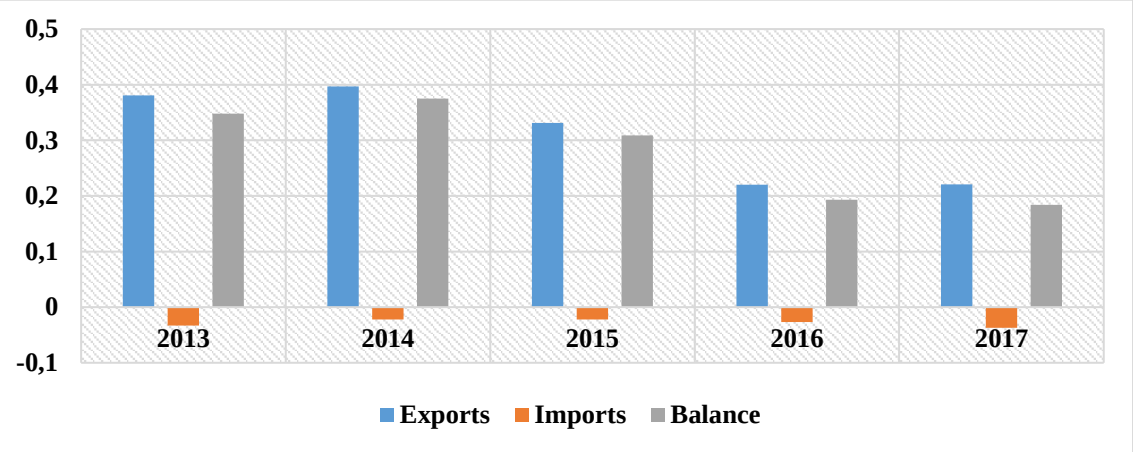


Source: INDEC. Elaborated by CGTI-EESP/FGV.

In the last five years, Argentina has had deficits in the trade balance regarding chemicals. While exports declined progressively in this period, imports alternated between periods of increase and decrease. The outcome of this dynamic was a constant trade deficit in the sector.

Analyzing the subsector of cosmetics, the trade balance reveals a surplus on the last five years. The exports fell from 2015 to 2016 and remained stable in 2017. The imports, on the same sense, experienced a steady fall from 2015 to 2017. These variations, thus, led to a fall on the balance of the subsector.

Figure 52 - Cosmetics Trade Flow



Source: INDEC. Elaborated by CGTI-EESP/FGV.

7.2.2. Mapping Technical Regulations

The main Argentine regulator cosmetic sector is the National Administration of Medicines, Food and Medical Technology (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* - ANMAT) was created by Decree No. 1.490/92, incorporating the INAME into its structure.

The main objectives of the ANMAT are the registration, inspection, control and monitoring of medicines, food and medical technology material whose purpose is to guarantee the population the efficacy, safety and quality of the products.

The INAME is a National Control Laboratory for quality control testing of medicines. Samples are collected by government inspectors for undertaking post-marketing surveillance testing.

Having a nationwide jurisdiction, ANMAT was created to fulfill the process of registration, authorization, standardization, vigilance and monitoring of the products used in the human medicine, food and cosmetic fields. Granted with an economic and financial autarky, in the technical and scientific field it is under the authority of the Ministry of Health.

In Argentina, each province has its own health authority that works on a par with ANMAT and is competent to pass legislation.

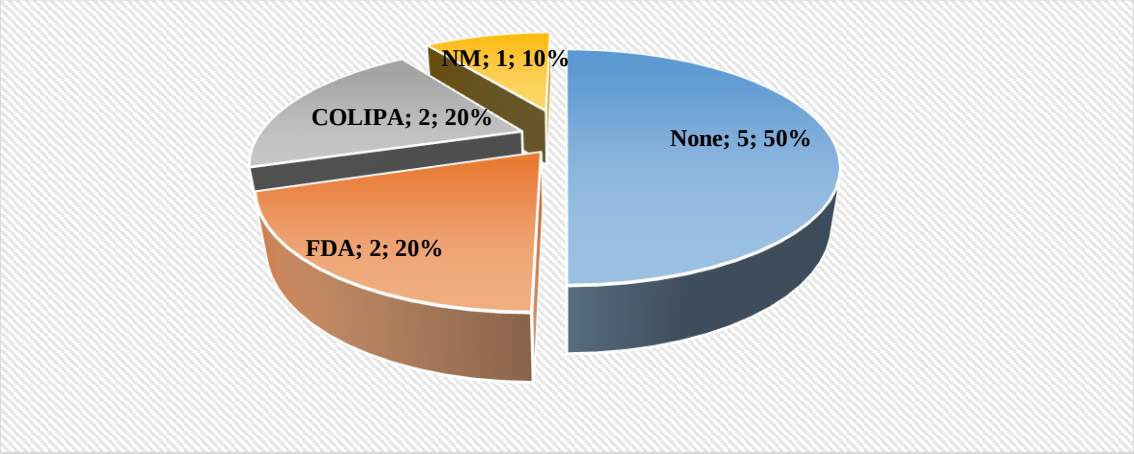
In this framework, ANMAT's principal areas of responsibility include:

- Registration of medicines, medical technology, food and cosmetic product before their manufacturing, import, distribution and commercialization.
- Authorization, control, supervision and inspection of the manufacturing, production, fractioning, packaging, distribution, commercialization, import and export of medicines, medical technology, food and cosmetic products.

- Control, supervision, inspection and authorization of all clinical trials performed in Argentina.
- Authorization, control, supervision and inspection of manufacturing and commercialization of household cleaning products.

The following figure gives the overview of the international standards adopted by the Argentine technical regulation notified to WTO/TBT Committee on the cosmetic sector.

Figure 53 - Standards in the technical regulation notified to WTO/TBT



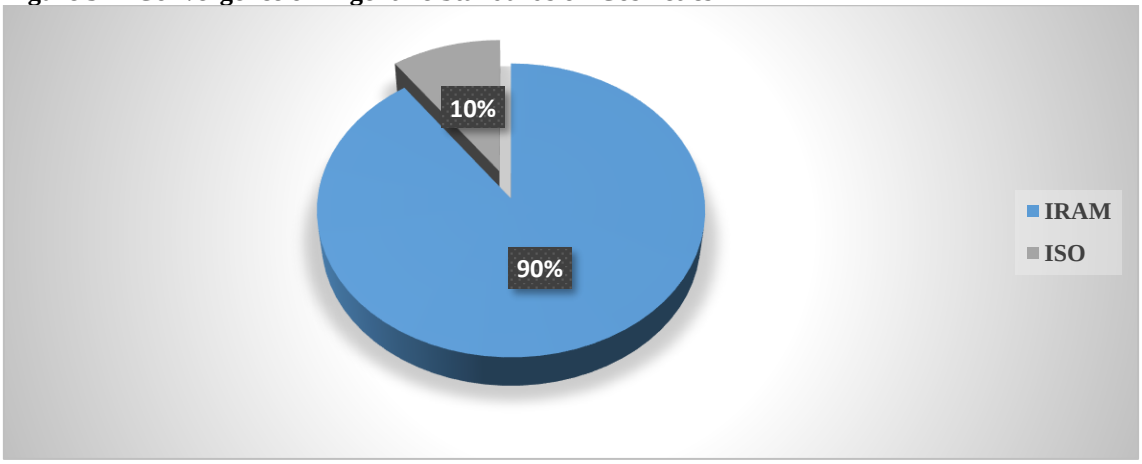
Source: WTO. Elaborated by CGTI-EESP/FGV .

So although all standards produced by IRAM which are voluntary, technical regulations notified to WTO/TBT Committee do not seem to follow them or any other international standards. The Annex 3 contains the full list of regulation.

7.2.3. Mapping Technical Standards

The main standardization body in Argentina is IRAM, a non-profit institution that brings together specialists in standardization from various sectors of the country's economy. IRAM is a body that represents Argentina within the scope of the International Standardization Organization (ISO), Pan-American Commission of Standards (*Comisión Panamericana de Normas Técnicas*, COPANT) and the Mercosul Association of Standardization (*Asociación Mercosul de Normalización*, AMN).

Figure 54 - Convergence of Argentine Standards on Cosmetics



Source: IRAM. Elaborated by CGTI-EESP/FGV.

Product 5: Final document consolidating the results, information and analysis obtained in previous steps; policy indications

Most of the IRAM standards on cosmetics can be considered homegrown standards (see Annex 3). Of the ten standards identified, only one is derived from an ISO standard, which makes up 10% of the total standards on the subject. It should be noted, however, that IRAM is an important participant in the international standardization bodies, which indicates a coherence between the Argentine standardization policy and international standardization practices.

7.2.4. Mandatory conformity assessment procedures

Like most chemicals, cosmetic conformity assessment procedures are more related to the registration process of these products. The registration of this type of product is necessary for its commercialization in the Argentine market. The registration is usually by public agency and has a predefined term of duration.

For example, Disposition 2723/97 provides firstly the obligation of the previous registry on ANMAT by the firms of cosmetic products. The corresponding authorization of importation is also required. In order to fulfill this need, the form "Authorization for the importation of medicines, cosmetics, reagents of diagnosis of use in vitro and/or disposable material, apparatus and equipment of medical and dental use". When necessary, ANMAT can require the aggregation of the documents of origin to the authorization of importation.

More details on registry and other mandatory procedures can be seen in Annex 3 of this document.

8. PROCESSED FOOD

8.1. Processed food (Brazil)

8.1.1. Overview

According to data from the Eurostat website[46], the three largest industrial activities in terms of value added in the G20 were food and beverages, chemicals and vehicles, which, according to Eurostat, Brazil, like Australia, revealed that the 'food and beverage' industries represent around one fifth of the manufacturing sector.

Eurostat data also indicate that between 2010 and 2015, for the EU-28's the highest growth rate for food, beverages and tobacco exports was recorded, an increase of 49.5% over the previous period. In the same period, imports of these same products also increased sharply, 33.8%, according to the same source.[47]

According to records from the European Commission website[48], the food and beverage industry is the largest industrial sector in the EU in terms of employment and value added (in the last 10 years, EU food and drink exports have doubled, reaching of 90 billion euros (which contributed to a positive balance of almost 30 billion euros).

Its representativeness in the global export market, however, still according to the European Commission, has declined in the last ten years, to the detriment, above all, of Brazil and China.[49]

According to the Brazilian Food Processors' Association (ABIA), in 2016, the Brazilian food processing industry generated a nominal revenue of R$ 614.3 billion, increasing 9.3% compared to 2015. Brazil relies on a well-developed food processing industry, with around 45,000 food companies established throughout the country. In addition to domestic enterprises there are major European multinational companies such as Nestle, Unilever, Bunge, Danone, Heineken operating in Brazil.

8.1.2. Mapping Technical Regulation

Food regulations issued at the Brazilian federal level are contained in various types of legal documents (Laws, Decrees, Executive Orders, Directives, Circulars, Resolutions) and to become official, or in order to be implemented, must be published in Brazil's Diario Oficial (see Annex VI).

In this report the following hierarchy of Brazilian federal norms was taken into account: 1st, Federal Constitution (Magna Carta); 2º, Laws and Decrees-Law established by the Federal Legislative Power (National Congress); 3rd, Decrees, regulations of laws from the President of the Republic; and 4th, Resolutions and Normative Instructions from Regulatory Agencies and Ordinances by federal executive bodies, normative and administrative acts as a complement to higher hierarchical level norms.

[46] http://ec.europa.eu/eurostat/statistics-explained/index.php?title=The_EU_in_the_world_-_industry,_trade_and_services&oldid=170829
[47] http://ec.europa.eu/eurostat/statistics-explained/index.php/International_trade_in_goods
[48] http://ec.europa.eu//growth/sectors/food
[49] https://ec.europa.eu/growth/sectors/food/processed-agricultural-products/trade-overview_en

In terms of sanitary surveillance in Brazil, 1950 was the historical landmark, and still in force, when was enacted Law No. 1283 establishing the obligation of prior inspection of all products of animal origin, from an industrial and sanitary point of view. Despite of its 67 years, the Law No. 1283 was modified only once, by Law No. 7889, in 1989.

In turn, Decree No. 9013/2017 (known as New RIISPOA), that has the objective of establishing the set of regulations concerning the development of the industry and trade in products of animal origin, in accordance with the provisions of Law No. 1283/1950, includes the implementation of new technologies, standardization of technical and administrative procedures and harmonization with international legislation. It is compatible with the Brazilian Consumer Protection Code and the decree establishing the Unified Agricultural Health Care System (SUASA).

Another precursor regulation in Brazil was Decree-Law No. 986/1969, which establishes basic food technical regulation, including dispositions related to the labeling and use of additives.

In 1973, The National System of Metrology, Standardization and Industrial Quality was established by Law No. 5966 with the purpose of formulating and executing the national policy of metrology, industrial standardization and quality certification of industrial products.

Another important fact was the creation in 1999 of Anvisa (by Law No. 9782), which enforces most of the regulations regarding processed food products, and it has similar functions in regulating food as does the Food and Drug Administration (FDA) in the United States.

In Brazil, Anvisa is fundamental to guarantee the control and the inspection of products and services that involve risk to public health.

Therefore, Anvisa, SDA and Inmetro form, undisputedly, the sanitary and technical regulation tripod in Brazil in the food and beverage sector.
Besides, it should be remembered that Law No. 8171/1991 was the first Brazilian regulation on agricultural policy.

In 2006, Law No. 11346, known as the Organic Law on Food and Nutrition Security (LOSAN), set up the National System of Food and Nutrition Security (SISAN) and established definitions, principles, guidelines and objectives of the System. Through SISAN, public power with the participation of organized civil society must formulate and implement policies, plans, programs and actions with a view to ensure the human right to adequate food.

It is relevant to mention yet the Law No. 11105/2005 concerning the safety regulations and inspection mechanisms for activities that involve Genetically Modified Organisms (GMOs) and their by-products, establishes the National Biosafety Council (CNBS), re-structures the National Biosafety Technical Commission (CTNBio), defines the National Biosafety Policy. This Law provides safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, import, export, storage, research, marketing, environmental release and discharge of GMOs and their by-

products, guided by the objective of attaining scientific development in the biosafety and biotechnology areas, the protection of human, animal and plant health and life.

8.1.3. Mapping Technical Standards

Within ABNT, there are several committees that develop technical standards on food (see Annex VI). Some of these standards are the reproduction, in Portuguese, of ISO standards. In the food macro-sector, the following committees stand out: ABNT / CB-012 - Brazilian Committee of Agriculture and Livestock; ABNT / CB-013 - Brazilian Beverage Committee; ABNT / CB-030 - Brazilian Committee on Food Technology; ABNT / CB-052 - Brazilian Coffee Committee; ABNT / CB-056 - Brazilian Meat and Milk Committee; ABNT / CEE-072 - Special Study Commission on Tobacco and Tobacco Products; ABNT / CEE-087 - Commission for the Special Study on Beekeeping; ABNT / CEE-095 - Commission for the Special Study of Greenhouses and Agricultural Nurseries; ABNT / CEE-104 - Special Committee on Food Safety; ABNT / CEE-143 - Commission for the Special Study on Non Genetically Modified Grains; ABNT / CEE-156 - Special Sugar Cane Study Commission; ABNT / CEE-157 - Special Committee on Food Microbiology; ABNT / CEE-160 - Special French Bread Study Committee; ABNT / CEE-171 - Special Study Commission on Agrochemicals and Allied Products; ABNT / CEE-174 - Special Study Commission on Sensory Analysis; ABNT / CEE-176 - Special Study Commission for *Carbaúba* Wax; ABNT / CEE-182 - Special Study Committee on Soil Fertilizers and Corrective; ABNT / CEE-192 - Special Aquaculture Study Commission; ABNT / CEE-211 - Special Study Commission on Nutritional Supplements and Foods for Special Purposes; ABNT / CEE-213 - Special Study Committee on Sugarcane Bagasse; ABNT / CEE-214 - Special Poultry Study Commission; ABNT / CEE-227 - Commission of Special Study on Meliponiculture; ABNT / CEE-228 - Special Committee on Animal Welfare.

8.1.4. Mandatory conformity assessment procedures

ANVISA is the public agency responsible for register any food product before its commercialization in the Brazilian market. The registration number issued by ANVISA has to be on the label of the product.

ANVISA does not provide business operation permit (*Autorização de Funcionamento de Empresas* - AFE) for food. For settlement of food establishments, it is necessary to obtain license or health permit at the local health surveillance organization. According to Decree-Law n. 986/1969, the establishments where foodstuffs are manufactured, prepared, processed, packaged, transported, sold or deposited must receive a license from the competent health authority, municipal, state or Federal District, upon the issuance of the respective sanitary permit.

The Good Manufacturing Practices (GMPs) include a set of measures that ensure the quality of processed food. Current Brazilian food good manufacturing practices (GMPs) are in Ordinance SVS/MS nº 326/1997 (based on the Codex Alimentarius). It describes the methods, equipment, facilities, and controls for producing processed food. GMPs also serve as a basis for ANVISA inspections. It is important to highlight that there are also other specific rules on GMPs.

The certification system is also a relevant issue addressed by the Codex Alimentarius. Certification is a procedure by which official certification bodies, or officially recognized certification bodies, ensure, in writing, or equivalently, that foods or food control systems are in conformity with established requirements. There are also alternative measures for certification, which include inspection system and the requirements for an exporting country be equivalent to the importing country; trade partners may also decide for a bilateral or multilateral agreement such as of a mutual recognition nature.

ANVISA can grant or cancel the Certificate of Good Manufacturing Practices (Certificado de Boas Práticas de Fabricação - CBPF) of a company as per Federal Law n. 9,782/1999, albeit such subject requires further regulation for its full implementation. However, ANVISA has already ruled that palm heart (palmito) industries established in other countries shall have a CBPF to export to Brazil.

Although law No. 9782/1999 establishes that the ANVISA can grant and cancel the Certificate of Good Manufacturing Practices (Certificado de Boas Práticas de Fabricação - CBPF), this subject is not yet regulated, except for the industries of palm heart (palmito) installed abroad, which must possess the CBPF to export to Brazil.

Imported products subject to health surveillance for trade, industry or direct consumption should have ANVISA's consent to be imported. The sanitary authority verifies whether foodstuff products are in conformity with ANVISA regulations, which includes, when applicable, obligation of notification, registration, exemption from registration, or any other form of control established in the law.

According to ANVISA, there are two categories of food products: (i) products with compulsory registration; and (ii) products exempt from registration. Importers, like domestic producers, of food products under the compulsory list must register their products and pay fees, which vary according to the size of the company. Importers or producers of food products exempted from registration have also to request their product's exemption from registration by presenting the required documents by law.

ANVISA can also grant the Product Registration, which recognizes that a foodstuff product is in conformity with sanitary legislation in force. It is a control done prior to marketing. Resolution ANVISA RDC n. 23/2000 establishes the basic procedures for the registration and exemption of registration.

The activity of food registration is the responsibility of the Board of Authorization and Sanitary Registration (Diretoria de Autorização e Registro Sanitários - Diare) of ANVISA. Moreover, within Diare, the General Management for Food Products (*Gerência-Geral de Alimentos* - GGALI) manages the regulation, registration, inspection and clearance of food products.

The following categories of foods have compulsory registration, as set forth in annex II of the RDC No. 27/2010:

- Novel foods and novel ingredients
- Foods with claims of functional properties and/or health
- Infant foods
- Food for enteral nutrition
- Packaging with new technologies (recycled)

- Bioactive substances and probiotics isolated with claims of functional properties and/or health

The categories of foodstuffs that are exempt from the register prior to commercialization, but must deliver the Manufacturing Startup Notice (*Comunicado de Início de Fabricação*) are listed in annex I to the RDC No. 27/2010.

The manufacturer or importer of the foodstuffs exempt from registration will fill out the form of Manufacturing Startup Notice according to RDC No. 23/2000.
Lastly, there are foodstuffs that are exempt from the register and exempt from the Manufacturing Startup Notice, for example, bakery, pastry, pastry, confectionery, confectionery, rotisserie and ice cream products, when exclusively destined for direct sale to the consumer, carried out at the counter of the producer itself.

The manufacturer or importer is the responsible for the quality and safety of registered products at Anvisa.

Besides Anvisa, the Ministry of Agriculture, Livestock, and Food Supply (MAPA) has the regulatory authority to enforce federal laws regarding the registration and labeling of beer, distilled spirits, wine, soft drinks and juices (except beverages for athletes, water, energy drinks).

The major regulation for alcoholic and beverage products, both domestic and imported, is Decree No. 6871/2009, which provides for the control, inspection, standardization, classification, establishment registration and product registration of beverages.

In the case of grape beverages, establishments, producers or bottlers of wine and beverages derived from grapes, must be registered at MAPA, according to Law No. 7678/1988 and its subsequent amendments.

The DIPOA communicates that from 18/01/2017 the registration of animal origin products will start to be conducted in a PGA, Agriculture and Cattle Raising Management Platform, system in module PGA/SIGSIF. This change will cover all the registrations of animal origin products, whether of a registered (SIF), listed (ER) or foreign (EE) establishment in compliance with the provisions of Decree No. 30.691/1952, amended by Decree No. 8.681/2016.

The new electronic system designed by the MAPA can only be used to register new labels. MAPA also is responsible for the regulatory inspection and registration of all planting seeds and seeding (including biotech seeds), as well as for agricultural products such as grains, fruits and vegetables.

8.2. Processed food (Argentina)

8.2.1. Overview

Argentina is the world's leading exporter of soy oil and soy meal, the third largest soybean exporter, and a top exporter of corn.

The food and beverage industry is one of the main activities contributing to the Argentine

economy, accounting for about 30 percent of Argentina's total exports. Some of its main trends are as follows: i) significant investments in technology updates; ii) local production capacity being fully used, which requires additional investments to supply the growing food demand; iii) "Health and Nutrition" considered a strong concept in the food and beverage business; and iv) Greater interaction between the local industry and universities, fostering innovations.

Together food, beverage and agriculture products account for half of exports. Motor vehicles account for 12% of exports. Machinery is the largest import item, accounting for 30% of all imports, followed by transportation goods (17%) and chemical products (16%).

Brazil is Argentina's main trading partner, accounting for 18% of all exports and 21% of all imports. China and the European Union are also important trading partners. By contrast, Argentina trades relatively little with other Latin American countries, beyond Brazil. And barriers to entrepreneurship are high and regulatory procedures are complex (OECD Economic Surveys: Argentina 2017).

8.2.2. Mapping Technical Regulation and Authorities

The Argentine Food Code (*Código Alimentario Argentino – CAA*)[50] was created by Law 18284/1969 and regulated by Decree 2126/1971. The Code regulates locally produced and imported food products. The main Government of Argentina of CAA is to protect public health and the good faith in commercial transactions of foodstuffs within the national territory of Argentina.

The CAA incorporates rules agreed upon within the Southern Cone Common Market (Mercosul) framework, which in turn are influenced by standards from: 1) Codex Alimentarius, 2) the European Food Safety Authority (EFSA), and 3) the U.S. Food and Drug Administration (FDA).

The CAA is constantly being updated by joint resolutions from the Ministry of Health and the Ministry of Agroindustry. View latest CAA Modifications in http://www.conal.gob.ar/CAA_ultimas_modificaciones.php

In Addition, Decree 815/1999 sets the basis for the creation of the National Food Inspection System (*Sistema Nacional de Control de los Alimentos* – SNCA). The SNCA guarantees the enforcement of CAA. Also, Decree 815/1999 established the creation of the National Food Commission (*Comisión Nacional de Alimentos* - CONAL), which is an advisory body that provides support and monitoring to SNCA. The members of SNCA and CONAL belong to the Ministry of Health and the Ministry of Agroindustry.

There are four major government agencies that have the authority to enforce CAA regulation in Argentina (see Annex VI):

Within the Ministry of Agroindustry:

[50] http://www.alimentosargentinos.gob.ar/HomeAlimentos/Legislacion%20Alimentaria/codigo_alimentario_argentino.php

SENASA (*Servicio Nacional de Sanidad y Calidad Agroalimentaria*) - National Service of Agri-Food Health and Quality is responsible for executing the government's policy on animal and plant health and for ensuring compliance with the CAA for those food products that are under its exclusive competence listed in Annex I and II of Decree 815/1999 (including fresh, chilled, frozen, and thermo-processed products and by-products of animal, plant and seafood origin). It is also responsible for the control of imports and exports of products, by-products and derivatives of animal and vegetable origin, agri-food products, pharmaceuticals, agrochemicals and fertilizers.

INV (*Instituto Nacional de Vitivinicultura*) - National Wine Institute, which exerts control over wine and wine products during their production, manufacturing, and marketing stages.

Within the Ministry of Health:

ANMAT (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica*) - The National Administration of Drugs, Foods and Medical Devices is an agency decentralized from the National Public Administration that was created by decree 1490/92. It cooperates in the protection of human health by assuring the quality of the products it regulates: drugs, foodstuff, medicinal products, diagnosis reagents, cosmetic products, dietary supplements and household cleaning products.

INAL (*Instituto Nacional de Alimentos*) - National Food Institute, which is an agency under the ANMAT. It regulates consumer-ready food products, health supplements, and both alcoholic and non-alcoholic beverages, with the exception of wine. (Sometimes, SENASA and INAL have overlapping responsibilities).

The Argentine regulation on food covers three dimensions:

a) **Packaging and Container Regulations**. Overall, Argentina does not officially have any special packaging or container size requirements or preferences, with the exception of certain products such as salt. It is a marketing issue that the consumer determines what type or size of package/container. Although during the past few years the Government of the City of Buenos Aires has been working on creating awareness among the population on the importance of protecting the environment and getting involved in recycling waste, there are no official municipal waste disposal laws or product recycling regulations that affect imported food products in particular.

b) **Food Additives Regulations**. Argentina uses a positive list of food additives. Article 2 of Decree 2092/1991 states the following: "... all foods, condiments, beverages, or their raw material and food additives which are manufactured, fractioned, preserved, transported, sold, or exposed, must comply with CAA requirements. When one of those is imported, CAA requirements will be applied. The Government of Argentina also considers products from countries which have food controls comparable to those of Argentina, or when they use Codex Alimentarius (FAO/OMS) standards, to be in compliance with Argentina standards."

All additives used must be included in the Mercosul positive list of food additives. If the additive in question does not appear on that list, a presentation requesting its registration

for use must be submitted to CONAL. This list varies by product and can be obtained from an importer.

Also SENASA Resolution 256/2003 establishes the Maximum Residue Levels (MRLs) for products that are traded in the country. The mechanism to set them is as follows: a chemical company that applies for a pesticide to be released in the Argentine market must carry out a two-year study in three different agro-ecological areas of Argentina. The sampling method to be used in these cases must be one that is approved by FAO. Argentina uses the Acceptable Daily Intake suggested by *Codex Alimentarius* for the Latin American Region, as a reference. The required listed number is generally lower than the one suggested by Codex but higher than the one suggested by the EU. If SENASA is doubtful about the MRL established by the research, they use the Codex number.

c) **Agricultural Biotechnology**. Argentina continues to be the third largest producer of biotech crops, after the United States and Brazil, producing 14 percent of the world´s total biotech crops. Almost all soybean area is planted with biotech seed varieties, while 95 percent of corn area and 100 percent of cotton area are biotech varieties.

Argentina is one of the first countries with a regulatory framework with specific working regulation for products derived from Innovative Biotechnology or New Breeding Techniques (NBTs). This regulation is the outcome of a three-year debate which took into account the state of the art in NBTs and parallel discussions overseas. It is a product-by-product consideration of the genetic modifications in light of the concept of “novel combination of genetic material."

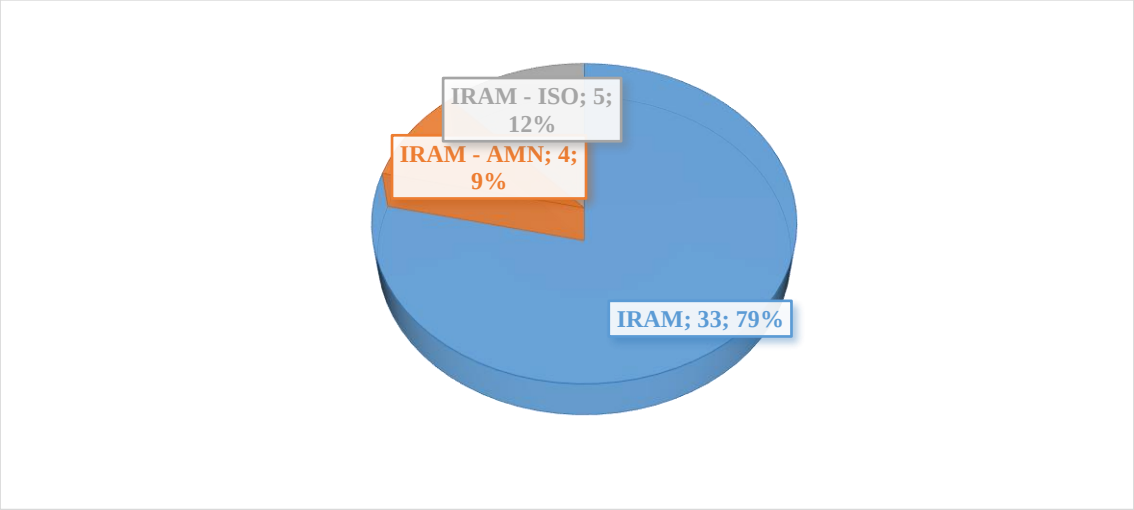
8.2.3. Mapping Technical Standards

A 1994 decree created the legal framework (Decree 1474/94) for standards-related activities in Argentina. There are two private sector organizations that work under the National System for Standards, Quality and Certification (IRAM and OAA).

The Argentine Standards Institute (*Instituto Argentino de Normalización* - **IRAM**) is the official national standards body for Argentina, created in 1935, it is the main developer of national voluntary standards in Argentina. Reliance on international standards as a basis for developing national standards continues to be a strong trend in Argentina. While many IRAM standards are compatible with U.S. standards and many others are patterned after requirements of various European countries.

IRAM has some standards for manufactured food sector (see Annex VI). Such sector, however, is not relevant for the standardization work of IRAM.

Figure 55 - IRAM Standards for the Food Sector



Source: IRAM. Elaborated by: CCGI-EESP/FGV

8.2.4. Mandatory conformity assessment procedures

On January 28, 2016, the Secretariat of Commerce in Argentina's Ministry of Production published Official Resolution 6/2016 to revoke the Label Supervision System that was established on October 14, 2015 by Official Resolution 420/2015. The Label Supervision System required label approval by the Office of Commercial Fairness, in addition to the initial approval by ANMAT (*Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica*), and was generally viewed as a potential obstacle to imports.

Approval of labels for food, beverage, cosmetic, and personal care products, and household cleaning products will now only be done by ANMAT, which is the government technical agency that has historically been in charge of label approval.

For food and beverage products, INAL (*Instituto Nacional de Alimentos*, within ANMAT) is responsible for the approval of labels.

An import authorization is required to import products through SENASA (fresh, chilled, frozen, and thermo-processed products and by-products of animal and seafood origin) and by-products of animal origin into Argentina. The permit is obtained from SENASA and should be requested by an importer who has already been registered at SENASA, and who has registered the facility for export to Argentina.

This authorization includes the registration numbers of the importer and product. After the permit is granted and within five (5) days prior to arrival of the product at the Argentine port of entry, the importer must advise SENASA of the arrival of the shipment. During the following fifteen (15) days, the importation must be completed. Only with a strong justification can this time period be extended.

To import into Argentina, products or by-products of vegetable origin as well as other articles regulated by phytosanitary risk, it is mandatory to have a Phytosanitary Import Authorization (*Autorización Fitosanitaria de Importación* - **AFIDI**), prior to any commercial transaction.

Those products that do not have phytosanitary requirements established through the AFIDI, must be submitted to the process of Pest Risk Analysis (see http://www.senasa.gob.ar/cadena-vegetal/aromaticas/comercio/importacion/requisitos-generales/fitosanitarios/previo-al-ingreso/analisis-de-riesgo-de-plagas?_ga=2.220070492.478498366.1511795460-772802131.1511795460)

Products imported through SENASA (products of plant origin), in order to obtain a phytosanitary Certificate required for all plant products entering into Argentina (which must be signed by an Animal and Plant Health Inspection Service/APHIS *official* inspector), the exporter will need to submit the AFIDI certificate to APHIS.

The AFIDI will explain in detail all the necessary requirements needed before the product can be exported. Upon arrival in Argentina, SENASA will hold the product at the port of entry for inspection and to verify that it meets all the requirements stated in the AFIDI. SENASA will then issue an import certificate for Customs to release the product (The SENASA import manual is available at: http://www.senasa.gob.ar/sites/default/files/ARBOL_SENASA/VEGETAL/AROMATICAS/PROD_PRIMARIA/manual_del_usuario_importador_v6_24_11_2015.pdf)

For products imported through INAL (processed foods, alcoholic and non-alcoholic beverages, except wine), the importer must register as an importer and register the product through the INAL, in other words, product and importer registration is required prior to importing a product into Argentina. If the product has no problems, its registration should be ready in less than thirty (30) days. The requirements to register imported processed foods are listed below:

- New importers must register as an importer by applying for a National Register of Establishment (*Registro Nacional de Establecimientos* - **RNE**) which is valid for five years. And in order to register the product, the importer along with his RNE, must apply for a National Register of Food Product number (*Registro Nacional de Productos Alimenticios* - **RNPA**).

- Once the RNPA has been issued and the product is in the port, the importer needs to obtain a Certificate of Free Circulation (*Certificado de Libre Circulación*) at INAL. Once the importer has an RNPA for a given product, he does not need to apply for a new one every time that he imports that same product. However, he must request a Certificate of Free Circulation for each shipment.

- For products imported through INV (wine only), the importer must have evidence of prior Tax Identification Registration with AFIP (in which the importer will obtain a *Código Único de Identificación Tributaria* - CUIT, or unique tax identification number) before registering with the INV. If approved, the INV will issue a Certificate of Inscription as Importer of Wine Products (*Certificado de Inscripción como Importador de Productos Vitivinícolas*) along with a registration number that may be requested by authorities in subsequent importations.

9. PLASTIC AND PLASTIC MATERIALS

9.1. Plastic (Brazil)

9.1.1. Overview

Economic data reveal that plastic initiated and continues a silent revolution in Brazil. Estimations of Abiplast, based on data from IBGE, indicate that additional R$ 1 million of production on the transformative sector increases other R$ 1 million on the production of the supplier sector and increase R$ 2 million on the total production of the country and R$ 1,3 million to the GDP (Abiplast, 2017, p. 59). In 2017, the industry of plastic transformed products registers an average annual production of 5,8 million of tons of artifacts, which is enough volume to supply a pulverized chain formed by 11459 companies and 313062 workers (Abiplast, 2017, p. 59-60).

9.1.2. Mapping Technical Regulation

The Brazilian Association of Plastic Industry (Abiplast) is the main national institution on the sector and comprises Sectorial Chambers of Producers of Plastic Transformed Products. The main goal of each chamber is to stimulate the growth of the sector of plastic transformation through the cooperation of companies that belong to the same market niche, through the analysis and debate of themes of common interest. The main strategies adopted are the following: (i) understand the needs and filters of each niche of the sector of transformation of transformation of plastic material, (ii) debate forms to develop the industrial sector of transformation of plastic material, considering the specificities of each segment and (iii) create projects, aiming to attend the needs of these segments. The table below lists the sectorial chambers.

Table 18 - Sectorial Chambers of Abiplast

SECTORIAL CHAMBERS
Sectorial Chamber of the Producers of Industrial Buckets
Sectorial Chamber of the Producers of Pre-forms of PET
Sectorial Chamber of the Producers of Blown Industrial Containers
Sectorial Chamber of the Producers of Automotive Components
Sectorial Chamber of Transformers by Rotomoulding
Sectorial Chamber of the Producers of Domestic Utilities
Sectorial Chamber of the Producers of Plastic Covers
Sectorial Chamber of the Producers of Mono and Bioriented Films – smooth technical coil (PP, PE, PET)
Chamber of Producers of Plastic Pallets
National Chamber of Recyclers of Plastic Material

Source: ABIPLAST. Elaborated by CCGI-FGV/EESP

The main recent initiatives of Abiplast on the plastic sector are the following: the applicative and website “Recycling of Plastics”, the National Label of Recycled Plastics (SENAPLAS), the primer Qualification on Identification and Separation of Plastic Materials, the primer of recyclability of post-consumption plastic materials and the database of plastic residues.

Abiplast also adopted a code of conduct with relevant norms that regulate the plastic sector. Principles as integrity, honesty and transparence must guide each collaborator on

its commercial activities. All the associates, suppliers and partners must be treated in conformity with the values of the association and according to the applicable laws and regulations.

The collaborators and associates responsible for any form of registry are responsible to guarantee that the information is precise, opportune, complete, clear and understandable. This rule is applied to any type of technical, commercial and financial registry. The financial registries must follow internal and legal procedures. It will not be admitted that a collaborator creates or participate on the creation of registries that contain intentionally wrongful information, aiming to incur someone in error or hide an improper activity.

When investigations are done by legitimate authorities, all collaborators must cooperate. Every visit of a public official relative to an investigation or inquiry must be received and coordinated by the responsible legal officer and by the responsible officer of the area involved on the investigation. The oversights of governmental authorities, on any sphere, must always be presented on the format of a craft. The answers to these crafts must be done formally, on a written form, with the due analysis of the responsible department and presented through protocol to the requiring body. Every administrative process must be forwarded to the responsible officer to adopt the due measures.

The code of conduct recognizes that the suppliers are fundamental parties on the activities of the association and play a relevant role on the satisfaction of the client. These relations must be ethical and mutually beneficial. The suppliers must be evaluated by objective criteria and without any discrimination. Any kind of favoring is prohibited. The objective of the association is to work with the best suppliers with the highest standards of integrity. Abiplast suppliers must divide and share the same ethical standards on anti-corruption, human rights, labor laws and sustainability issues. The suppliers must know the express conducts foreseen on the code and, through a term of accept, must declare their adequacy to Abiplast standards of conduct.

The code of conduct provides a chapter on anti-corruption policy. Abiplast prohibits any offer, promise, authorization or payment in money or any good of value to public officers or their familiars, directly or indirectly, through partners, aiming to obtain an improper advantage.

Considering issues of conflicts of interest, all the collaborators, associates, preposterous and third parties must remain in conformity with the code of conduct to avoid situations of conflicts of interests. The contracting of partners and suppliers must be based, exclusively, on objective competences, aiming at the best contracting for Abiplast. Every situation of potential conflict of interest must be reported to the immediate manager or to the responsible officer for the compliance.

Abiplast will investigate any violation to its policy of conflicts of interest and, when verified the non-information of a conflict of interest, sanctions will be applied. In the case of application of a sanction, the responsible person will be previously consulted.

The code of conduct also foresees a manual for sectorial chambers. This manual aims to establish the rules and the basic conducts of the meetings of the sectorial chambers. The principles of the sectorial chamber are the freedom of initiative, freedom of competition,

the right to expression and the principle of free association. The rules are binding on collaborators, associates, preposterous and third parties.

The bodies of each sectorial chamber are the secretariat, the coordination and the vice-coordination. The sectorial chamber is composed mandatorily by one coordinator and one secretary. The coordinator will be elected by at least 80% of the participants of the sectorial chamber. The secretary will be mandatorily elected by Abiplast. The function of coordinator will last for two years, being possible the reelection to the function. When there is no coordinator or in the absence on the function without an election on the term of 60 days, it is reserved to Abiplast the right to nominate a representative for the coordination that will also occupy the function of secretary.

The rights and obligations of the coordinator and of the vice-coordinator (if exists) are the following: approve the schedule and propose themes, conduct the meeting, represent the chamber when required by Abiplast, approve the minute and sign the term of conflict of interests. The rights and obligations of the coordinator cannot be transferred or derogated. The rights and obligations of the secretary are the following: organize and prepare the agenda of the meeting, prepare the day order, prepare and send the convocations and prepare the minute of the meeting.

The chambers can have the advice of an advisor through a unanimous approval of the participants present on the sectorial chamber. The conditions of the contract and the charges/fees with the contracting of the advisor will be decided by the participants of the chamber. The advisor will be an auxiliary on the coordination of the proposition of themes and on the execution of themes deliberated during the meetings of the chambers with the due technical and institutional support of Abiplast. It is up to the coordinator with the consent of the other participants of the chamber to allow that the meetings of the group be conducted by an advisor.

9.1.3. Mapping Technical Standards

There are several ABNT committees dealing with plastics and their products. The three main committees are as follows: ABNT / ONS-051 - Packaging and Packaging Sectorial Standardization Body; ABNT / CEE-101 - Special Study Commission on Plastic Pipes for Agricultural Irrigation and Drainage; ABNT / CEE-105 - Special Study Committee on Thermoformed Disposable Plastic Cups. These committees adopt technical standards produced by international standards bodies, such as ISO and IEC. For a list of standards, see Annex 8.

9.1.4. Mandatory conformity assessment procedures

Some products made of plastic has mandatory conformity assessment procedures. There is no such procedures for plastic products used as raw material. ABNT or ISO standards are the norms used to in the mandatory procedures.

9.2. Plastic (Argentina)

9.2.1. Overview

The international trade of plastic products reveals a significant imbalance in Argentina. The country depends greatly on imports of these products. Exports of plastic products on the last three years were always below 1 billion dollars, which may signal the reduced competitiveness of the sector in the Argentine industry. As observed in Brazil, the sector of plastic is regulated mainly on environmental aspects.

9.2.2. Mapping Technical Regulation (Annex 8)

The Argentine regulations of the plastic sector are of federal and provincial nature. Most of these regulations do not contain rules for raw plastics (raw material). Such regulation on plastics has special nature, because it covers specific products or specific aspects of plastic products. The Argentine regulation covers mainly aspects concerning the protection of the environment and the consumer. Bearing in mind that plastic products are used in practically all economic sectors (e.g. in food packaging, in automotive accessories, in toys and household articles), the Argentine regulatory authorities, in line with the international initiatives, focused mainly on the correct disposal of plastic products, as well as in the environmentally sustainable forms of use of these products.

Argentine regulations on the plastics sector deal with the following themes: safety requisites for school goods, the use of bags of polyethylene and other conventional plastic material, the sale of plastic bags that are not degradable, oxi biodegradable or hidro degradable, the production, trade and use of plastic bags, packaging and recipients that are non-pollutant and degradable and the dumping on the sea of all plastic materials.

Therefore, the regulation of plastics does not intend to determine how the product will be produced or what the general characteristics of the raw plastic should be. The regulation focuses mainly on the final products of plastic, whether they are accessories to the main article consumed or the product itself consumed. Often this regulation refers to technical standards produced in Argentina or other standardization bodies.

For example, Resolution 680/2015 of the Trade Secretariat (*Secretaria de Comercio*) establishes safety requisites for school goods that must be traded on the country. Plastic packaging of continuous use must comply with requisites of resistance to fall, small parts, cutting edge, sharp point, articles of polymeric material and of rubber, including the ones reinforced with textile components and articles with plasticizer. When the packaging has painting and/or coating, this class of packaging must also comply with the requisites of painted articles – coating. The plastic cannot also exceed the limits indicated on table I of standard IRAM NM 300-3:2003 determined according to what is foreseen on chapters 7, 8 and 9 of the aforementioned standard.

Provincial Law 9696/2009 prohibits on the territory of the province of Cordoba the use of bags of polyethylene and any other conventional plastic material, used and delivered by supermarkets, auto services, warehouses and commercial establishments in general for the transport of goods. The owners of the establishments must act in order to replace the aforementioned materials, replacing them by containers of degradable and/or biodegradable material that are compatible with the reduction of environmental impact.

The Secretariat of the Environment or the body that on the future replaces it will apply the law. The application authority must create a program of substitution of plastic bags by degradable and/or biodegradable recipients that will contemplate (i) the diffusion, information, awareness and capacitation on the theme, (ii) the coordination with municipalities, communes and national bodies recognized on the issue, (iii) the determination of the authorized manufacturing technology, (iv) the creation of a registry of manufacturers, distributors and importers, (v) the creation of identification methods of authorized containers and (vi) the determination of criteria of degradability and biodegradability. The authority must also create a program of recycling of degradable and/or biodegradable materials, aiming to reduce the ones that are not used and to recover and reuse them.

The regime of sanctions determined by the application authority comprises the warning, fines, confiscation of the product that is not in conformity with the law and the temporary or definitive closing of the establishment. The guidelines for the gradation of sanctions according to the magnitude of the violation of the law, the economic condition of the violator and the recidivist character will be fixed on regulations.

Law 2455/2008 of the province of La Pampa prohibits the sale of plastic bags that are not degradable, oxi biodegradable, biodegradable or hidro degradable for transport of goods bought by its clients on the markets and/or industries of the province of La Pampa. The sale of the same bags that are applied for residues is also prohibited. On all cases, the materials used must be innocuous to food. The main objectives of the provincial program are the following: programmed elimination on the territory of the province of bags of polyethylene that are not produced with degradable, oxi biodegradable, biodegradable or hidro biodegradable materials; the practice of diffusion campaigns through brochures, different means of mass communication, nongovernmental organizations and intermediate institutions about the protection of the environment directed to the population; the practice of information campaigns on public and private schools about the implementation of the law and about the protection of the environment and the information to all stakeholders about the implementation of the law.

The shops must deliver to their clients bags of degradable, oxi-biodegradable, biodegradable or hidro-degradable endorsed by the corresponding national and international norms. The following goods are exempted from the prohibition: elaborated or pre elaborated recipients that contain food or wet input that for safety and conservation reasons cannot be replaced by materials that are degradable, oxi-biodegradable, biodegradable or hidro-degradable.

The application authority will be the Subsecretariat of Industry and Trade dependent of the Production Ministry that will enforce the controls in coordination with bodies of comptroller of the municipal shops and industry. A regulation will establish the regime of sanctions and the value of fines as well as a system of prizes to shops and industries that comply with the rules of the law. The application authority will concede technical assistance to allow the owners of shops and industries to internalize the different existing options on the market and to reconvert the affected sectors by the law. The authority must also have a registry of the violating stores aiming to control and follow the established program.

Law 7806/2007 of the province of Mendoza creates the program to foster the production, trade and use of plastic bags, packaging and recipients that are non-pollutant and degradable. The program will comprise the following components: (i) studies and statistical analysis about volume of consumption of plastic bags, packaging and recipients and their impact; market potential for the non-pollutant and degradable plastic material and possible tax incentives for trade and its finance impact, (ii) survey of all varieties of non-pollutant plastic materials that are on the market, (iii) actions of the Executive power with universities, research bodies and private sectors, (iv) technical advice for the industry, research areas and environmental action on the private and public sectors, (v) general information to the society about viability, environmental and economic impact, advantages, costs and other technical issues related to the use of degradable plastic, (vi) actions to clarify the public and (vii) the interaction between professionals of different technical areas and the public.

The execution of the program must foresee the implementation of actions aimed at the participation in activities on primary and secondary schools, events of recreation and leisure in parks and centers of recreation in a cultural, sportive and artistic manners; training about the program with different professional activities through advice, seminars, practical exercises, exhibition of videos, publication and distribution of pertinent explaining brochures and creation of jobs and sustainable economic activities, mainly in cooperatives of production of non-pollutant bags and recipients as a consequence of the program.

The executive power will regulate the application of the program on all its steps and technical specifications. The Ministry of Environment and Public Services of the province of Mendoza will be the application authority and must foresee on its annual budget the necessary expenses to implement the program.

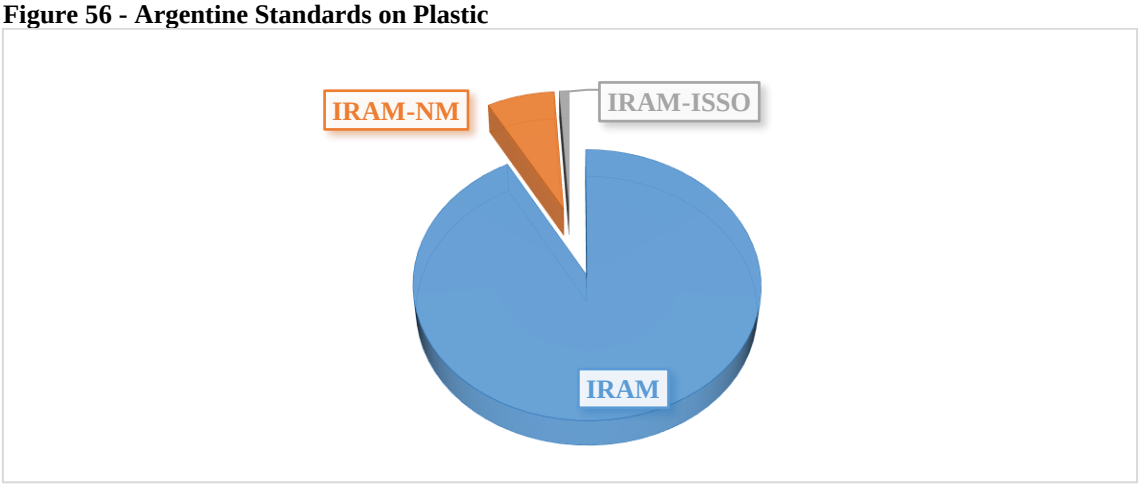
Law 24089/92 approved the international convention to prevent pollution by boats of 1973 and its protocols I and II and annexes. The convention prohibits the dumping on the sea of all plastic materials, which includes the fishing nets of synthetic fibers and plastic bags for rubbish.

9.2.3. Mapping Technical Standards

The Argentine standards on the plastics sector are described on the table below. The vast majority of the standards were created by IRAM and do not follow regional or international standards. In the list with a hundred standards on plastic 6% of the standards are in conformity with ISO standards (see Annex 8). Only one standard follows a regional NM standard.

In Argentina, most of the voluntary technical standards in the plastics sector are produced domestically by the Argentine Institute of Standardization and Certification (*Instituto Argentino de Normalización y Certificación*, IRAM).

Figure 56 - Argentine Standards on Plastic



Source: IRAM. Elaborated by CCGI-FGV/EESP.

Only a small part of these standards are adoptions of international or regional technical standards. ISO and Mercosul standards represents the universe of non-domestic standards adopted by IRAM.

9.2.4. Mandatory conformity assessment procedures

Some products made of plastic has mandatory conformity assessment procedures. There is no such procedures for plastic products used as raw material. IRAM or ISO standards are the norms used to in the mandatory procedures.

10. SPECIFIC PROBLEMS OF TRADE CAUSED BY REGULATORY SYSTEMS ON BRAZIL AND ARGENTINA

In this report, the research analyses the non-tariff difficulties to international trade of Brazil and Argentina, especially (but not limited to) the bilateral trade. The report also identified the more problematic topics concerning the regulatory framework of Brazil and Argentina, suggesting possible solutions for the problems identified in selected sectors. The methodology applied is based on different sources of information subjected to a crosschecking verification. The purpose was to gather evidences on the more important difficulties to international trade of Brazil and Argentina. At the end, the study aims to comprehend not only particular problems of trade, the types of restriction imposed to the commerce and the level of difficult to eliminate them, but also the level of convergence between these two countries' regulatory frameworks.

The first approach to the theme of trade difficulties between Brazil and Argentina was based on the annually reports produced by United Stated Trade Representative (USTR) and the European Commission, complemented by the information provided the Trade Policy Review of Brazil and Argentina. Although there are other reports on barriers to international trade, the ones herein examined are more completed and encompassing. And despite the issues analyzed in such reports do not apply fully for the case of bilateral trade between Brazil and Argentina, they provide important hints on problematic structures of foreign trade of the two countries. In other words, such reports contain a detailed analysis of the regulation applied to external trade, and the conclusions, in some circumstances, can be used to scrutinize the general problems on barriers to trade.

The second source of information of possible difficulties for the trade between Brazil and Argentina are the specific trade concerns (STCs) raised against Argentina and Brazil in Technical Barriers to Trade (TBT) and Sanitary and Phitossanitary Meassures (SPS) Committees. STCs are instruments used to rise formal concerns against potentially non-legal measures adopted by the members. The history of concerns raised against both countries provides a useful tool for describing specific regulatory problems, which affects directly the bilateral trade.

The third source of information on trade difficulties is the interviews performed with stakeholders from the sectors selected, including companies, associations, standardization bodies and government representatives. Such interviews provide useful information to identify and to fully comprehend the regulatory difficulties of each sector. Only through information provided by actors directly involved in international trade, regulation, standardization and conformity assessment procedures we could check current difficulties involving international trade.

In this study, the concept of difficulties to trade has a broad meaning, encompassing any kinds of regulatory measures that restrict international trade practices. Thus, by definition, tariff measures, quotas and other forms of quantitative restrictions on trade are not included in the report. Moreover, the report focuses only trade in goods, because of specificities not applied to other sectors, such as trade in services, capital flow and intellectual property. In other words, the report centers only on technical barriers to trade and sanitary and phitossanitary measures that interfere in trade flows.

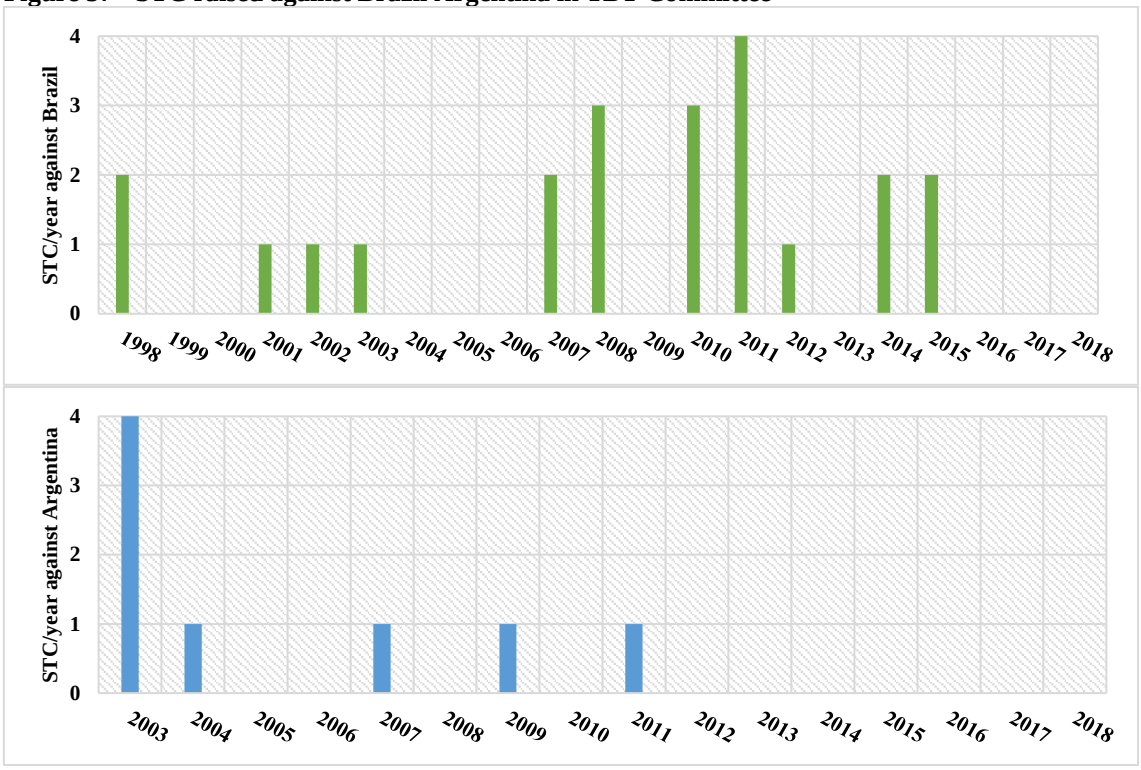
The legal framework that allows the identification of regulatory barriers to international trade imposed by each country are the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade Agreement (TBT), both inserted in the multilateral trade system centered on the World Trade Organization (WTO). SPS aims to protect human, animal and plant life or health and is applied to all sanitary or phytosanitary measures with direct or indirect effects on international trade. TBT aims to fulfil legitimate objectives of national security and of deceptive practices prevention and is applied to technical regulations, standards and conformity assessment procedures.

The use of technical regulation and sanitary and phitossanitary measures are admitted by multilateral rules, including the art. XX of General Agreement on Tariffs and Trade (GATT). However, as set forth in TBT and SPS Agreements, the use of such rules cannot unnecessarily affect the trade flow. The measures cannot be a disguised form of protectionism. If the country complies with some agreements' provisions and if its activities is based on international standards, there is a presumption it is in conformity with multilateral rules.

Specific Trade Concerns

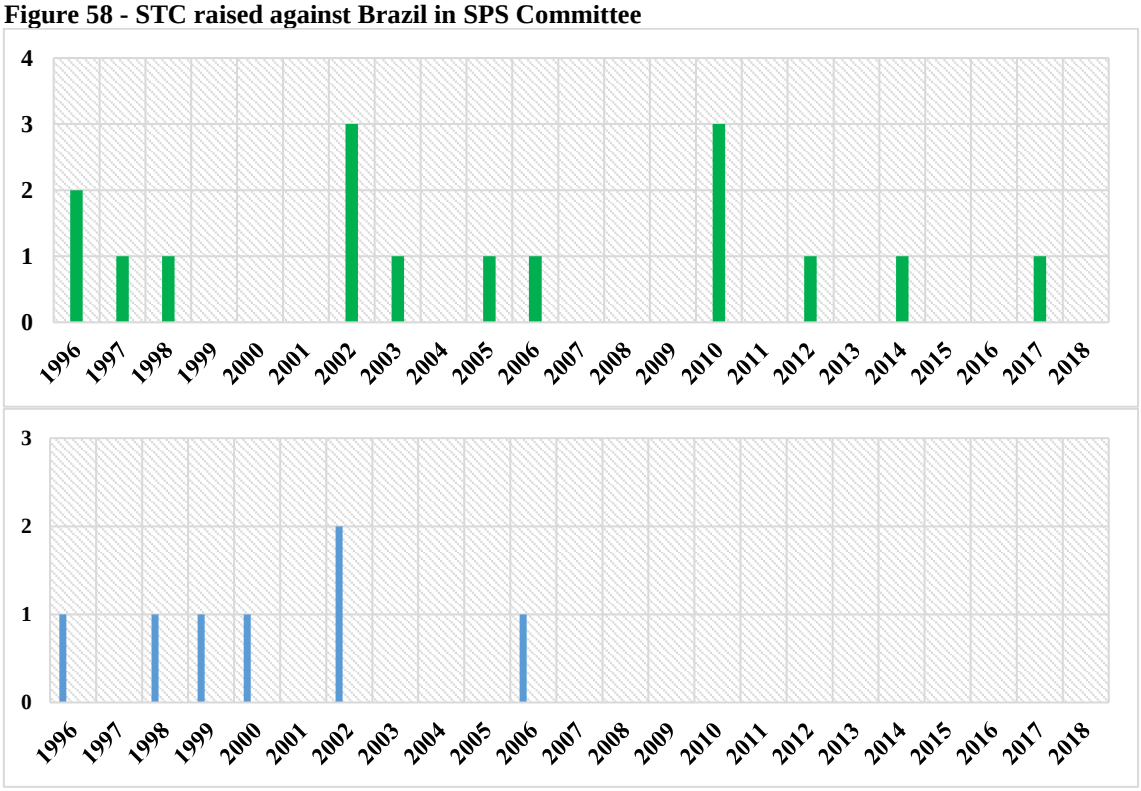
Below the graphs represent the specific trade concerns raised against Brazil and Argentina by all WTO partners. They offer indications of barriers imposed by the two Mercosur members to third countries.

Figure 57 - STC raised against Brazil Argentina in TBT Committee



Source: WTO. Elaborated by CCGI/EESP-FGV.

Figure 58 - STC raised against Brazil in SPS Committee



Source: WTO. Elaborated by CCGI/EESP-FGV.

In case of Brazil and Argentina, it must be stressed also the regional framework on trade, which constitutes two free trade areas partially overlapped. Both Common Market of South (Mercosul) and Latin American Association of Integration (ALADI) create a free trade region and customs union in which barriers to trade, including non-tariff barriers, have to be gradually eliminated.

The difficulties identified are limited to the sectors analyzed during the research project on regulatory coherence and on regulatory convergence initially between Brazil, European Union and United States and later expanded to Argentina[51]. As mentioned in previous reports, the sectors analyzed are the following: a) electrical and electronic appliances and machinery (inserted in HS 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); b) vehicles and auto-parts (inserted in HS 87 -vehicles other than railway or tramway rolling-stock, and parts and accessories thereof); c) cosmetics (inserted in HS 33 - essential oils and resinoids, perfumery, cosmetic or toilet preparations); d) machinery and mechanical equipment (inserted in HS 85 - electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); e) medical devices (inserted in HS 90 - optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof); f) processed food (inserted in HS 1 to 24); g) pharmaceutical products (inserted in HS 30 - pharmaceutical products; h) plastics and plastic products (inserted in HS 39 plastic and articles thereof).

[51] See the website of Center for Global Trade and Investment: https://ccgi.fgv.br/

Bearing in mind that the sectors have different characteristics, they have therefore diverse types of difficulties. Some of them are connected with rules on registry and performance of products, others result from discriminatory conformity assessments requirements applied do imported products. For some sectors, the researchers identified no specific barrier or difficulty.

It is also important to highlight the nature of the difficulties. Some problems may be simply a conjuncture and restricted to a specific aspect of the product. This is the case, for example, of the existence of distinct levels of contaminants to ensure the safety of a food product. Other problems may be more serious as they concern the structural aspects of a regulatory system or a set of regulations or technical standards.

The expected results from this analysis is not only the identification of barriers, but also to rank them according to the level of effects to trade. The effect, in turn, will be verified independently of the amount of trade affected, concentrating only on the difficulty of overcoming the barrier. In this way, the greater the difficulty of overcoming the barrier, the greater the level of obstruction. Some barriers will be described in details in order to exemplify how they impose obstacles to trade. Such methodology is useful to policy makers design public policies and adopt mandatory measures, because, by previously knowing the level of the barrier difficulty, simple problems can be prioritized and solved rapidly in first place.

The case of vehicles is emblematic when applying such methodology. The accomplishment of a full regulatory convergence between Brazil and Argentina faces different challenges depending on the dimension of the vehicle regulated. For safety parts of vehicles, the regulation in Brazil and Argentina are very similar, because both follow basic safety requirements demanded internationally. So in this specific case, the regulatory convergence is not a hard task. However, the environmental regulation dimension, especially concerning the greenhouse gas emissions, requires a greater convergence effort since these regulations have fundamental discrepancies.

Thus, based on this context and methodology this report is structured as follows: first main technical barriers to trade as well as sanitary and phytosanitary measures from Brazil are identified, followed by the same possible barriers from Argentina. At the end an effort to detect bilateral challenges and regulatory convergence was also pursued. It is important to note that the identification of convergence efforts is as relevant as the clear perception of trade barriers.

Table 19 - Comparative table: difficulties in trade relations by Brazil and Argentina

BRAZIL	**ARGENTINA**
OVERVIEW OF BARRIERS AND DIFFICULTIES TO TRADE	
MACHINERY SECTOR AND ELECTRICAL APPLIANCES	
Norma Regulamentadora (NR) n. 12, of the Ministry of Labor and Employment, is considered by many importers as an important regulatory difficulty in the machinery and equipment sector in Brazil. NR 12 was designed to regulate labor aspects related to the use of	On the machinery sector, the main issue is that the Ministry of Labor and Employment (MTE – *Ministério do Trabalho e Emprego*) constitutes the regulating body of machinery and equipment, which can generate the same problems observed in Brazil with NR 12.

BRAZIL	ARGENTINA
various machines, in a factory and non-factory environment. However, because of the extent of its scope, the NR 12 interferes with the importation of machinery, many of which have differences in safety mechanisms. Several regulations apply international technical standards such as those from ISO and IEC, but Brazil's MTE NR 12 that establishes rules for workers' safety is a hybrid regulation based on Brazilian, international and foreign standards. *Nota Técnica MTE n.* 48/2016 is an important source of interpretation of NR 12, and it adds some specifications of NR. It determines: a) the exclusion of the expression "fail-safe" of NR12; b) the inclusion of the concept of state of art; c) and the correlation between the category of safety and levels of performance. The last point is relevant due to the possibility of a non NR12 conformity of that new machines, produced in Europe according to international standards ISO or IEC, or harmonized EN type C standards. Regarding the principle of fail-safe, it used to be applied to specify failures to which a product or a system must be resistant to. However, considering that NR 12 establishes general principles of mandatory compliance and due to the possible conflict between NR 12 and standards in force or in phase of creation/translation, the principle of fail-safe was removed from the norm. The concept of state of art, mentioned in *Nota Técnica* MTE n. 48/2016, has no precise definition, but it includes technical and economic aspects in a way that technical solutions adopted must apply the most efficient technical means available. The machine producers have to be attentive to technical progress applying the most efficient technical solutions that are adequate to each machine. In cases in which it is not possible to fully satisfy the essential requisites of safety and health on the current state of art, the producer of the machine must comply to the highest extension the objectives foreseen on the essential requisites of safety and health. The NR 12 is in permanent update, which does not result in permanent modernization. The Thematic Tripartite National Commission of the NR 12 (CNTT) was created to regulate it, always considering national characteristics. Evidences of the application of the state of art are the application of international standards and the application of EN harmonized norm of type "c" on specific cases.	However, as the MTE is not a consenting body on foreign trade, it cannot act on customs clearance. Another barrier is present on restrictions imposed on the importation of certain used goods for consumption, such as parts and components that are not used in the manufacture of other products (USTR, 2017, p. 27). The conformity assessment and safety certificate requirements for electrical products constitute a technical barrier to trade. Since 2013, Argentina has maintained conformity assessment requirements that obligate foreign manufacturers and importers to obtain safety certifications from Argentine certification bodies for all imported and electronic products before they can be traded in Argentina (USTR, 2017, p. 21). The restrictive elements present on the conformity assessment procedures are the repetitive testing requirements applicable only to foreign manufacturers, the imposition of significant delays, increase of costs and the imposition on importers of low voltage electrical equipment of safety certificates from the Argentine Gas Institute (IAPG, according to initials in Spanish) for their imports (USTR, 2017, p. 21). Recent infra-legal norms can contribute to reduce the costs and burdens present on the conformity assessment procedures. The approval of dispositions E 578/2016 to E 586/2016 that authorize the recognition of international certification results for specific electronic products has the potential to reduce the testing requirements for these goods. The sectoral research on electrical products revealed that another barrier is present on the standards applied in the sector. Most of the standards used in the electrical sector are homegrown standards, mainly those standards produced by Argentine Institute for Standardization and Certification (IRAM). The international standards such as the IEC and those produced by some Committee of the Mercosul Standardization Association (AMN) correspond to a little more than 20% of the IRAM standards, which may indicate a low degree of the sector internationalization. On the regional sphere, the same profile is repeated as there is a reasonable number of technical standards adopted by AMN, although these are not always adopted by the Argentine standardization body. Another peculiar fact is the relevant number of adopted norms that create technical regulations for specific products and specified tariffs. The protectionist effect of those regulations, however, remains uncertain.
VEHICLES	
In the Brazilian automotive sector, some specific problems and barriers can be identified. In addition to the high tariffs and sectoral stimulus programs directed at companies operating in Brazil, some important technical obstacles should be mentioned, such as the requirement for certification for parts and environmental and safety requirements for the approval of vehicles. The participation of INMETRO in the regulation and determination of mandatory certification for auto parts for the aftermarket is considered to be especially important, as well as the performance of CONTRAN and IBAMA in homologation procedures for the whole vehicle, a necessary condition for the car to be able to travel through the Brazilian roads.	On vehicles, the requirement of compliance of strict active and passive safety regulations imposes an excessive burden on traders and can constitute a barrier. Domestic producers, for example, must present certificates of compliance with specific IRAM standards. Argentina also presents test methods and cycles different from the Brazilian ones. In Brazil, the method follows an American norm. In Argentina, the European method is applied, which leads to variations of fuel, cycle and limit. Argentina will change from Euro 5 method to Euro 6 method. Each method corresponds to a specific level of emissions from light passenger and commercial vehicles. Different measures need to be adopted by Argentina and the first steps are present on

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	the action on the accreditation of laboratories, the action on the committee of the automotive industry of Mercosul subgroup of work 3. These measures aim to identify coherence of positions on the sectorial fora. On vehicles, a barrier is present on the new gaseous pollutant emissions certification of January 15, 2018. Its scope of application comprises light automotive vehicles belonging to categories M1 and N1. This certification must incorporate the certified values of CO2 emission and fuel consumption for the use of the approved fuel type according to rules without an international nature. The certification procedure is specified on IRAM-AITA 10274 standard, the ECE R. 101 regulation and on the European Directive 715/2007.
MEDICAL DEVICES	
In the Brazilian medical devices sector the main trade restrictive barrier reported is the complex regulatory system coordinated by Brazilian Health Regulatory Agency (Anvisa), which is responsible for the registration of these products in concordance with its classification. Products are classified in: i) Lower risk Class I and II devices that follow the *Cadastro* registration route and require a simplified application; and ii) higher risk Class III and IV devices that follow the *Registro* registration process. For some products ANVISA also requires a Brazil Good Manufacturing Practice (BGMP) certification. Some measures have been adopted to mitigate the complexity the regulation of the sector. Inside the regulatory system, the Medical Device Single Audit Program (MDSAP) was implemented aiming to allow that producers of health products contract a third party auditing body to do a unique auditing that will encompass the relevant requisites of participating regulatory authorities. The report produced after the auditing will be accepted by different regulators to deal with different requisites of the management systems of quality and good manufacturing practices. The conformity assessment costs will, thus, be reduced. Those submitted to a MDSAP auditing can also accelerate the process of obtaining an ANVISA good manufacturing practice certificate, that is a pre-requisite for trade authorization (BSI, 2018). The ANVISA international partners for MDSAP are the following: Therapeutic Goods Administration (TGA) of Australia; Health Canada of Canada; U.S. Food and Drug Administration of the USA and the Ministry of Health, Labor and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan. The RE 2347/15 recognized the MDSAP and established that the auditing bodies that comply with the requirements established on the scope of the program will be recognized by ANVISA through the publication of an individual normative act. ANVISA will use the results of the program, including the reports, to constitute an important conformity assessment procedure before and after sale, providing key information that are expected to support the technical evaluation of the regulations on these issues (BSI, 2018).	

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The RDC n. 185/2001 was subsequently altered by the RDC nº 207/2006 and the RDC nº 40/2015. However, there was no modification concerning the class and the types of products. The RDC n° 207/2006 provided on the following aspects: i) the legal condition of the distributor of a medical product; ii) the procedures for registry; iii) the conformity to information; iv) and the information of medical devices labels and instructions. The distributor of medical product that requires the registry of the product manufactured in Brazil is not equated to a importer regarding presentation of documents for registry, alteration, revalidation or cancelling of registry. The medical product submitted to clinical research are exempted of registry in case of compliance with legal norms of the competent sanitary authority. Additionally, the necessary information for the correct and safe use of the medical product must be on the product or on the label of its individual packaging or on the label of its commercial packaging. A barrier may be present on the information on these labels as, despite the existence of general principles for environmental labels on an ISO norm, it is still significant the use of environmental standards that are not recognized internationally. The RDC nº 40/2015 altered the producers or the importers' obligations. They are no longer obliged to register their products on a given agency if the registration is not a requirement. The absence of the obligation to register products without a legitimate and transparent criterion can lead to a discriminatory treatment of products and, thus, constitute a regulatory barrier. Thus, although the regulation of the sector, especially that imposed by ANISA, is complex, it is evident that Brazil has been struggling to conform to international standards. In addition, international convergence schemes, such as the MDSAP, allow for continued convergence in the industry, including in relation to conformity assessment.	
PHARMACEUTICAL PRODUCTS	
ANVISA established the relevant regulations for the pharmaceutical sector to public protect health standards through the sanitary control of the production and consumption of products and services subject to health surveillance. This includes the certification of good practices, the registration of pharmaceutical products and the establishment of medicine prices. The registration of a drug in Brazil faces a complex and time-consuming process. The steps are: the registration of the company in ANVISA's Petitioning System; the authorization of operation of the company (the authorization will only be granted to companies with a commercial representation or subsidiary registered under the Brazilian Law); the Certificate of Good Manufacturing Practices (*Certificado de Boas Práticas de Fabricação* - CBPF); and, finally, the drug registration. The deadlines for the final decision in drug registration processes are different for the priority category (120 days) and for the ordinary category (365	On the pharmaceutical sector, products face a range of burdensome and costly registration, licensing and certification procedures which creates difficulties to the exportation of these products. This barrier is present even when a medicine analyzed by another regulatory agency is consumed due to the confidence on the regulatory agency of another country. Besides, the majority of technical regulation notified to TBT committee has no standards indicated, which means that international standards are not supporting them. One example of barrier present on the pharmaceutical sector are measures that affect market access for pharmaceutical products. Concerns were raised about the Argentine system applied for the entry of pharmaceuticals in the country, specifically with regard to the classification of countries and the resulting application of conformity assessment procedures (WTO, 2008, p. 3). The issue could be dealt within the pertinent Mercosul bilateral group, but no

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days) and it only starts to be valid with the publication in the Brazilian Federal Gazette (*Diário Oficial da União* – DOU). Thus, one possible barrier is the amount of time required by the registration process because the drug can only be marketed after all this registration process. The RDC n. 81/2008 is particularly important regarding regulation on pharmaceuticals, and it can create some difficulties for exporters. The RDC n. 81/2008 provides a *Technical Regulation to Imported Goods and Products for Sanitary Surveillance*, mainly for pharmaceutical products, adopting definitions, categories of imports, registration of the import license, among others. The RDC n ° 81/2008 stipulates that only an authorized firm can import pharmaceutical products. The RDC n ° 81/2008 also determines characteristics and basic information of the imported medicine, prescribes the use of the Portuguese language in the documents with technical information about the products[52]. These determinations may create difficulties for the foreign company that wishes to sell in the Brazilian pharmaceutical market. Finally, it was reported that one important problem is related to the chronogram of inspection that is not updated on the website[53] (the last update was in August/2016). Therefore, companies cannot have the control of the date scheduled for their inspection to happen. The point of the inspection is to obtain a certificate of good practices. The international certificate issued by ANVISA depends on the inspection procedure performed in several stages, including the analysis of the basic documentation of the inspection request, establishment of an inspection schedule, formation of inspection teams, international travel logistic planning and hosting for members of the team of inspectors. It should be noted that ANVISA only informs and deals with the applicant regularly established in the national territory[54]. Some of the problems identified do not actually consist of regulatory barriers to trade. They are the simple result of the slow and sometimes bureaucratic functioning of the public administration, which often does not have enough employees to carry out the necessary inspection procedures for the liberalization of certain products.	initiatives on this sense have been taken up to now. On the last TBT Committee meeting in which this concern was debated, the representative of Colombia informed that, despite the dialogue between Argentine and Colombian authorities, the necessary authorization to allow Colombian companies to export medical products into the Argentine market had not been given (WTO, 2009, p. 56). The representative of Argentina, on the other hand, informed that intensive consultations had taken place between the different federal government agencies, including ANMAT, on how to address the issue (WTO, 2009, p. 56). After consultations, it was agreed that necessary administrative procedures would be initiated to address the concern appropriately (WTO, 2009, p. 56). On the pharmaceutical sector, a barrier is present on the Argentine guidelines for good pharmacovigilance practices that are not wholly in conformity with internationally accepted standards. The guidelines provide a quality system and standard operative procedures for activities of pharmacovigilance. This system presents control mechanisms in order to guarantee its correct functioning and efficiency as the authority of the pharmacovigilance worker to change the pharmacovigilance system in order to guarantee the compliance of the guidelines and the regulatory measures that can be the result of a pharmacovigilance inspection, namely advise, re-inspection, warning, restrictions due to security reasons and other pertinent measures. Another barrier is present on the content of a specific document of the sector, the periodic informs of safety updates. There are documents in which all the pharmacovigilance data of a medicine gathered on a specific period are presented. This data can be later compared to international standards of the sector. The main goal of these informs is to allow that pharmaceutical laboratories that can be either governmental or accredited participate on the collection of data and notifications, evaluate the safety information gathered and present it on a standardized form to the regulatory authority that registered the medicine. The offer of the national and international experience by these laboratories about the safety of a medicine allows: • the communication of new relevant information about safety from adequate sources, • the presentation on a concise manner of the situation of the registry and trade authority on different countries, whenever applicable, and any important change related to safety and

[52] The use of Portuguese language was not a spontaneous decision by ANVISA. It was determined by judicial decision, after the request of federal prosecutors.

[53] BRASIL. *Cronograma de Inspeção*. ANVISA. Available at: <http://portal.anvisa.gov.br/documents/33864/2871295/Cronograma+de+Inspe%C3%A7%C3%B5es+de+Medicamentos+-Janeiro+a+Agosto+de+2016.pdf/ecb178c9-6c5e-497b-93b5-d8245780adbc>. Acessed on: June 12th, 2017.

[54] *See* the portal for registration and authorization for companies http://portal.anvisa.gov.br/registros-e-autorizacoes/empresas/cbpf/inspecao-para -certification. More details on technical requirements and inspection formalities are set on Resolution RDC n. 39/2013. Finally, ANVISA publishes each year its agenda of international inspections (http://portal.anvisa.gov.br/inspecoes-internacionais), which indicates the beginning, the end and the country of the inspection.

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	• the periodical facilitation of the opportunity to reevaluate the relation benefit/risk and to decide the modification of security and therapeutic information of the medicinal specialty.
COSMETICS SECTOR	
Labeling requirements, such as the obligation to list all ingredients in Portuguese, are unusual by international standards and have been pointed out by Brazilian and foreign manufacturers as a trade barrier, which led to court challenges against ANVISA. Documentation requirements for the import of cosmetics is also considered a trade barrier. ANVISA has to approve the product registration for the imported cosmetics. The registration process at ANVISA normally lasts on average 490 days for regularization of registered products and more than 730 days for new products, according to ANVISA. The same observation made for pharmaceutical products is valid for the cosmetic sector Some of the problems identified do not actually consist of regulatory barriers to trade. They are the simple result of the slow and sometimes bureaucratic functioning of the public administration, which often does not have enough employees to carry out the necessary inspection procedures for the liberalization of certain products.	
FOOD AND AGRICULTURE SECTOR	
The Food Industry Sector is regulated by several public bodies and there is not a centralized authority responsible for coordinating and collecting all legislation applied to the food industry products. Despite of that, ANVISA seems to have a relevant role in regulating this sector because of all health issues associated to food industry products. Furthermore, the Brazilian food and beverage regulatory framework is frequently modified. Many resolutions are published in short periods of time. The most recent regulations in force in this area are often publicly available. It is important to provide some context to the ANVISA work. Since the agency has started its work only about 20 years ago while its counterparts in developed economies are more prepared. For that reason, the agency is still working to adequate the Brazilian regulation for food industry products with relevant international sanitary standards, especially those of the Codex Alimentarius. The analysis of this sector, when discussed with Brazilian producers and importers, shows some other relevant points: - Burdensome regulation on allergenic ingredients labelling in foodstuff products - ANVISA has adopted a new regulation on allergenic labelling in foodstuff products on July 2015 (enforcement date July 2016). This new requirement is mandatory for foodstuff, beverages, additives and ingredients used in food processing. Its main purpose is to inform consumers about the presence or traces of foods that are commonly associated with food allergies. The initiative was approved after a large popular mobilization of parents who face difficulties in identifying which foods their	On the processed food sector, the then existing European Communities had submitted comments with regard to Argentine notifications on olive oil and on labelling of pre-packaged food. Argentina, on the provision of answers to the comments, explained that consultations had been taking place and that authorities were ready to continue the exchange of views, to receive further comments and to provide responses to them (WTO, 2003, p. 8). The notification of pre-packaged food involved a more complex issue as an Argentine measure was not being questioned, but a Mercosul one. This Mercosul regulation was later surpassed by the Resolution 26/03, which took into account the comments made by the European Communities (WTO, 2003, p. 14). Affidavits of Foreign Sales (*Declaraciones Juradas de Ventas al Exterior* – DJVE) imposed by Argentina since 2015 constitute another technical barrier on the sector. Exporters of grains, oilseeds and their derivatives are required to obtain affidavits and to register the exportation with the Office of Coordination and Evaluation of Subsidies to Domestic Consumption (UCESCI) (USTR, 2017, p. 28). Approved DJVEs are valid for 180 days, except DJVEs for wheat, which are valid for 45 days (USTR, 2017, p. 28). On September 26, 2016, the Ministry of Agroindustry, together with the Ministry of Production and the Ministry of Treasury and Public Finances, issued Joint Resolution 1-E, extending the DJVE requirement for the 2016-2017 agricultural year (USTR, 2017, p. 28). On the processed food sector, Argentina creates some obstacles for the following products: live cattle, beef and beef products, pork and poultry. Most of these obstacles affect imports originating in the US, however, they can pose problems that can be extended to other trading

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children can or cannot consume. Either way, this means additional costs to the product. - Technical Regulation on food additives and technology authorized on wine - A regulation (Resolution RDC n. 123/2016) with respect to food additives and technology authorized to use in wine has been published on the website of ANVISA and it entered into force in November 2017. In addition to that, there are other laws and MAPA regulations affecting the production and sales of wine and grape products, two of which were raised as a Specific Trade Concern at the WTO CTBT (See TBT 613/675 and TBT 719). These regulations may not be in conformity with any international and even MERCOSUL standards. - Backlog of market access applications (undue delays by Brazil) - The backlog of evaluations of the inspection and certification systems by the relevant services of the Ministry of Agriculture, Livestock and Food Supply of Brazil remains a serious obstacle to trade. - Slow approval of labels of products of animal origin - To be able to export products of animal origin to Brazil (e.g. meat, dairy and fishery products), establishments must apply for the registration of each label in the Ministry of Agriculture, Livestock and Food Supply (MAPA). New developments have been announced by MAPA regarding the electronic registration of labels, which should speed up the approval of labels.	partners. Analyzing the first subsector, Argentina imposed restrictions on imports of all U.S. live cattle, beef and beef products since 2002 due to concerns with bovine spongiform encephalopathy (BSE) (USTR, 2017, p. 21). In 2015, Argentina changed its trade position through resolution 238/15, in which Argentina recognized the OIE's classification of the United States as a country with negligible BSE risk (USTR, 2017, p. 21-22). A historic evolution allows a clearer understanding of the issue. Similar restrictions were imposed on the European Union since 1999. The issue of import restrictions on bovine semen and embryos due to BSE was solved with the lift of the restrictions in 2005. Different countries of the Eastern Europe also drew attention to the notifications of emergency measures banning imports of certain animal products from countries that were BSE-free and not included in the OIE list of countries with reported cases of BSE (WTO, 2001, p. 4). The affected countries were ready to provide Argentina and other Members imposing restrictions with the necessary documentation warranting their status as being BSE-free (WTO, 2001, p. 4-5)[55]. Bulgaria later reinforced in the same year the STC was presented that would keep monitoring the situation. Canada was another country that questioned Argentine measures, which allegedly copied the EC geographical BSE risk categorization scheme (GBR), was not in conformity with an international standard and did not conduct a risk assessment. In its last manifestation of will, the representative of Argentina declared that significant progress had been reached on the issue and he was confident that a resolution could be achieved. On the following year, Canada informed the Secretariat that a solution had been found to the issue. An analysis beyond the STCs raised by Argentina can provide a more objective scenario of the subsector. The OIE members' official BSE risk status map reveals that United States, different European Union countries, Eastern Europe countries, including Bulgaria and Canada present a negligible BSE risk. Besides the issue of the BSE, Argentina was questioned by the European Communities for restrictions placed on its own beef exports, which led to a reduction in the amount of beef it exported under the Hilton Quota. This trade disruption could lead to a weakening of the SPS controls necessary to ensure that beef exports met the SPS requirements of the European Communities (WTO, 2006, p. 8). The European Communities sought guarantees of compliance of its sanitary requirements, especially in terms of traceability in circumstances of substantial reduction of export quantities. On the pork subsector, Argentina currently does not allow imports of US pork (USTR, 2017, p. 22). Despite United States' proposals to review sanitary certificates to debate concerns previously raised by Argentina, SENASA pointed that only imports of US pork from herds that have tested negative for *Trichinellosis* and

[55] Even if Brazil and Argentina are considered BSE-free, this situation can be changed quickly. The list of countries declared BSE-free is dynamic. At present, Brazil and Argentina are recognized as having a negligible BSE risk by the OIE. The updated list with country categories is available at: http://www.oie.int/en/animal-health-in-the-world/official-disease-status/bse/en-bse-carte/

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	without Porcine Reproductive and Respiratory Syndrome (PRRS) would be imported (USTR, 2017, p. 22). In the past, the European Union had questioned Argentina's temporary prohibition of fresh pork and pork products. The representative of the then European Communities indicated that the region had taken measures to regionalize the three EC member States which had restrictions in this regard, in particular some parts of Germany, the South of Netherlands and parts of Spain, but, in all of these regions the situation was under control (WTO, 1998, p. 9). By introducing a restriction applying across the board to all these countries, Argentina had not abided by Article 6 of the SPS Agreement - Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence - nor the OIE guidelines (WTO, 1998, p. 9). On the poultry subsector, the imports of fresh, frozen and chilled poultry from the United States were prohibited after worries with Avian Influenza. Argentina also has not recognized the US sanitary inspection system as equivalent to the Argentine system (USTR, 2017, p. 22). More recently, Argentina has indicated it would accept cooked poultry products from the United States, but there is no agreement yet on the terms of the necessary sanitary certificate as Argentina has maintained that the US poultry inspection system is not equivalent to the Argentine system (USTR, 2017, p. 22). On the bilateral trade between Brazil and Argentina, three relevant products identified in which barriers are present are red shrimp, citric fruits and olive oil. The issues involving these products will be explained below. On March 2013, Brazil and Argentina reached an agreement in which that country compromised to limit its exports of red shrimp to five tons per year. With the agreement, enabled Argentine companies were authorized to export to Brazil. The Brazilian government complied with the agreement reached on March 2013 when removing technical barriers to importations of red shrimp from Argentina. Importations are, however, currently suspended due to judicial determination. Considering citric fruits, Argentina complains that the Brazilian market on the sector remains closed to its products. According to information provided by MAPA, there is, in Brazil, legislation that restricts the movement of citric fruits on the country, aiming to avoid the risk of dissemination of citrus canker. The allowance of importation of lemons from Argentina would have potentially negative impacts on Brazilian producers as Argentina is one of the greatest exporters of lemon on the world. Regarding the entrance of Argentine orange, the immediate opening of the Brazilian market is also seen as potentially negative to the Brazilian producers. Finally, analyzing olive oil, Argentina claims that great part of olive oil exported to Brazil goes through reclassification through the verification of the percentage of the substance campesterol. After the reclassification, Argentine olive oil could compete with the European product highly subsidized. In this sense, the limit of 4% for the substance campesterol, object of the reclassification, aims to assure the degree of purity and quality of olive oil consumed on the country, as it is very common the adulteration of this product with the use of other vegetable oil or of low quality olive oil.

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10.1 Bilateral challenges and regulatory convergence

Concerning only Brazil and Argentina, it is possible to exam the level of convergence of their regulatory and standardization policies. This exam can help these countries to prioritize sectors and better design strategies to enhance their international trade flow. To do so, the degree of difficulties in terms of technical regulation and supporting standards were analyzed and classified. Whether sectorial regulations are harmonized according to the Mercosur system and the supporting standards applied by each country are similar, a high degree of convergence was inferred.

It was assumed that the smaller the number of barriers in a specific sector bilateral trade, the greater the degree of convergence. Also, it was considered harmonized the regulations subject to publication and internalization at the Common Market Group Resolutions, but in cases of non-regulatory harmonization the criterion to identify possible regulatory convergence was to compare the similarities of supporting technical standards existent in each national regulation.

The sector covered are the same ones: a) electrical and electronic appliances and machinery (inserted in HS 85 - Electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); b) vehicles and auto-parts (inserted in HS 87 -vehicles other than railway or tramway rolling-stock, and parts and accessories thereof); c) cosmetics (inserted in HS 33 - essential oils and resinoids, perfumery, cosmetic or toilet preparations); d) machinery and mechanical equipment (inserted in HS 85 - electrical machinery and equipment and parts thereof; sound recorders and reproducers, television image and sound recorders and reproducers, and parts and accessories of such articles); e) medical devices (inserted in HS 90 - optical, photographic, cinematographic, measuring, checking, precision, medical or surgical instruments and apparatus; parts and accessories thereof); f) processed food (inserted in HS 1 to 24); g) pharmaceutical products (inserted in HS 30 - pharmaceutical products; h) plastics and plastic products (inserted in HS 39 plastic and articles thereof).

Each one of this sectors were classified according to the following rules:

1) FULLY CONVERGED: when no mandatory impediment to trade between Brazil and Argentina was identified;

2) PARTIALLY CONVERGENT: where the regulation of the sector is in part harmonized in Mercosur and/or the supporting standards applied in both countries' technical regulation are similar;

3) DIVERGENT: for the situation where no trade in a specific sector is allowed.

Starting with the broader regulatory framework, only the cosmetic sector could be considered fully harmonized. The other sectors were considered partially harmonized since only some sectorial norms and/or parts of the sector were identified at the Common Market Group Resolutions.

Table 20 - Level of convergence of regulation

SECTOR	REGULATION
Electrical and electronic appliances and machinery	Partially harmonized in Mercosur. The Mercosur regulation covers only a small part of electrical products.
Vehicles and auto-parts	The sector is not formally included in Mercosur, but there are a few norms on traffic and safety so the regulation can be considered partially harmonized.
Cosmetics	Fully harmonized in Mercosur.
Machinery and mechanical equipment	Partially harmonized in Mercosur.
Medical devices	Partially harmonized in Mercosur.
Processed food	Partially harmonized in Mercosur.
Pharmaceutical products	Partially harmonized in Mercosur.
Plastics and plastic products	Lack of regulation. The regulation in two countries is limited to sustainable use of plastic, which is also regulated by Mercosur regulation so it is considered partially harmonized.

Regarding standards, it was observed a lack of mutual strategies between Brazil and Argentina. In some sectors Argentina is more internationalized than Brazil, but regarding medical devices the situation is contrary, Brazil is more internationalized than Argentina. In others, both countries are equally not internationally standardized, although the cosmetic and pharmaceutical sectors are regulated by compulsory rules issued by Common Market Group (GMC), which turns this sector more convergent in terms of technical standards. There are also cases, such as in the vehicles and plastic sectors, equally not internationally standardized. Only the processed food can be similar although Argentina does not indicate Codex as supporting standard.

Table 21 - Level of convergence of standards

SECTOR	ARGENTINE STANDARDIZATION	BRAZILIAN STANDARDIZATION	SIMILARITIES
Electrical and electronic appliances and machinery	High degree of internationalization, and regional production based on ISO and IEC.	Low degree of internationalization and production of few regional regulations on the sector. Most of them are national standards (ABNT NBR adapted from IEC).	Argentine standard choices are more internationalized. Brazilian national standards adaptation can indicate protectionism.
Vehicles and auto-parts	Lack of regional standards creates a difficult environment for convergence although some NM regional standards were identified.	Low degree of internationalization, absence of a common regime in Mercosur, common technical regulation on safety and environment regarding	Equally not internationally standardized.

		the sector, creation of standards by AMN.	
Cosmetics	There is no relevant voluntary standard on cosmetics in Argentina.	Few standards, but mainly based on ISO and few regional resolutions adopted by ANVISA.	Equally not internationally standardized. However, the sector is regulated by compulsory rules issued by Common Market Group (GMC), which turns this sector more convergent in terms of technical standards.
Machinery and mechanical equipment	High degree of internationalization, and regional production based on ISO and IEC.	Majority of national standards, but increasing application of international standards and development of regional standards usually in conformity with the work of ISO	Argentine standard choices are more internationalized. Brazilian national standards adaptation can indicate protectionism.
Medical devices	Lack of regional standards creates a difficult environment for convergence although some NM regional standards were identified.	High degree of internationalization and few regional regulations on the sector	Brazilian standard choices are more internationalized. Argentine national standards adaptation can indicate protectionism.
Processed food	Only few regional standards were identified. Codex standards were not chosen in most cases.	Regulations based on Codex standards and regional recommendations aiming to harmonize foodstuff products regulations	Can be similar although Argentina does not indicate Codex as supporting standard.
Pharmaceutical products	There is no relevant voluntary standards.	Low degree of internationalization and few regional regulations on the sector.	Equally not internationally standardized. However, the sector is regulated by compulsory rules issued by Common Market Group (GMC), which turns this sector more convergent in terms of technical standards.
Plastics and plastic products	No standards were identified.	No data on standards and few regional regulations on the sector	Equally not internationally standardized.

In summary, sectors level of convergence can be observed by comparing each sector.

Table 22 - Level of convergence of regulation and standards

SECTOR	REGULATION	STANDARDS INTERNATIONALIZATION SIMILARITIES	CONVERGENCE
Electrical and electronic	Partially Harmonized	Not similar.	No

appliances and machinery			
Vehicles and auto-parts	Partially Harmonized	Similar: not internationalization	Low
Cosmetics	Higly Harmonized	Similar: not internationalization	High
Machinery and mechanical equipment	Partially Harmonized	Not similar.	No
Medical devices	Partially Harmonized	Not similar.	No
Processed food	Partially Harmonized	Similar	Low
Pharmaceutical products	Partially Harmonized	Similar: not internationalization	Low
Plastics and plastic products	Partially Harmonized	Similar: not internationalization	Low

The only sector that appear to present better degree of convergence is the cosmetic sector that has the technical regulation completely harmonized in Mercosur, by means of the Resolution created by Common Market Group, which approves the projects from Working Subgroups of Mercosur. Plastic sector, pharmaceutical, processed food and vehicles (for vehicles, see Annex) are considered poorly convergent because even though both countries are not adopting international standards, but the technical regulations have been partially harmonized. Specifically for the plastics sector, it is possible to notice the absence of compulsory rules, which avoids the existence of contradictions and regulatory inconsistencies, indicating that regulation is not a relevant impediment to trade. Machinery, electrical products and medical devices are considered not convergent and the most complicated sectors to think on regulatory and standardization common policies.

Further studies are needed to evaluate the conformity assessment procedures applied by each country and also to deeply investigate each sector to comprehend whether there is part of the sectors presenting specific difficulties, which could lead to better strategic movements towards convergence.

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APPENDIX 1 - Electrical Appliances

Table 23 - Regulation on Electrical Appliances (Brazil)

Name	Theme
Decree 4508/02	Electric motors
Law 10295/01	Electric energy consumption bands and goals, water usage and gas consumption
ILO convention 119/94	Machinery protection
Resolution 336/89 of Federal Council of Engineering and Agronomy (CONFEA)	Regulates the engineering profession
Ordinance SIT 3214/78	Establishes the regulatory norms
Law 6496/77	Creates the Technical Liability Annotation
Resolution 218/73	Regulates the engineering profession
Law 5194/66	Regulates the engineering profession
Decree 5452/43	Consolidation of the labor laws
Ordinance 104/13	Distribution transformers
Ordinance 1008/10	Fuorescent compact lamps
Ordinance 1007/10	Incandescent lamps
Ordinance 959/10	Electromagnetic reactors for lamps
Ordinance 371/09	Basic compulsory standards for all electronic products that do not fall under Inmetro's PBEs
Ordinance 298/08	Water heaters
Ordinance 364/07	Air conditioning
Ordinance 363/07	Gas ovens and stoves
Ordinance 362/07	Refrigerators and freezers
Ordinance 132/06	Fluorescent compact lamps
INMETRO ordinance 54/16	Certification of electrical equipment under health surveillance scheme
INMETRO ordinance 144/15	Certification of LED lamps with integrated device based
INMETRO ordinance 563/14	Supplier's declaration of televisions
INMETRO ordinance 8/13	Digital certificate standard equipment ICP – Brazil
INMETRO ordinance 640/12	Certification of wires, cables and flexible electrical cords
INMETRO ordinance 446/12	Certification of commercial electric ovens
INMETRO ordinance 497/11	Certification of microwave ovens
INMETRO ordinance 480/11	Certification of electronic point recorder
INMETRO ordinance 335/11	Approves Mercosul technical regulation on essential safety requirements for low-voltage electrical products
INMETRO ordinance 4/11	Supplier's declaration of systems and equipment for photovoltaics (module, charge controller, inverter and battery)
INMETRO ordinance 489/10	Supplier's declaration of compact fluorescent lamps with integrated ballast to base
INMETRO ordinance 488/10	Supplier's declaration of electric motors three-phase induction squirrel-cage rotor
INMETRO ordinance 483/10	Supplier's declaration of sodium vapor lamps high pressure
INMETRO ordinance 454/10	Supplier's declaration of electromagnetic ballasts for lamps and sodium vapor lamps to metal vapour (hydrogen Halides)
INMETRO ordinance 267/09	Certification of AC powered electronic ballasts for tubular fluorescent lamps, circular and compact retilineas
INMETRO ordinance 179/10	Electrical equipment for explosive atmospheres under conditions of flammable gases and vapors and combustible dusts
INMETRO ordinance 283/08	Supplier's declaration of household lamps-incandescent Line
INMETRO ordinance 234/08	Certification of switches for household and similar fixed electrical installations
INMETRO ordinance 348/07	Certification of circuit breakers
INMETRO ordinance 324/07	Certification of plugs and sockets adapters
INMETRO ordinance 262/07	Certification of single-phase voltage stabilizers, with alternating voltage output with nominal voltage of up to 250 V for powers up to 3 kVA/3kW
INMETRO ordinance 261/07	Supplier's declaration of hot rolled steel bars for assembling electric power transmission towers
INMETRO ordinance 85/06	Certification of plugs and Sockets for domestic and similar use
INMETRO ordinance 190/04	Supplier's declaration of carbon steel tubes or micro-ligados steel tube, with or without stitching for assembling electric power transmission towers
INMETRO ordinance 20/02	Certification of ballasts for tubular fluorescent lamps
NR-28	Supervision and penalties
NR-26	Safety signs determining colors used in workplaces to identify safety equipment
NR-14	Safety in ovens and stoves
NR-12	Labor safety
NR-10	Safety in electric installations and services
NR-9	Programs on environmental risk prevention

Source: INMETRO and MTE. Prepared by CCGI-EESP/FGV.

Table 24 - Standards on Electric and Electronic Appliances (Brazil)

ABNT NBR 10505:2017 Electrical insulating liquids-determination of corrosive sulfur
ABNT NBR 13506:2017 Fiber optics-determination of optical sensitivity the camber

ABNT NBR 14199:2017 Stationary lead-acid accumulator ventilated — Essays
ABNT NBR IEC 61439-1:2016 Errata 1:2017 Sets and low voltage command Part 1: General requirements
ABNT NBR IEC 60529:2017 Degrees of protection provided by enclosures (IP Code)
ABNT NBR IEC 60270:2017 Techniques of high-voltage electrical testing-measurement of partial discharges
ABNT NBR 14198:2017 Stationary lead-acid accumulator ventilated-Terminology
ABNT NBR 14197:2017 Stationary lead-acid accumulator ventilated — specification
ABNT NBR IEC 60309-2:2017 Plugs and Sockets for industrial use Part 2: dimensional interchangeability requirements for PIN and contact tubular accessories
ABNT NBR IEC 61000-4-5:2017 Electromagnetic compatibility (EMC) Part 4-5: testing and measurement techniques – surge immunity test
ABNT NBR 5356-8:2017 Power transformers Part 8: application guide
ABNT NBR IEC 61892-7:2017 Marine fixed and mobile units-electrical installations Part 7: hazardous areas
ABNT NBR IEC 61439-2:2016 Sets and low voltage command Part 2: Sets and power command
ABNT NBR IEC 61439-1:2016 corrected version: 2017 Sets and low voltage command Part 1: General requirements
ABNT NBR 16487:2016 Vented lead-acid battery stationary-Maintenance
ABNT IEC/TS 60079-40:2016 Explosive atmospheres Part 40: requirements for process sealing between flammable fluids and electrical system
ABNT NBR 5123:2016 Errata 1:2016 Interchangeable fotocontrol relay and socket for lighting-specification and testing
ABNT NBR IEC 60079-28:2016 Explosive atmospheres Part 28: protection of equipment and transmission systems using optical radiation
ABNT NBR 16264:2016 Residential structured cabling
ABNT NBR 15701:2016 Errata 1:2016 Conduletes screw-type and metal for electrical conduit systems
ABNT NBR IEC 60079-14:2016 Explosive atmospheres Part 14: design, selection and installation of electrical installations
ABNT NBR 5356-9:2016 Power transformers Part 9: Receipt, storage, installation and maintenance of power transformers and reactors immersed in an insulating liquid
ABNT NBR IEC 60695-2-11:2016 Errata 1:2016 Tests relating to risk of fire
Part 2-11: incandescent wire test — test method of flammability for finished products (GWEPT)
ABNT NBR IEC 60079-2:2016 Explosive atmospheres Part 2: equipment protection by pressurized enclosure "p"
ABNT NBR 16527:2016 Grounding for distribution systems
ABNT NBR 16521:2016 Industrial cabling
ABNT NBR 9512:2016 Electric wires and cables-artificial Weathering under condensation of water, temperature and ultraviolet B radiation from fluorescent lamps
ABNT NBR 9885:2016 Power cables with aerial cover — artificial Weathering under electrical tension — test method
ABNT NBR IEC 61892-1:2016 Marine fixed and mobile units-electrical installations Part 1: General requirements and conditions
ABNT NBR 5356-11:2016 Errata 1:2016 Power transformers Last 11: dry-type Transformers-specification
ABNT NBR 15701:2016 corrected version: 2016 Conduletes screw-type and metal for electrical conduit systems
ABNT NBR 10502:2016 Phone cord CCE-APL-ASF polyethylene or polypropylene insulated, protected by a cover APL-specification
ABNT NBR 11788:2016 Aluminum connectors for air services of electrical conductors in power systems
ABNT NBR IEC 60079-19:2016 Explosive atmospheres Part 19: repair, overhaul and equipment recovery
ABNT NBR 14401:2016 Amendment set for optical cables-specification
ABNT NBR 14416:2016 Amendment set for optical cables (air and underground)-temperature variation-test method
ABNT NBR IEC 60079-26:2016 Explosive atmospheres Part 26: equipment with equipment protection level (EPL) Ga
ABNT NBR IEC 60079-5:2016 Explosive atmospheres Part 5: equipment protection by immersion in sand "q"
ABNT NBR 14408:2015 Amendment 1:2016 Amendment set for air and underground optical cables — — Vibration test method
ABNT NBR 14408:2016 Amendment set for air and underground optical cables — — Vibration test method
ABNT NBR 25415:2016 Methods of measurement and reference levels for exposure to electric and magnetic fields in the frequency of 50 Hz and 60 Hz
ABNT NBR IEC 60079-18:2016 Explosive atmospheres Part 18: equipment protection by encapsulation "m"
ABNT NBR 11789:2016 Cables with extruded thermoplastic polyethylene insulation for descent of antenna-requirements and test methods
ABNT NBR IEC 60079-1:2016 Explosive atmospheres Part 1: equipment protection by flameproof enclosure "d"
ABNT NBR IEC 60079-10-2:2016 Explosive atmospheres Part 10-2: classification of areas – explosive dust Atmospheres
ABNT NBR 10488:2016 Telephone cable with tinned conductors, insulated with thermoplastic and cover protected core APL — specification
ABNT NBR 10501:2016 Shielded telephone cable for internal networks — specification
ABNT NBR 7286:2015 Errata 1:2016 Power cables with extruded insulation etilenopropileno rubber (EPR, HEPR or EPR 105) to 1 kV voltages the 35 kV — performance requirements
ABNT NBR IEC 60079-0:2013 Errata 2:2016 Explosive atmospheres Part 0: equipment – General requirements
ABNT NBR 5356-11:2016 corrected version: 2016 Power transformers Part 11: dry-type Transformers-specification
ABNT NBR IEC 60060-2:2016 Techniques of high-voltage electrical testing Part 2: Measuring Systems
ABNT NBR 14014:2016 Instant water heaters and electric taps — determination of the maximum increment of temperature
ABNT NBR 14015:2016 Instant water heaters and electric taps — determination of electric energy consumption
ABNT NBR 14409:2016 Underground seam set for optical cables-compression-test method
ABNT NBR 14410:2016 Set of underground optical cables amendment-current drain capacity-test method
ABNT NBR 14411:2016 Set of underground optical cables-seam resistance to chemical attack-test method
ABNT NBR 14412:2016 Amendment set to aerial optical cables and underground-traction-test method
ABNT NBR 14414:2016 Set air splicing optical cables-accelerated Weathering-test method
ABNT NBR 14415:2016 Amendment set for optical cables (air and underground)-variation of the attenuation after fiber case accommodation-test method
ABNT NBR 16458:2016 Interlocking coils for power systems in alternating current (AC)
ABNT NBR IEC 62722-2-1:2016 Luminaire performance Part 2-1: particular requirements for LED fixtures
ABNT NBR IEC 60695-2-11:2016 corrected version: 2016 Tests relating to risk of fire
Part 2-11: incandescent wire test — test method of flammability for finished products (GWEPT)
ABNT NBR 11635:2016 Mineral oils of high flash point for electrical equipment
ABNT NBR 9655:2016 WM power cables, GM and GM-CT equipment, mobile connections with insulation etilenopropilene rubber (EPR) for voltages up to 750 V — specification
ABNT NBR 5123:2016 corrected version: 2016 Interchangeable fotocontrol relay and socket for lighting — specification and tests
ABNT NBR 16426:2016 Non-compound type pillar insulators for voltages above 1 000 V – dimensions and characteristics
ABNT NBR 15123:2016 Insulators for overhead lines with a nominal voltage above 1 000 V-Strings and orchestration of insulators for a.c. systems
ABNT NBR 7285:2016 Power cables with extruded thermosetting polyethylene insulation (XLPE) for 0.6/1 kV voltage-without cover-performance requirements

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ABNT NBR 7290:2016 Control cables with extruded insulation of XLPE, EPR or HEPR for voltages up to 1 kV-performance requirements
ABNT NBR 16432:2016 Mineral insulating oil — determination of chlorinated products
ABNT NBR 6007:2016 Electrodes and connecting pins of graphite for electric arc furnaces — requirements
ABNT NBR 17094-2:2016 Rotating electrical machines Part 2: single-phase induction motors — requirements
ABNT NBR 17094-4:2016 Rotating electrical machines Part 4: single-phase induction motors — Test Methods
ABNT NBR 8159:2013 Amendment 1:2016 Electrotechnical fittings for overhead electrical distribution — Standardization
ABNT NBR 8159:2016 Electrotechnical fittings for overhead electrical distribution — Standardization
ABNT NBR IEC 60357:2016 Tungsten halogen lights (except bulbs for automotive vehicles) — performance specifications
ABNT NBR 12160:2016 Sulfur hexafluoride to electrical equipment — verification of properties
ABNT NBR IEC 61434:2016 Secondary cells and batteries containing alkaline or other non-electrolyte acid — Guide to the designation of current in standards of secondary batteries alkaline cells
ABNT NBR 12090:2016 Electric showers — determination of the leakage current-test method
ABNT NBR 5356-5:2015 Power transformers Part 5: ability to withstand short circuits
ABNT NBR IEC/CISPR 15:2014 Errata 1:2015 Limits and methods of measurement of radio disturbances characteristics of electrical lighting and similar
ABNT NBR 12087:2015 Electric showers-determination of electrical power-test method
ABNT NBR 12088:2015 Electric showers-determination of minimum operating pressure and maximum temperature increase-test method
ABNT NBR 12089:2015 Electric showers-determination of electric energy consumption test method
ABNT NBR 12483:2015 Electric showers-General requirements
ABNT NBR 14011:2015 Instant water heaters and electric taps-General requirements
ABNT NBR 14013:2015 Instant water heaters and electric taps-determination of electrical power-test methods
ABNT NBR 14016:2015 Instant water heaters and electric taps-determination of leakage current-test method
ABNT NBR IEC 62444:2015 Cable glands for electrical installations
ABNT NBR 16431:2015 Electric equipment-determination of compatibility of materials with insulation vegetable oil
ABNT NBR IEC 60695-2-10:2015 Essays concerning fire risks Part 2-10: incandescent wire test/warm-stereo and common test method
ABNT NBR 15422:2015 Vegetable oil insulation for electrical equipment
ABNT IEC GUIDE 115:2015 Application of measurement uncertainty in conformity assessment activities in the electrical sector
ABNT NBR 16446:2015 Synthetic insulating liquids based on aromatic hydrocarbons for electrical equipment
ABNT NBR IEC 60670-24:2015 Boxes and enclosures for electrical appliances for fixed electrical installations for household and similar use Part 24: specific requirements for wrappers for protection devices and other electric devices that dissipate power
ABNT NBR 16442:2015 Non-halogenated and control cables with low smoke for voltages up to 1 kV-performance requirements
ABNT NBR 14203:2015 Alkaline nickel-cadmium accumulator stationary vented-Terminology
ABNT NBR 16429:2015 Fiber optic connectors for mounting on field-specification
ABNT NBR 14305:2015 Ballast and ignitor for metal vapor lamp (halides)-requirements and tests
ABNT NBR 13248:2014 Errata 1:2015 Power cables and insulated conductors without coverage, and not with low smoke, for voltages up to 1 kV-performance requirements
ABNT NBR IEC 60432-2:2015 Incandescent lamps — safety Specifications Part 2: halogen lamps for domestic and similar general lighting
ABNT NBR 16415:2015 Paths and spaces for structured cabling
ABNT NBR 16412:2015 Mineral insulating oil-determination of disulfide dibenzil by gas chromatography
ABNT NBR 16404:2015 Lead-acid battery-stationary vented installation and Assembly Requirements
ABNT NBR 14405:2015 Amendment set for optical cables (air and underground)-Bending-test method
ABNT NBR 14406:2015 Amendment set for optical cables (air and underground)-twist-test method
ABNT NBR 14407:2015 Amendment set for optical cables (air and underground)-Pressure-test method
ABNT NBR 7286:2015 corrected version: 2016
Power cables with extruded insulation Ethylpropylene brubber (EPR, HEPR or EPR 105) to 1 kV voltages the 35 kV — performance requirements
ABNT NBR 5419-1:2015 On lightning protection Part 1: General principles
ABNT NBR 5419-2:2015 On lightning protection Part 2: risk management
ABNT NBR 5419-3:2015 On lightning protection Part 3: physical damage to structures and dangers to life
ABNT NBR 5419-4:2015 On lightning protection Part 4: electrical and Electronic Systems in structure
ABNT NBR 14403:2015 Set of underground optical cables amendment — immersion in water — test method
ABNT NBR 14404:2015 Set of underground optical cables amendment — — Impact test method
ABNT NBR 5435:2015 Bushings for liquid-immersed transformer insulation-rated voltage 15 kV, kV, and kV-36.2 24.2 Specifications
ABNT NBR 16367-1:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 1: air dryer
ABNT NBR 16367-3:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 3: oil emperature indicators and rewinding
ABNT NBR 16367-4:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 4: digital Monitor temperature of oil and winding
ABNT NBR 16367-6:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 6: valves for transformers
ABNT NBR 16367-7:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 7: relay type gas detector Buchholz
ABNT NBR 16367-2:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 2: pressure relief Device
ABNT NBR 16367-5:2015 Accessories for power transformers and reactors for power systems immersed in an insulating liquid Part 5: oil level indicator
ABNT NBR 14074:2015 Lightning cables optical fibers (OPGW) for transmission overhead lines-requirements and test methods
ABNT NBR 16361:2015 Interpretation of dissolved gas analysis (AGD) in mineral insulating oil of electrical equipment in factory testing
ABNT NBR 16362:2015 Copper cables with aluminum core, naked, for electrical purposes — specification
ABNT NBR IEC 60079-33:2015 Explosive atmospheres Part 33: equipment protection by special protection "s"
ABNT NBR IEC 60947-6-1:2015 Maneuver and control devices of low voltage Part 6-1: multiple function Equipment – transfer switching equipment
ABNT NBR IEC 62660-2:2015 Lithium-ion secondary cells for propulsion of electric road vehicles Part 2: reliability testing and abuse
ABNT NBR 14633:2013 Amendment 1:2015 Flexible cords and cables with extruded insulation of polyethylene Chlorosulfonate (CSP) for voltages up to 500 V — performance requirements

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ABNT NBR 14633:2015 Flexible cords and cables with extruded insulation of polyethylene Chlorosulfonate (CSP) for voltages up to 500 V — performance requirements
ABNT NBR 6856:2015 Current transformer-specification and testing
ABNT NBR 16345:2015 Bakery machines-electric ovens of ballast-Method for performance measure
ABNT NBR 6234:2015 Mineral insulating oil-determination of interfacial tension of oil-water by the method of the ring-test method
ABNT NBR IEC 62262:2015 Degrees of protection provided by enclosures of electrical equipment against external mechanical impacts (IK code)
ABNT NBR 16343:2015 Bakery machines-electric ovens to convection-Method for performance measure
ABNT NBR 16344:2015 Bakery machines-electric ovens combined-Method for performance measure
ABNT NBR IEC 60670-23:2015 Boxes and enclosures for electrical appliances for fixed electrical installations for household and similar use Part 23: particular requirements for boxes and enclosures of floor
ABNT NBR IEC 61000-4-4:2015 Electromagnetic compatibility (EMC) Part 4-4: testing and measurement techniques-test of immunity to electrical fast transient/saves
ABNT NBR 7302:2015 Electrical conductors of stress-strain in aluminum aluminum conductors-test method
ABNT NBR 8664:2015 Signs for identification of airline transmission of electrical energy-Requirements
ABNT NBR IEC 60309-1:2015 Plugs and Sockets for industrial use Part 1: General requirements
ABNT NBR IEC 61892-6:2014 Marine fixed and mobile units-electrical installations Part 6: installation
ABNT IEC/TS 60815-3:2014 Selection and design of high-voltage insulator for use under conditions of pollution Part 3: polymeric Insulators for a.c. systems
ABNT IEC/TS 60815-1:2014 Selection and design of high-voltage insulator for use under conditions of pollution Part 1: definitions, principles and general information
ABNT NBR 15643:2014 Polymeric insulators for indoor and outdoor use with a nominal voltage above 1 000 V – project Trials
ABNT NBR 16327-1:2014 Polymeric insulator for pin-type cable networks covered fixed at voltages above spacers, 1 000 V Part 1: definition, test methods and acceptance criteria
ABNT NBR 16327-2:2014 Polymeric insulator for pin-type cable networks covered fixed at voltages above spacers, 1 000 V Part 2: dimensions and characteristics
ABNT IEC/TS 60815-2:2014 Selection and design of high-voltage insulator for use under conditions of pollution Part 2: porcelain and glass Insulators for a.c. systems
ABNT NBR 10301:2014 Electric wires and cables-fire resistance
ABNT NBR 16326:2014 Polymeric insulators for high voltage, for external and internal use-squeezing and erosion test, by squeezing wheel and method for testing of 5 000 h
ABNT NBR 16323:2014 Guidelines for producing, testing and diagnosis of compound insulators with respect to brittle fracture of core material
ABNT NBR IEC 60079-29-4:2014 Explosive atmospheres Part 29-4: gas detectors – performance requirements of open path detectors for flammable gases
ABNT NBR ISO/IEC 80079-34:2014 Explosive atmospheres Part 34: application of quality systems for the manufacture of equipment
ABNT NBR 7272:2014 Aluminium electrical conductor-breakage and dimensional feature
ABNT NBR 9311:2014 Electrical cables isolated-classification and designation
ABNT NBR 9326:2014 Connectors for power cables-testing of thermal cycles and short circuits
ABNT NBR 5405:2014 Solid insulating materials-determination of dielectric strength under industrial frequency voltage
ABNT NBR 9152:2014 Wires and cables for telecommunications-thermal Shock test method
ABNT NBR IEC 60079-17:2014 Explosive atmospheres Part 17: inspection and maintenance of electrical installations
ABNT NBR IEC 60669-2-1:2014 Switches for household and similar fixed electrical installations Part 2-1: particular requirements-electronic Switches
ABNT NBR 5032:2014 Insulators for overhead lines with voltages above 1 000 V – porcelain or glass Insulators for a.c. systems
ABNT NBR 5034:2014 Bushings for alternating voltages above 1 kV
ABNT NBR 5175:2014 Numbers of the functions of the devices of maneuver, control and power systems-protection Coding
ABNT NBR IEC 60079-31:2014 Explosive atmospheres Part 31: equipment protection against ignition of dust wrappers "t"
ABNT NBR IEC/CISPR 24:2014 Information technology equipment-immunity characteristics-limits and methods of measurement
ABNT NBR 6248:2014 Brown insulator — dimensions, characteristics and test procedures
ABNT NBR 6249:2014 Pulley type insulator made of porcelain or glass — dimensions, characteristics and test procedures
ABNT NBR IEC 60947-5-1:2014 Maneuver and control devices of low voltage Part 5-1: circuit devices and switching elements-electromechanical devices for control circuit
ABNT NBR IEC 60947-5-5:2014 Maneuver and control devices of low voltage Part 5-5: circuit devices and switching elements-electrical emergency stop Devices with mechanical locking
ABNT NBR IEC 62660-1:2014 Lithium-ion secondary cells for propulsion of electric road vehicles Part 1: performance test
ABNT NBR 5356-6:2012 Errata 1:2014 Power transformers Part 6: Reactors
ABNT NBR 13248:2014 corrected version: 2015 Power cables and insulated conductors without coverage, and not with low smoke, for voltages up to 1 kV-performance requirements
ABNT NBR IEC 60079-0:2013 Errata 1:2014 Explosive atmospheres Part 0: equipment – General requirements
ABNT NBR 16305:2014 Electrical instant water heating fixed — safety and performance Requirements
ABNT NBR 10296:2014 Electric insulating material — evaluation of squeezing and erosion resistance under harsh environmental conditions
ABNT NBR IEC/CISPR 15:2014 corrected version: 2015 Limits and methods of measurement of radio disturbances characteristics of electrical lighting and similar
ABNT NBR IEC 60079-20-1:2011 Errata 2:2014 Explosive atmospheres Part 20-1: characteristics of substances for classification of gases and vapours-Test Methods and data
ABNT NBR IEC 61058-2-1:2014 Switches for appliances Part 2-1: particular requirements for switches for flexible cables
ABNT NBR 5356-3:2007 Errata 2:2014 Power transformers Part 3: insulation Levels, dielectric tests and external air spacing
ABNT NBR 5440:2014 Errata 1:2014 Overhead distribution transformers-requirements
ABNT NBR 5440:2014 corrected version: 2014 Overhead distribution transformers-requirements
ABNT NBR 9147:2014 Wires and cables for telecommunications — Fluidity — test method
ABNT NBR 7289:2014 Control cables with extruded insulation of PE or PVC for voltages up to 1 kV — performance requirements
ABNT NBR IEC 60669-2-2:2014 Switches for household and similar fixed electrical installations Part 2-2: particular requirements — command Switches remote-control switches (RCS)
ABNT NBR IEC 60669-2-3:2014 Switches for household and similar fixed electrical installations Part 2-3: particular requirements — time switches (minuterias)
ABNT NBR IEC 60969:2014 Fluorescent lamps with integrated ballast to base for general lighting — performance requirements
ABNT IEC/TR 60783:2014 Wiring and connectors of electric road vehicles

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ABNT NBR 14206:2014 Stationary lead-acid accumulator controlled by valve — terminology
ABNT NBR IEC 60432-3:2014 Incandescent lamps — safety Specifications Part 3: tungsten halogen lamps (except automotive lamps for road vehicles)
ABNT NBR IEC 60670-1:2014 Boxes and enclosures for electrical accessories for household and similar fixed electrical installations
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ABNT NBR IEC 60968:2014 Fluorescent lamps with integrated ballast to base for general lighting – safety requirements
ABNT NBR IEC 62035:2014 Discharge lamps (excluding fluorescent lamps) — safety Specifications
ABNT NBR IEC 61195:2014 Tubular fluorescent lamps — safety Specifications
ABNT NBR 16274:2014 Photovoltaic systems connected to the network — minimum requirements for documentation, commissioning, inspection testing and performance evaluation
ABNT NBR 9893:2014 Cupilhas PIN or hinge screws – specification and test methods
ABNT NBR IEC 60947-3:2014Maneuver and control devices of low voltage Part 3: switches, disconnectors, switch-disconnectors and fuse combination units
ABNT NBR 16270:2014 Electrical insulating liquids – determination of passivator content in mineral insulating oil — test methods
ABNT NBR IEC 60947-7-1:2014 Maneuver and control devices of low voltage Part 7-1: ancillary equipment — connecting Blocks for copper conductors
ABNT NBR IEC 60947-7-2:2014 Maneuver and control devices of low voltage Part 7-2: auxiliary Devices — connection Blocks for protection conductor for conductors in copper
ABNT NBR IEC 60079-30-1:2014 Explosive atmospheres Part 30-1: resistive electric Tracing — General requirements and tests
ABNT NBR IEC 61000-4-3:2014 Electromagnetic compatibility (EMC)
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ABNT NBR 16254-1:2014 Materials for grounding systems Part 1: General requirements
ABNT NBR IEC 60695-2-12:2013 Tests relating to risk of fire Part 2-12: incandescent wire test methods/heated — flammability test method for materials
ABNT NBR IEC 60695-2-13:2013 Tests relating to risk of fire
Part 2-13: incandescent wire test methods/heated — test methods for flammability incandescent wire temperature (GWIT) for materials
ABNT NBR IEC 60112:2013 Method for the determination of resistance to squeezing and squeezing comparative index of solid insulating materials
ABNT NBR 16236:2013 Errata 1:2013 Appliance of water supply for human consumption with built-in cooling — performance requirements
ABNT NBR 14565:2012 Amendment 1:2013 Structured cabling for commercial buildings and data centers
ABNT NBR 14565:2013 Structured cabling for commercial buildings and data centers
ABNT NBR 13488:2013 Fiber optic Singlemode normal dispersion type — specification
ABNT NBR 15155-1:2013 Pipeline systems of polyethylene (PE) for power cables infrastructure and telecommunications
Part 1: requirements for external wall ducts
ABNT NBR 8158:2013 Electrotechnical fittings for overhead electrical distribution — specification
ABNT NBR IEC 60947-2:2013 Maneuver and control device of low voltage Part 2: circuit-breakers
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ABNT NBR IEC 61000-4-2:2013 Electromagnetic compatibility (EMC)
Part 4-2: testing and measurement techniques – electrostatic discharge immunity test
ABNT NBR IEC 62196-2:2013 Plugs, sockets, sockets for electric vehicle and electric vehicle fixed plugs — electric vehicle conductive Charging
Part 2: dimensional Requirements of compatibility and interchangeability for AC accessories with pins and tubular contacts
ABNT NBR 16238:2013 Sulfur hexafluoride to electrical equipment — guidelines for supervision and maintenance
ABNT NBR 14136:2012 Errata 4:2013
Plugs and Sockets for domestic and similar use up to 20 A/250 V AC — Standardization
ABNT NBR 10899:2013 Solar photovoltaics — terminology
ABNT NBR 16236:2013 corrected version: 2013 Appliance of water supply for human consumption with built-in cooling — performance requirements
ABNT NBR 14275:2013 Electrical equipment — insulating Liquid — determination of the content of particles
ABNT NBR 8840:2013 Guidelines for sampling of insulating liquids
ABNT NBR IEC 61892-3:2013 Marine fixed and mobile units — electrical installations Part 3: equipment
ABNT NBR 17094-1:2013 Rotating electrical machines-Induction Motors Part 1: three-phase Motors
ABNT NBR 13882:2008 Amend 1:2013 Electrical insulating liquids-determination of polychlorinated biphenyls (PCBs)
ABNT NBR 8121:2013 Cables of copper coated steel wires, naked, for electrical purposes — specification
ABNT NBR 14274:2013 Mineral insulating oil — determination of compatibility of materials used in electrical equipment
ABNT NBR IEC 62208:2013 Empty enclosures intended for the set and low-voltage control — general requirements
ABNT NBR IEC 60079-30-2:2013 Explosive atmospheres
Part 30-2: resistive electric Tracing — procedure for application in design, installation and maintenance
ABNT NBR IEC 60034-7:2013 Rotating electrical machines
Part 7: classification of types of construction, mounting arrangements and terminal box position (IM Code)
ABNT NBR IEC 60034-6:2013 Rotating electrical machines Part 6: methods of cooling (IC Code)
ABNT NBR 16219:2013 Copper-clad aluminum wire, naked, for electrical purposes — specification
ABNT NBR IEC/CISPR 22:2013 Information technology equipment — radio disturbances characteristics — limits and methods of measurement
ABNT NBR 6251:2012 Errata 1:2013 Power cables with extruded insulation for voltages from 1 kV to 35 kV — constructive Requirements
ABNT NBR 16207:2013 Optical cables — determination of the coefficient of dynamic friction-test method
ABNT NBR 16205-1:2013 LED lamps without built-in control device base only
Part 1: safety requirements
ABNT NBR 16205-2:2013 LED lamps without built-in control device base only Part 2: performance requirements
ABNT NBR IEC 61347-2-12:2013 Lamp control device
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ABNT NBR 14433:2013 Fiber-optic connectors and optical mount adapters — Specification
ABNT NBR 14136:2012 Errata 3:2013 Plugs and Sockets for domestic and similar use up to 20 A/250 V AC — Standardization
ABNT NBR IEC 60335-2-42:2013 Household and similar appliances — Safety
Part 2-42: particular requirements for electric ovens the forced convection, steam ovens and vacuum Pan
ABNT NBR 10300:2013 Instrumentation cables with extruded insulation of PE or PVC for voltages up to 300 V — performance requirements
ABNT NBR IEC 61537:2013 Cable routing systems — cable trays made for cables and cable trays systems
ABNT NBR 16188:2013 Plugs and Sockets for household and similar use — Adapters provided with protective and/or strip — particular requirements

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ABNT NBR IEC 62196-1:2013 Plugs, sockets, sockets for electric vehicle and electric vehicle fixed Plugs — conductive Charging for electric vehicles Part 1: General requirements
ABNT NBR 15751:2009 Amendment 1:2013 Substation grounding systems — requirements
ABNT NBR 15751:2013 Substation grounding systems-Requirements
ABNT NBR 16190:2013 Mounted connectors and optical adapters — moisture Determination — test method
ABNT NBR 16191:2013 Mounted connectors and optical adapters — Determination of the thermal cycle — test method
ABNT NBR 16192:2013 Mounted connectors and optical adapters — determination of dry heat — test method
ABNT NBR 16193:2013 Mounted connectors and optical adapters — determination of return loss — test method
ABNT NBR 16194:2013 Mounted connectors and optical adapters — determination of the loss by inserting — test method
ABNT NBR IEC 60079-0:2013 corrected version 2:2016 Explosive atmospheres Part 0: equipment – General requirements
ABNT NBR IEC 60079-35-1:2013 Explosive atmospheres Part 35-1: Lanterns for helmets for use in mines subject to firedamp — General requirements — construction and testing in relation to the risk of explosion
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Part 35-2: Lanterns for helmets for use in mines subject to firedamp — performance and other security-related requirements
ABNT NBR 14136:2012 Errata 2:2013 Plugs and Sockets for domestic and similar use up to 20 A/250 V AC — Standardization
ABNT NBR IEC 60947-1:2013 Maneuver and control device of low voltage Part 1: General requirements
ABNT NBR IEC 61851-1:2013 Conductive charging system for electric vehicles
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ABNT NBR IEC 61851-21:2013 Conductive charging system for electric vehicles Part 21: electric vehicle Requirements for conductive connection to an a.c/d.c. supply
ABNT NBR IEC 61851-22:2013 Conductive charging system for electric vehicles
Part 22: AC recharging station for electric vehicles
ABNT NBR IEC 60598-2-6:2013 Light fixtures
Part 2: particular requirements — Section 6: luminaires with built-in transformers or converters for tungsten filament lamps
ABNT NBR IEC 62560:2013 LED bulbs with built-in control device for general lighting services for a voltage > 50 V – safety Specifications
ABNT NBR IEC 62031:2013 LED modules for general lighting – safety Specifications
ABNT IEC/PAS 62612:2013 LED bulbs with built-in control device for general lighting services – performance requirements
ABNT NBR 14136:2012 Errata 1:2013 Plugs and Sockets for domestic and similar use up to 20 A/250 V AC — Standardization
ABNT NBR 15232:2013 Pillar type composite insulator for overhead lines of alternating current, with voltages above 1 000 V – definitions, test methods and acceptance criteria
ABNT NBR 15122:2013 Insulators for overhead lines – composite suspension type Insulators and anchorage type AC systems with nominal voltages above 1 000 V – definitions, test methods and acceptance criteria
ABNT NBR 5181:2013 Tunnel lighting systems — requirements
ABNT NBR 15688:2012 Errata 1:2013 Air distribution systems of electric energy with bare conductors
ABNT NBR NM 60335-2-102:2013 Safety of household and similar appliances
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ABNT NBR 16164:2013 Optical termination cable dielectric, protected against the attack of rodents — specification
ABNT NBR ISO/CIE 8995-1:2013 Lighting of work environments Part 1: Interior
ABNT NBR 16157:2013 Mounted connectors and optical adapters — Determination of vibration-test method
ABNT NBR 16159:2013 Insulated with thermoplastic shielded telephone cable for internal application in signal transmission with xDSL technology
ABNT NBR 14775:2013 Optical cables — resistance to action of rodents-test method
ABNT NBR 16156:2013 Waste electrical and electronic equipment — requirements for reverse manufacturing activity
ABNT NBR IEC 61242:2013 Electrical accessories — up Extensions on spool for household and similar use
ABNT IEC/TS 62504:2013 Terms and definitions for LEDs and LED modules for general lighting
ABNT NBR 8120:2013 Copper coated steel wires, naked, for electrical purposes — specification
ABNT NBR 9150:2013 Wires and cables for telecommunications — Separation of the veins (bipartiment) — test method
ABNT NBR IEC 61892-2:2013 Marine fixed and mobile units — electrical installations Part 2: electrical systems design
ABNT NBR IEC 60998-2-1:2013 Connecting devices for low-voltage circuits for household and similar use
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ABNT NBR 16150:2013 Photovoltaic systems (PV) — characteristics of the connection interface with the power of distribution — conformance test procedure
ABNT NBR 16149:2013 Photovoltaic (PV) systems – characteristics of the connection interface with the power of distribution
ABNT NBR 16145:2013 Lithium-ion battery for stationary application in 48 V DC — specification
ABNT NBR 15992:2011 Errata 1:2013 Air distribution systems of electric power cables covered fixed at voltages up to 36.2 kV spacers
ABNT NBR NM 60335-2-45:2004 1:2013 Errata Safety of household and similar appliances
Part 2: particular requirements for mobile heating tools and similar appliances (IEC 60335-2-45:1996, MOD)
ABNT NBR 13593:2011 Errata 1:2013 Ballast and ignitor for sodium vapor lamp high pressure – Specification and tests
ABNT NBR IEC 60745-2-14:2013 Portable electric motor-operated tools-Safety
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ABNT NBR IEC 60060-1:2013 Techniques for high-voltage electrical testing
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ABNT NBR IEC 60079-20-1:2011 Errata 1:2013 Explosive atmospheres
Part 20-1: characteristics of substances for classification of gases and vapours – Test Methods and data
ABNT NBR IEC 60335-2-6:2012 Household and similar appliances — Safety Part 2-6: particular requirements for stationary stoves, stovetops, ovens and similar appliances
ABNT NBR 8667-1:2012 Bypass switches Part 1: specification and tests
ABNT NBR 8667-2:2012 Bypass switches Part 2: application guide
ABNT NBR IEC 60534-1:2012 Industrial process control valves Part 1: terminology and general considerations of control valves
ABNT NBR 16132:2012 Non-halogenated, power cables with low smoke, isolated, with coverage for 3 kV voltages the 35 kV — performance requirements
ABNT NBR 5356-6:2012 corrected version: 2014 Power transformers Part 6: Reactors
ABNT NBR IEC 61191-3:2012 Assembly of printed circuit boards Part 3: sectional Specification-requirements for through holes in welded assemblies
ABNT NBR IEC 61191-4:2012 Assembly of printed circuit boards (PCBs) Part 4: sectional Specification-requirements for Terminal mounting soldiers
ABNT NBR 9329:2012 Receptacle for fluorescent lamps and starters — test methods

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ABNT NBR 16126:2012 Mechanical design of power transformers and reactors for power systems
ABNT NBR 14936:2006 Amendment 1:2012 Plugs and Sockets for household and similar use — adapters — specific requirements
ABNT NBR 14936:2012 Plugs and Sockets for household and similar use-adapters-specific requirements
ABNT NBR IEC 62474:2012 Statement of material for electrical and electronic equipment
ABNT NBR 16112:2012 Mounted connectors and optical adapters — determination of durability
ABNT NBR 16115:2012 Mounted connectors and optical adapters — Determination of the axial extension
ABNT NBR 16116:2012 Mounted connectors and optical adapters — determination of angular retention
ABNT NBR 16117:2012 Mounted connectors and optical adapters — determination of the axial retention
ABNT NBR 16118:2012 Mounted connectors and optical adapters — determination of twist
ABNT NBR 16119:2012 Mounted connectors and optical adapters — determination of folding
ABNT NBR IEC/CISPR 11:2012 Industrial, scientific and medical equipment – radio-frequency disturbance characteristics — limits and methods of measurement
ABNT NBR 16113:2012 Mounted connectors and optical adapters — Determination of the impact
ABNT NBR 16114:2012 Mounted connectors and optical adapters — determination of stability
ABNT NBR 16109:2012 Stationary lead-acid accumulator controlled by valve for application in uninterrupted power systems (UPS) — specification
ABNT NBR 16110:2012 Stationary lead-acid accumulator controlled by valve for application in uninterrupted power systems (UPS) — test method
ABNT NBR 14136:2002 Amendment 1:2012 Plugs and Sockets for domestic and similar use up to 20 A/250 V AC — Standardization
ABNT NBR 14136:2012 corrected version 4:2013 Plugs and Sockets for domestic and similar use up to 20 A/250 V AC-Standardization
ABNT NBR 10576:2012 Mineral insulating oil of electrical equipment — guidelines for supervision and maintenance
ABNT NBR 16094:2012 Polymeric accessories for overhead electrical distribution — specification
ABNT NBR 16095:2012 Polymeric accessories for overhead electrical distribution — Standardization
ABNT NBR 14106:2012 Optical cord
ABNT NBR 14703:2012 Telematics of 100 Ω cables for structured internal networks — specification
ABNT NBR 16093:2012 Flexible insulated conductors for internal links with rubber-silicone insulation for voltages up to 200° C and 750 V — performance requirements
ABNT NBR 13521:2012 Optical cables-determination of tensile breaking strength in optical cord — test method
ABNT NBR 16092:2012 Aerial baskets — specifications and tests
ABNT NBR IEC 60745-2-4:2012Portable electric motor operated tools — safety
Part 2-4: particular requirements for Sanders and polishing machines different from disk
ABNT NBR 16089:2012 Telephonic cable insulated with thermoplastic and cold cover protected core APL, applied for transmission of signals in xDSL technology
ABNT IEC/PAS 62596:2012 Electrical and electronic products — determination of restricted substances — sampling Procedure — Guidelines
ABNT NBR 16081:2012 Porcelain or glass insulator for voltages above 1 000 V DC — specification, test method and acceptance criteria
ABNT NBR IEC 60598-2-1:2012 Light fixtures Part 2: particular requirements — Chapter 1: fixed Luminaires for use in general lighting
ABNT NBR 14683-1:2012 Subduct systems of polyethylene (PE) for telecommunications infrastructure Part 1: requirements for external wall subduct lisa
ABNT NBR 15129:2012 Lamps for street lighting — particular requirements
ABNT NBR IEC 60085:2012 Electrical insulation – thermal evaluation and designation
ABNT NBR IEC 60749-23:2012 Semiconductor devices – mechanical and climatic test methods
Part 23: life in high temperature
ABNT NBR 5472:2012 Insulators for Electrotechnical — terminology
ABNT NBR 7117:2012 Resistivity measurement and determination of soil stratification
ABNT NBR IEC 60335-2-5:2012 Safety of household and similar appliances — Safety Part 2-5: particular requirements for dishwashers
ABNT NBR IEC 61189-3:2012 Test methods for electrical materials, interconnection structures and assemblies Part 3: test methods for interconnection structures (printed circuit boards)
ABNT NBR 6251:2012 corrected version: 2013 Power cables with extruded insulation for voltages from 1 kV to 35 kV — constructive Requirements
ABNT NBR IEC 60079-15:2012 Explosive atmospheres Part 15: protection of equipment type of protection "n"
ABNT NBR 16063:2012 Insulators for overhead lines for voltages above 1 000 V of — power arc test in insulators chains and reduced arrangements
ABNT NBR 12459:2012
Insulator-porcelain-pillar dimensions and characteristics
ABNT NBR 7103:2012 1 350 aluminum rods for electrical purposes-specification
ABNT NBR IEC 61189-5:2012 Test methods for electrical materials, interconnection structures and assemblies
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ABNT NBR 15688:2009 Amendment 1:2012 Air distribution systems of electric energy with bare conductors
ABNT NBR 15688:2012 corrected version: 2013 Air distribution systems of electric energy with bare conductors
ABNT NBR 7108-2:2012 Hardware standard insulators to jail members of glass and porcelain
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ABNT NBR IEC 60079-13:2012 Explosive atmospheres Part 13: equipment protection by pressurized environment "p"
ABNT NBR 16051:2012 Pre-formed metallic materials for air distribution networks of electricity — specification
ABNT NBR 16052:2012 Pre-formed metallic materials for air distribution networks of electricity — Standardization
ABNT NBR 8346:2012 Receptacles bases lamps — Classification
ABNT NBR IEC 60745-2-11:2012 Portable electric motor operated tools — safety
Part 2-11: particular requirements for Reciprocating Saws (tico-tico and sabre saw)
ABNT NBR 16050:2012 Lightning rod of non-linear metal-oxide resistor without sparklers, to AC power circuits
ABNT NBR 5101:2012 Street lighting — Procedure
ABNT NBR IEC 61400-12-1:2012 Wind generators Part 12-1: Measurements of wind turbine power performance
ABNT NBR IEC 62116:2012 Anti-ilhamento test procedure for inverters of photovoltaic systems connected to the grid
ABNT NBR 16028:2012
Type single mode optical fiber with low sensitivity the camber (BLI) — specification
ABNT NBR 16026:2012 Electronic control device DC or AC for LED modules – performance requirements
ABNT NBR 16027:2012 Aerial optical cable Figure 8 type autosustainable — specification
ABNT NBR IEC 61347-2-13:2012 Lamp control device Part 2-13: particular requirements for electronic control devices fed in c. c or c. for LED modules
ABNT NBR 13487:2012 Optical fiber type multimode graded index — specification

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ABNT NBR 15142:2012 Telephonic cable insulated with thermoplastic and cover protected core APL, applied for transmission of signals in xDSL technology
ABNT NBR 7274:2012 Gas analysis interpretation of power transformers in service
ABNT NBR 9146:2012 Wires and cables for telecommunications — applied electrical Voltage — test method
ABNT NBR 16024:2012 Cables for telecommunications — return loss — test method
ABNT NBR IEC 60745-2-3:2011 Portable electric motor operated tools — safety
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ABNT NBR IEC 60745-2-5:2011 Portable electric motor operated tools — safety Part 2-5: particular requirements for circular saws
ABNT NBR IEC 60079-25:2011 Explosive atmospheres
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ABNT NBR 16019:2011 Prefabricated electrical lines (armored buses) low voltage – requirements for installation
ABNT NBR IEC 60749-11:2011 Semiconductor devices-mechanical and climatic test Methods
Part 11: rapid Transfer of temperature-bath method in two fluids
ABNT NBR IEC 61967-1:2011 Integrated circuits – measurement of electromagnetic emissions, 150 kHz to 1 GHz
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ABNT NBR IEC 62132-1:2011 Integrated circuits — Measures of electromagnetic immunity, 150 kHz to 1 GHz
Part 1: General Conditions and definitions
ABNT NBR 16008:2011 Extension cords, power strips and protectors – particular requirements
ABNT NBR IEC 61000-4-6:2011 Electromagnetic compatibility (EMC)
Part 4-6: test and measurement techniques-immunity to conducted disturbances, induced by radio-frequency fields
ABNT NBR 14204:2011 Stationary lead-acid accumulator controlled by valve — specification
ABNT NBR 14205:2011 Stationary lead-acid accumulator controlled by valve — test method
ABNT NBR 14519:2011 Electric energy electronic meters — specification
ABNT NBR 14520:2011 Electric energy electronic meters-test method
ABNT NBR 14521:2011 Acceptance of lots of electronic electricity meters — Procedure
ABNT NBR 15992:2011 corrected version: 2013
Air distribution systems of electric power cables covered fixed at voltages up to 36.2 kV spacers
ABNT NBR 8182:2011 Power cables with extruded insulation autossustentados multiplexed of PE or XLPE, for voltages up to 0.6/1 kV — performance requirements
ABNT NBR IEC 61241-2-3:2011 Electrical apparatus for use in the presence of combustible dust
Part 2: test methods – section 3: method for determination of minimum ignition energy of dust mixes with the air
ABNT IEC/PAS 62545:2011 Environmental information for electrical and electronic equipment
ABNT NBR 11873:2011 Cables covered with polymeric material for air distribution systems of electric power fixed spacers, in 13.8 kV voltages to 34.5 kV
ABNT NBR 7108-1:2011 Hardware standard insulators to jail members of glass and porcelain Part 1: shell and ball type Coupling
ABNT NBR 10712:2011 Hawsers aluminum coated steel, naked, for airlines – Specification
ABNT NBR 10711:2011 Aluminum-clad steel wires for electrical purposes, nude — specification
ABNT NBR 15977:2011 Flexible cable, insulated with etilenopropileno rubber (EPR or HEPR) and covered with PVC STF, to 90° C and tensions to 750 V — specification
ABNT NBR IEC 60079-20-1:2011 corrected version 2:2014 Explosive atmospheres
Part 20-1: characteristics of substances for classification of gases and vapours-Test Methods and data
ABNT NBR 15956:2011 Polymeric crosspieces-specification, test methods, acceptance criteria and standardization
ABNT NBR 9133:2011 Cables for telecommunications — transmission signal attenuation — test method
ABNT NBR IEC 60050-426:2011 International Electrotechnical Vocabulary
Part 426: equipment for explosive atmospheres
ABNT NBR 10841:2011 Reinforced aluminum cables for aluminum coated steel wire for aerial lines-specification
ABNT NBR 13515:2011 Optical cables — — Vibration test method
ABNT NBR 13518:2011 Optical cables — Folding — test method
ABNT NBR 9129:2011 Cables for telecommunications — verification of the electrical continuity of the shielding — test method
ABNT NBR 9135:2011 Cables for telecommunications — cable folding — test method
ABNT NBR 15957:2011 Aluminum coated steel wires, to soul and reinforcement of aluminum cables — specification
ABNT NBR IEC 61189-2:2011 Test methods for electrical materials, interconnection structures and assemblies
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ABNT NBR 8459:2011 Wooden crosspieces-Dimensions
ABNT NBR IEC 60034-14:2011 Rotating electrical machines
Part 14: measurement, evaluation and limits of vibration severity of machines with shaft heights 56 mm or more
ABNT HSPM/QC 080000:2010 1:2011 Errata Management system for hazardous substances in electrical and electronic products and components – requirements
ABNT NBR IEC 60268-3:2010 Errata 1:2011 Sound systems equipment
Part 3: Amplifiers
ABNT IEC/TR 62476:2011 Guide to product evaluation with reference to the use of restricted substance in electrical and electronic products
ABNT NBR 8559:2010 Errata 1:2011 Solid insulating materials-determination of the electrical resistance and resistivity at high temperatures
ABNT NBR 7282:2011 High voltage fuses devices — expulsion type Devices — requirements and test methods
ABNT NBR 9131:2011 Cables for telecommunications — crosstalk test
ABNT NBR 9312:2011 Containers for fluorescent lamps and starters-Specification
ABNT NBR 8604:2011 Handling, handling, transportation and storage of wood packaging for Insulators — Procedure
ABNT NBR IEC 60079-29-2:2011 Explosive atmospheres
Part 29-2: gas detectors – selection, installation, use and maintenance of detectors for flammable gases and oxygen
ABNT NBR NM 244:2009 Amendment 1:2011 – Insulated cables sparking test
ABNT NBR NM 244:2011 – Insulated cables sparking test
ABNT NBR NM 280:2002 Amendment 1:2011 Conductors of insulated cables (IEC 60228, MOD)
ABNT NBR NM 280:2011 Conductors of insulated cables (IEC 60228, MOD)
ABNT NBR 9368:2011 Maximum voltage power transformers up to 145 kV — electrical and Mechanical Characteristics
ABNT NBR IEC 60947-4-2:2011 Maneuver and control devices of low voltage
4-2 part: contactors and motor-starting starting AC motor Controllers to semiconductors

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ABNT NBR IEC 60749-29:2011 Semiconductor devices – mechanical and climatic test Methods Part 29: latch-up test
ABNT NBR IEC 60749-26:2011 Semiconductor devices – mechanical and climatic test Methods
Part 26: electrostatic discharge (ESD)-human body model (HBM)
ABNT NBR IEC 60749-27:2011 Semiconductor devices-mechanical and climatic test Methods
Part 27: electrostatic discharge (ESD)-machine Model (MM)
ABNT NBR 11902:2011 Sulphur hexafluoride for electrical equipment-Specification
ABNT NBR 7307:2011 Electric wires and cables – embrittlement test
ABNT NBR 8186:2011 Application guide for insulation coordination
ABNT NBR 10299:2011 AC power cords and surge-statistical analysis of dielectric strength
ABNT NBR 10676:2011 Power supply the individual buildings in secondary voltage — air distribution network
ABNT NBR 15920:2011 Electric cables – calculation of the nominal current — operating conditions — economic Optimization of the sections of the cables
ABNT NBR IEC 61000-4-30:2011 Electromagnetic compatibility
Part 4-30: techniques of measurement and testing-methods of measurement of power quality
ABNT NBR 14418:2011 AC powered electronic ballasts for tubular fluorescent lamps-Performance Requirements
ABNT NBR 10506:2011 Silicone for electrical applications — verification of properties
ABNT NBR IEC 60749-25:2011 Semiconductor devices – mechanical and climatic test Methods Part 25: thermal cycling
ABNT NBR IEC 60749-30:2011 Semiconductor devices – mechanical and climatic test Methods
Part 30: preconditioning of surface mount devices not airtight, before tests for reliability
ABNT NBR IEC 62080:2011 Sound signaling device for household and similar use
ABNT NBR IEC 60998-2-2:2011 Connection device for low-voltage circuits for household and similar
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ABNT NBR 14417:2011 AC powered electronic ballasts for tubular fluorescent lamps — General and safety requirements
ABNT NBR IEC 60749-3:2011 Semiconductor devices – mechanical and climatic test Methods Part 3: external visual inspection
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ABNT NBR IEC 60749-6:2011 Semiconductor devices – mechanical and climatic test Methods Part 6: storage at high temperature
ABNT NBR 13593:2011 corrected version: 2013 Ballast and ignitor for sodium vapor lamp high pressure — specification and tests
ABNT NBR 7571:2011 Disconnectors-technical characteristics and dimensional
ABNT NBR 5060:2010 Guide for installation and operation of power capacitors-Procedure
ABNT HSPM QC/080000:2010 corrected version: 2011 Management system for hazardous substances in electrical and electronic products and components – requirements
ABNT NBR 10202:2010 Nominal voltage bushings of 72.5 kV-145 kV and 242 kV power transformers and reactors-electrical characteristics, dimensional and General construction
ABNT NBR 15910:2010 Portable electric motor operated tools — safety: particular requirements for band saws-marble
ABNT NBR 6865:2010 Enameled copper wire, row and covered with wax (litz wire) – requirements
ABNT NBR 9372:2010 Flexible control cables SO-M with insulation of ethylene-propylene rubber (EPR) for voltages up to 750 V — requirements and test methods
ABNT NBR 6864:2010 Enameled copper wire row – requirements
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ABNT NBR 6994:2010 Enameled copper wire, row and covered with one or two spirals (LITZ wire)-Specification
ABNT NBR 9114:2010 Flexible insulated conductors for internal links with rubber insulation Ethylpropylene (EPR) to 130° C and tensions to 750 V-Spec
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ABNT NBR 10298:2010 Aluminum-magnesium alloy cables-silicon, naked, to airlines — specification
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ABNT NBR NM 60317-13:2007 Specifications for particular types of winding wires Part 13: enamelled copper wire of circular cross-section, based on polyester or polyesterimide with polyamideimide, thermal 200 class (IEC 60317-13:1997, MOD)
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ABNT NBR 15214:2005 Errata 1:2006 Electric power distribution network-infrastructure sharing with telecommunications networks
ABNT NBR IEC 60050-444:2005 International Electrotechnical Vocabulary Part 444: elementary Relays
ABNT NBR IEC 60050-446:2005 International Electrotechnical Vocabulary Part 446: electrical Relays
ABNT NBR NM IEC 60811-3-1:2005 Errata 1:2005 Common test methods for insulating and sheathing materials of electric cables and ópitcos coverage Part 3: methods specific to PVC compounds-Chapter 1: pressure test at high temperature-tests for resistance to cracking
ABNT NBR IEC 60238:2005 corrected version: 2006 Edison screw lampholder
ABNT NBR NM 60669-1:2004 1:2005 Errata Switches for household and similar fixed electrical installation Part 1: General requirements (IEC 60669-1:2000, MOD)
ABNT NBR 14103:2005 Application dielectric optical cable buried
ABNT NBR 14160:2005 Dielectric aerial self-supported optical cable
ABNT NBR 15254:2005 Stationary lead-acid accumulator-Guidelines for sizing
ABNT NBR 15255:2005 Composite insulator units for jail, for airlines with voltage above 1 000 V-Classes of hardware and standard members
ABNT NBR NM 61008-1:2005 Differential-residual current switches for household and similar purposes without overcurrent protection device (RCCB) Part 1: General requirements (IEC 61008-1:1996, MOD)
ABNT NBR NM 61008-2-1:2005 Differential-residual current switches for household and similar purposes without overcurrent protection device (RCCB) Part 2-1: applicability of the General rules to RCCB's functionally independent of line voltage (IEC 61008-2-1:1990, MOD)
ABNT NBR 10621:2005 Insulators used in high-voltage systems in AC-artificial pollution tests
ABNT NBR 15237:2005 Sphere of daytime signaling for transmission lines of electricity-specification
ABNT NBR 15238:2005 Signaling system for transmission lines of electricity
ABNT NBR 6535:2005 Airlines signal transmission with the safety of the air inspection
ABNT NBR 7276:2005 Warning lightbar in transmission lines of electricity-Procedure
ABNT NBR 14039:2003 Amendment 1:2005 Electrical installations of medium voltage switchgear 1.0 kV to 36.2 kV
ABNT NBR 14039:2005 Electrical installations of medium voltage switchgear 1.0 kV to 36.2 kV
ABNT NBR 15214:2005 corrected version: 2006 Electric power distribution network-infrastructure sharing with telecommunications networks

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ABNT NBR 8371:2005 Askarel transformers and capacitors-characteristics and risks
ABNT NBR IEC 60050-161:2005 International Electrotechnical Vocabulary Chapter 161: Electromagnetic Compatibility
ABNT NBR 15204:2005 Semiconductor converter-uninterrupted power supply system with AC output (UPS)-security and performance
ABNT NBR 9115:2005 Phone cord FI insulated with polyvinyl chloride (PVC)-specification
ABNT NBR 9886:2005 Internal CCI-telephone cable Specification
ABNT NBR NM 60335-2-3:2005 Safety of household and similar appliances Part 2: particular requirements for electric irons, ironing (IEC 60335-2-3:1993 MOD)
ABNT NBR NM IEC 60332-1:2005 Methods of tests on electric cables under fire conditions Part 1: test on a single single insulated conductor or cable upright
ABNT NBR NM IEC 60332-3-10:2005 Test methods for electric cables under fire conditions Part 3-10: test for vertical flame spread of vertically bundles cables-test equipment
ABNT NBR NM IEC 60332-3-21:2005 Test methods for electric cables under fire conditions Part 3-21: test for vertical flame spread in conductors or cables into bundles mounted vertically-category A F/R
ABNT NBR NM IEC 60332-3-22:2005 Test methods for electric cables under fire conditions Part 3-22: test for vertical flame spread in conductors or cables into bundles mounted vertically-category A
ABNT NBR NM IEC 60332-3-23:2005 Test methods for electric cables under fire conditions Part 3-23: test for vertical flame spread in conductors or cables into bundles mounted vertically-category B
ABNT NBR NM IEC 60332-3-24:2005 Test methods for electric cables under fire conditions Part 3-24: test for vertical flame spread in conductors or cables into bundles mounted vertically-category C
ABNT NBR NM IEC 60332-3-25:2005 Test methods for electric cables under fire conditions Part 3-25: test for vertical flame spread in conductors or cables into bundles mounted vertically-category D
ABNT NBR NM IEC 60811-3-1:2005 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 3: methods specific to PVC compounds-Chapter 1: pressure test at high temperature-tests for resistance to cracking
ABNT NBR NM IEC 60811-3-2:2005 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 3: methods specific to PVC compounds Chapter 2: loss of mass test-thermal stability test
ABNT NBR NM IEC 60811-4-1:2005 Common test methods for insulating and sheathing materials of electric cables-coverage Part 4: methods specific to polyethylene and polypropylene compounds-Chapter 1: resistance to environmental stress cracking per share-winding test after thermal ageing in air-measurement of index of fluidity-determination of carbon black and/or mineral loading in polyethylene
ABNT NBR IEC 60156:2004 Insulating liquids-determination of dielectric strength at industrial frequency-test method
ABNT NBR IEC 60998-1:2004 Connecting devices for low-voltage circuits for household and similar Part 1: General requirements
ABNT NBR NM 60335-2-45:2004 corrected version: 2013 Safety of household and similar appliances Part 2: particular requirements for mobile heating tools and similar appliances (IEC 60335-2-45:1996, MOD)
ABNT NBR 15149:2004 Subduct polyethylene systems for telecommunications-verification of tensile strength of corrugated subdutos
ABNT NBR IEC 61058-1:2004 Switches for appliances Part 1: General requirements
ABNT NBR NM 60669-1:2004 Switches for household and similar fixed electrical installation Part 1: General requirements (IEC 60669-1:2000, MOD)
ABNT NBR 5410:2004 corrected version: 2008 Low-voltage electrical installations
ABNT NBR IEC 60439-2:2004 Sets and low-voltage control Part 2: particular requirements for prefabricated electrical lines (armoured bus systems)
ABNT NBR 15110:2004 Optical cable with dielectric and metal protection for core application buried
ABNT NBR 15121:2004 For high-voltage insulator-radio interference measurement test
ABNT NBR 15124:2004 Porcelain or glass insulator for voltages above 1 000 V-perforation test under boost
ABNT NBR NM 60898:2004 Circuit-breakers for overcurrent protection for household and similar installations (IEC 60898:1995, MOD)
ABNT NBR 14566:2004 Dielectric optical cable for underground application in air and duct espinado
ABNT NBR 15108:2004 Optical cable with dielectric and metal protection for core application in pipeline lines
ABNT NBR NM IEC 60335-2-8:2004 Safety of household and similar appliances Part 2: particular requirements for electric shavers, hair clippers and similar appliances
ABNT NBR 14702:2001 Amendment 1:2004 Flexible coaxial cables with 75 Ω impedance-specification
ABNT NBR 14702:2004 Flexible coaxial cables with 75 Ω impedance to broadband networks-specification
ABNT NBR 14770:2001 Amendment 1:2004 Coaxial cables 75 Ω impedance hard for broadband networks-specifications
ABNT NBR 14770:2004 Coaxial cables 75 Ω impedance hard for broadband networks-specifications
ABNT NBR IEC 60439-3:2004 Sets and low-voltage control Part 3: particular requirements for installation of low voltage accessories intended for the installation in places accessible to people not qualified for your use-distribution boards
ABNT NBR 10511:2004 Residual mechanical strength test for string insulator units of ceramic or glass after mechanical damage of the dielectric
ABNT NBR NM 274:2001 1:2004 Errata Insulated flexible cables with silicone rubber bounce and Multipole-polar with cover, heat resistant, for rated voltages up to and including 450/750 V
ABNT NBR 15014:2003 Semiconductor converter-uninterrupted power supply system, with AC output (UPS)-Terminology
ABNT NBR 15001:2003 Appliance appliance fixed instant water heating-Determination of energy efficiency
ABNT NBR IEC 60269-3-1:2003 Devices-low-voltage fuses Part 3-1: supplementary requirements for fuses for use devices by unskilled persons (fuses mainly use devices and similar domestic)-sections I to IV
ABNT NBR NM IEC 60811-1-4:2003 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 1: methods for general application-Chapter 4: Tests at low temperatures
ABNT NBR NM IEC 60811-2-1:2003 Common test methods for insulating and sheathing materials of electric and optical cables-coverage Part 2: methods specific to elastomeric materials-chapter 1: trials of ozone resistance, hot set and mineral oil immersion
ABNT NBR 14977:2003 Fiber optics-determination of optical loss in amendment by backscatter
ABNT NBR 14532:2000 Amendment 1:2003 Household and similar appliances-Safety-particular requirements for ceiling fans
ABNT NBR IEC 60439-1:2003 Sets and low-voltage control Part 1: type test assemblies with fully tested (TTA) and partially type assemblies with test tested (PTTA)
ABNT NBR 13937:1997 Errata 1:2002 Enameled copper wire of circular cross-section, based on modified polyester, covered with poliamidaimida-thermal Class 200° C-specification
ABNT NBR 14897:2002 Cables and flexible cords insulated with polyvinyl chloride (PVC), for special applications in appliances, devices connectors cords in tensions up to 500 V
ABNT NBR 14898:2002 Insulated flexible cables with etilenopropileno rubber (EPR), for special applications in appliances, devices connectors cords in tensions up to 500 V
ABNT NBR NM IEC 60335-2-10:2002 Safety of household and similar appliances Part 2-10: particular requirements for floor treatment machines and wet rubbing washing

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ABNT NBR NM 247-1:2002 corrected version: 2011 Insulated cables with policroreto chloride (PVC) for rated voltages up to 450/750 V Part 1: General requirements (IEC 60227-1, MOD)
ABNT NBR NM 247-2:2002 corrected version: 2011
Insulated cables with polyvinyl chloride (PVC) for nominal voltage up to 450/750 V, including Part 2: methods of test (IEC 60227-2, MOD)
ABNT NBR NM IEC 60983:2002 Miniature lamps
ABNT NBR 5383-1:2002 Rotating electrical machines Part 1: three-phase induction motors-Essays
ABNT NBR NM 247-3:2002 corrected version: 2002 Insulated cables with polyvinyl chloride (PVC) for rated voltages up to and including 450/750 V
Part 3: isolated Conductors (without cover) for fixed wiring (IEC 60227-3, MOD)
ABNT NBR NM IEC 60335-2-13:2002 Safety of household and similar appliances Part 2-13: particular requirements for deep fryers, frying pans and similar appliances
ABNT NBR NM IEC 60335-2-2:2002 Safety of household and similar appliances Part 2-2: particular requirements for vacuum cleaners and water suction cleaning
ABNT NBR NM IEC 60335-2-23:2002 Safety of household and similar appliances Part 2-23: particular requirements for appliances for skin or hair care
ABNT NBR NM IEC 60335-2-9:2002 Safety of household and similar appliances Part 2-9: particular requirements for tostadores, "grills", roasters and similar appliances
ABNT NBR NM 274:2001 Insulated flexible cables with silicone rubber bounce and Multipole-polar with cover, heat resistant, for rated voltages up to and including 450/750 V
ABNT NBR 13511:2001 Optical fibers and cables-chemical attack to test optical fiber dyed-test method
ABNT NBR 13519:2001 Optical fibers and cables-test of thermal cycles in optical fiber dyed-test method
ABNT NBR 9888:2001 Telephonic cable insulated with thermoplastic and geleado cover protected core APL-specification
ABNT NBR 9889:2001 Phone cord CIP-APL, insulated with thermoplastic, covers protected core APL and self-sustained by strand of steel-specification
ABNT NBR NM IEC 60811-1-1:2001 Common test methods for insulating and sheathing materials of electric cables-coverage
Part 1: methods for general application-Chapter 1: measurement of thickness and external dimensions-Tests for determining the mechanical properties
ABNT NBR NM IEC 60811-1-2:2001 Common test methods for insulating and sheathing materials of electric cables-coverage
Part 1: methods for general application-Chapter 2: thermal ageing methods
ABNT NBR NM IEC 60811-1-3:2001 Common test methods for insulating and sheathing materials of electric cables-coverage
Part 1: methods for general application-Chapter 3: methods for determining the density-water absorption tests-shrinkage Test
ABNT NBR 14684:2001 Subduct polyethylene systems for telecommunications-determination of density of plastics by displacement
ABNT NBR 14685:2001 Subduct polyethylene systems for telecommunications-determination of carbon black
ABNT NBR 14686:2001 Subduct polyethylene systems for telecommunications-verification of dispersion of pigments
ABNT NBR 14687:2001 Subduct polyethylene systems for telecommunications-rsistence check to crushing
ABNT NBR 14688:2001 Subduct polyethylene systems for telecommunications-determination of dimensional stability
ABNT NBR 14689:2001 Subduct of polietilleno systems for telecommunications-verification of resistance to impact
ABNT NBR 14690:2001 Subduct polyethylene systems for telecommunications-verification of internal hydrostatic pressure resistance
ABNT NBR 14691:2001 Subduct polyethylene systems for telecommunications-determination of dimensions
ABNT NBR 14692:2001 Subduct polyethylene systems for telecommunications-determination of oxidation induced time
ABNT NBR 14693:2001 Subduct polyethylene systems for telecommunications-rsistance to compression check
ABNT NBR 14694:2001 Subduct polyethylene systems for telecommunications-verification of resistance to artificial weathering
ABNT NBR 14695:2001 Subdutos polyethylene systems for telecommunications-resistance check the curvature
ABNT NBR 14704:2001 External phone cord binado FEB-specification
ABNT NBR 14706:2001 Optical cables, wires and telephone cables-determination of ultraviolet absorption coefficient-test method
ABNT NBR 9116:2001 External phone cord FE, insulated with polyvinyl (PVC), polyethylene (PE) or copolymer-specification
ABNT NBR 9123:2001 FDG insulated phone cord with polyvinyl chloride (PVC)-specification
ABNT NBR 6814:1985 Errata 1:2001 Electric wires and cables-electrical resistance test
ABNT NBR 6939:2000 Coordination of isolation-Procedure
ABNT NBR 11880:2000 Telephonic cable insulated with thermoplastic expanded, core filled with jelly and protected-specification
ABNT NBR 14602:2000 Optical fiber dispersion single mode type taken off-specification
ABNT NBR 14603:2000 Sampling and factory inspection of optical fibers-Procedure
ABNT NBR 14604:2000 Optical fiber dispersion-shifted single mode type and non-null-specification
ABNT NBR 14607:2000 Telephonic cable insulated with thermoplastic expanded and protected by cover core APL-specification
ABNT NBR 14613:2000 Telephone-wire tensile strength and elongation under tension the wire FEB-dielectric test method
ABNT NBR 13489:2000 Fiber optics-determination of bandwidth-test method
ABNT NBR 13490:2000 Fiber optics-determination of numerical aperture-test method
ABNT NBR 13491:2000 Fiber optics-determination of optical attenuation-test method
ABNT NBR 13492:2000 Fiber optics-determination of cutoff wavelength-test method
ABNT NBR 13493:2000 Fiber optics-determination of modal field diameter-test method
ABNT NBR 13502:2000 Fiber Optics-Optical attenuation uniformity check-test method
ABNT NBR 13503:2000 Fiber optics-mechanical constant-voltage test test method
ABNT NBR 13504:2000 Fiber optics-determination of chromatic dispersion-test method
ABNT NBR 13520:2000 Óptical fibre-determination of optical attenuation variation-test method
ABNT NBR 14584:2000 Optical cable with metal protection for underground facilities-verification of susceptibility to damage caused by atmospheric discharge-test method
ABNT NBR 14585:2000 Optical cables-determination of strength of DPE cable duct removal-test method
ABNT NBR 14587-1:2000 Fiber optics-measurement of polarization mode dispersion Part 1: spectral Scan-test method
ABNT NBR 14587-2:2000 Fiber optics-measurement of polarization mode dispersion Part 2: Method interferométrico-test method
ABNT NBR 14588:2000 Fiber optics-Determination of bending-test method
ABNT NBR 14589:2000 Optical cable with metal protection for underground installations-determination of current drain capacity-test method
ABNT NBR 14591:2000 Fiber optics-thermal cycle-test method
ABNT NBR 14538:2000 Fluorescent lamp with integrated ballast to base for general lighting – safety requirements
ABNT NBR 14539:2000 Fluorescent lamp with integrated ballast for general lighting based-performance requirements
ABNT NBR 13500:1999 Fiber optics-geometrical parameters Determination of coating-test method
ABNT NBR 13505:1999 Fiber optics-determination of length-test method

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ABNT NBR 14422:1999 Fiber optics-determination of geometric parameters of optical fiber-test method
ABNT NBR 9124:1999 corrected version: 2000 Telephonic cable insulated with thermoplastic and cover protected core APL-specification
ABNT NBR 9154:1999 Sampling and factory inspection of wires and telephone cables-Procedure
ABNT NBR IEC 60598-2-19:1999 Light fixtures Part 2: particular requirements-Chapter 19: light fixtures to air-conditioning systems (safety requirements)
ABNT NBR 9124:1999 Errata 1:2000 Telephonic cable insulated with thermoplastic and cover protected core APL-specification
ABNT NBR 5314:1999 Plastic spools for winding wire-packing Specification
ABNT NBR 9142:1999 Wires and telephone cables-test of resistance to cracking-test method
ABNT NBR 9143:1999 Wires and telephone cables-contraction tests-test method
ABNT NBR 9144:1999 Wires and telephone cables-check the electrical continuity and contact-test method
ABNT NBR 9134:1998 Optical cables and test phone grip tape APL-test method
ABNT NBR 9136:1998 Optical cables and telephone penetration test of moisture test method
ABNT NBR 9137:1998 Optical cables and pressurization test phone-test method
ABNT NBR 9138:1998 Telephone cables-capacitive unbalance test-test method
ABNT NBR 9140:1998 Optical cables and wires and telephone cables-color comparison test-test method
ABNT NBR 9141:1998 Optical cables and wires and telephone cables-testing of traction and stretching to break-test method
ABNT NBR 9148:1998 Optical cables and wires and telephone cables-accelerated aging test-test method
ABNT NBR 9149:1998 Telephone cables-flow Testing of the filling compound-test method
ABNT NBR 14201:1998 Alkaline nickel-cadmium accumulator stationary-specification
ABNT NBR 14202:1998 Alkaline nickel-cadmium accumulator stationary-Essays
ABNT NBR 14221:1998 Insulator-cylinder of glass or porcelain-units and columns-Standardization of dimensions and characteristics
ABNT NBR 6524:1997 Amendment 1:1998 Wire and cables of copper hard and a little stiff with or without protective cover for aerial installations
ABNT NBR 6524:1998 Wire and cables of copper hard and a little stiff with or without protective cover for aerial installations
ABNT NBR 6882:1998 Insulator-porcelain pedestal-support units and columns-Standardization of dimensions and characteristics
ABNT NBR 6983:1998 Copper wire of rectangular or square section, enamelled or not, covered with one or two whorls of fiberglass-polyester, thermal class 155° C specification
ABNT NBR 10510:1998 Insulator-porcelain Rod-Standardization of dimensions and characteristics
ABNT NBR 7110:1998 PIN insulator made of porcelain or glass-Standardization of dimensions and characteristics
ABNT NBR 13910-3:1998 Errata 1:1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 3: procedures for determining and verifying declared noise emission values
ABNT NBR 14159:1998 Optical cable with cold cover protected core APL-specification
ABNT NBR 14161:1998 Emergency-dielectric optical cable Specification
ABNT NBR 13910-2-2:1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 2: particular requirements for hair dryers
ABNT NBR 13910-2-3:1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 2: particular requirements for blenders
ABNT NBR 13910-3:1998 corrected version: 1998 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 3: procedure for determining and verifying declared noise emission values
ABNT NBR 14104:1998 Sampling and inspection in the factory of cables and optical cords-Procedure
ABNT NBR 5282:1998 Shunt power capacitors for nominal voltage above 1 000 V
ABNT NBR 8603:1998 Internal fuses for power capacitors-performance requirements and tests
ABNT NBR 8763:1998 Series capacitors for power systems
ABNT NBR 7095:1981 Errata 1:1998 Electrotechnical fittings for transmission lines and substations, high voltage and extra high voltage
ABNT NBR IEC 60061-1:1998 Bases of lamps, lamps, as well as feedbacks for the control of interchangeability and safety Part 1: lamp Bases
ABNT NBR 14075:1998 Cord-determination of optical fiber optic doformação for optical cord pull
ABNT NBR 14076:1998 Optical cables-Determination of the wavelength of single mode fiber wired-test method
ABNT NBR 5429:1977 Errata 2:1998 Sampling plans and procedures for inspection by variables
ABNT NBR 7312:1998 Rolls of wires and electrical cables-dimensional features
ABNT NBR 13975:1997 Fiber optics-determination of strength of coating-extraction method
ABNT NBR 14012:1997 Instant water heaters and electric taps-verification of resistance to wear or marking removal-test method
ABNT NBR IEC 60809:1997 Filament lamps for automotive vehicles-dimensional, electrical and luminous Requirements
ABNT NBR 13974:1997 Optical cables-determination of air-resistance test method
ABNT NBR 13976:1997 Optical cables-Immersion test method
ABNT NBR 13977:1997 Optical cables-Determination of the oxidative induction time (OIT)-test method
ABNT NBR 13978:1997 Optical cables-cable Pull-test method
ABNT NBR 13989:1997 Optical cable underground – determination of performance when subjected to the test of coefficient of static friction-test method
ABNT NBR 13990:1997 Optical cable underground – determination of performance when subjected to vibration-test method
ABNT NBR IEC 61167:1997 Metallic vapor lamps (halides)
ABNT NBR 13942:1997 Enameled aluminum wire of circular cross-section based on modified Polyester-180° C thermal Class-specification
ABNT NBR 8661:1997 Cables with extruded insulation plan format of polyvinyl chloride (PVC) for voltage up to 750V-specification
ABNT NBR 8762:1997 Extra-flexible cables for electric arc-welding machines and other applications-specification
ABNT NBR 9511:1997 Electric cables-minimum bending Radii for installation and minimum diameter reel cores for packaging
ABNT NBR 13910-1:1997 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 1: General requirements
ABNT NBR 13910-2-1:1997 Test guidelines for the determination of acoustic noise of aircraft appliances and similars Part 2: particular requirements for refrigerators, freezers, combined and similar
ABNT NBR 5416:1997 Application of loads in power transformers-Procedure
ABNT NBR IEC 60081:1997 Tubular fluorescent lamps for general lighting
ABNT NBR 5111:1997 Bare copper wires, of circular cross-section, for electrical purposes
ABNT NBR 5368:1997 Soft tinned copper wire for electrical purposes-specification
ABNT NBR IEC 60662:1997 Sodium vapor lamps high pressure
ABNT NBR 5349:1997 Naked soft copper cables for electrical purposes-specification
ABNT NBR IEC 60901:1997 Basic fluorescent lamps-Performance Requirements

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ABNT NBR IEC 60360:1996 Standard method for determining the temperature increase of the lamp base
ABNT NBR 5125:1996 Ballast for mercury vapor lamp high pressure
ABNT NBR 5170:1996 Ballast for mercury vapor lamp high pressure-Tests
ABNT NBR 13570:1996 Electrical installations in crowds-specific requirements
ABNT NBR 13571:1996 Copper steel grounding rod and accessories-specification
ABNT NBR 13486:1995 Fiber optics-Terminology
ABNT NBR 13508:1995 Optical cables-bend test
ABNT NBR 13509:1995 Optical cables-impact test
ABNT NBR 8377:1995 Active power meter-specification
ABNT NBR 8378:1995 Active power meter-test method
ABNT NBR 13418:1995 Fire resistant cables for security installations-specification
ABNT NBR 6245:1995 Electric wires and cables-determination of oxygen content
ABNT NBR 13223:1994 Telephone cables-cable pull-test test method
ABNT NBR 5462:1994 Reliability and maintainability with
ABNT NBR 7288:1994 Power cables with extruded solid insulation of polyvinyl chloride (PVC) or polyethylene (PE) for 1 kV voltages the 6 kV
ABNT NBR 9375:1994 Power cables with solid insulation extrututada etilenopropileno rubber (EPR), for mobile equipment links to 3 kV voltages the 25 kV-specification
ABNT NBR 13018:1993 Rope to work on energized installation-Transmission-specification
ABNT NBR 12694:1992 Specifying colors according to the Munsell notation system-specification
ABNT NBR 12479:1992 Shunt power capacitors, for nominal voltage above 1000 V-electrical characteristics and constructive-Standardization
ABNT NBR 5460:1992 Electrical power systems
ABNT NBR 11855:1991 Insulating platform to work on energized distribution networks-specification
ABNT NBR 11857:1991 Shielded cable for provisional jampe for aerial energized up to 15 kV-specification
ABNT NBR 11858:1991 Device for washing equipment energized distribution network-specification
ABNT NBR 12132:1991 Telephone cables-compression test-test method
ABNT NBR 12133:1991 Electrical insulating liquids – Determination of the dielectric loss factor and relative permittivity (dielectric constant)-test method
ABNT NBR 12134:1991 Mineral insulating oil-determination of 2.6-di-tertiary butyl para--test method
ABNT NBR 12135:1991 Mineral insulating oil inhibited-determination of oxidation stability-test method
ABNT NBR 12139:1991 Electric wires and cables-test for determining the toxicity index of gases developed during combustion of polymeric materials-test method
ABNT NBR 5461:1991 Lighting
ABNT NBR 11835:1991 Accessories plug-in power cables insulated for 15 kV voltages the 35 kV-specification
ABNT NBR 11809:1991 Voltage regulators-specification
ABNT NBR 11633:1990 Electric wires and cables-test for determination of degree of acidity of gases developed during combustion of components-test method
ABNT NBR 12454:1990 Maximum voltage power transformers up to 36, 2kV and power of 225 kVA up to 3750 kVA-Standardization
ABNT NBR 12460:1990 Nominal voltage 15 kV bushings, 24.2 kV and 36.2 kV power transformers and reactors-Standardization
ABNT NBR 7036:1990 Receipt, installation and maintenance of power distribution transformers, immersed in insulating liquids
ABNT NBR 5370:1990 Copper connectors for conductors in electrical power systems
ABNT NBR 11300:1990 Electric wires and cables-determination of density of smoke emitted in burning conditions-test method
ABNT NBR 6869:1989 Electrical insulating liquids – determination of the dielectric strength (electrodes)
ABNT NBR 5779:1989 Mineral insulating oils-qualitative determination of chlorides and sulfates, inorganic
ABNT NBR 10860:1989 Three-pole keys for distribution networks-laden Operation-specification
ABNT NBR 7277:1988 Transformers and reactors-determining the noise level
ABNT NBR 5438:1987 Bushing for transformers-1.3 kV nominal voltage, 2000, 3150, the 5000-dimensions
ABNT NBR 5471:1986 Electrical conductors
ABNT NBR 5474:1986 Electric connector
ABNT NBR 5474:1980 Amendment 1:1986 Electrotechnics and electronics-electrical connectors
ABNT NBR 6814:1985 Amendment 1:1986 Electric wires and cables-electrical resistance test
ABNT NBR 6814:1986 corrected version: 2001 Electric wires and cables-electrical resistance test
ABNT NBR 9029:1985 Use of relays for Busbar protection in power system-Procedure
ABNT NBR 5422:1985 Airline project of electric power transmission
ABNT NBR 5437:1984 Bushing for conservative oil transformers-1.3 kV nominal voltage-160, 400, 800 A-Dimensions
ABNT NBR 8449:1984 Design of lightning conductor cables for overhead lines of electric-power transmission Procedure
ABNT NBR 5052:1984 Synchronous machine-Essays
ABNT NBR 5310:1982 Plastic materials for electrical purposes-determination of water absorption
ABNT NBR 7303:1982 Aluminum electrical conductors-fluency in aluminium conductors
ABNT NBR 7095:1981 corrected version: 1998 Electrotechnical fittings for transmission lines and substations, high voltage and extra high voltage
ABNT NBR 6811:1981 Electric wire and cable-grip test and continuity in tinned copper wires
ABNT NBR 6813:1981 Electric wires and cables-insulation resistance Test
ABNT NBR 5079:1975 Amendment 1:1976 Enameled copper wire of circular cross-section weldable polyurethane base covered with nylon, thermal class 130° C

Source: ABNT. Elaborated by CCGI-EESP/FGV.

Table 25 - Regulation Electrical Products (Argentina)

NAME	THEME
LAW 19587/72	Hygiene and safety at work
DECREE 351/79	Amends law 19587
DECREE 911/96	Amends law 19587
RESOLUTION 197/04	Provides models of conformity assessment
RESOLUTION 171/16	Defines technical expressions and prescribes the certification of low voltage electrical products

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REGULATION AEA 90364-7-701	Bathrooms and places with baths, showers and other objects with water emitting taps
REGULATION AEA 90364-7-771	Regulation for the execution of electrical facilities on property – homes, offices and premises
REGULATION AEA 90364-0	Regulation for the execution of electric facilities on property – guide of application
REGULATION AEA 90364-1	Regulation for the execution of electric facilities on property – reach, object and fundamental principles
REGULATION AEA 90364-2	Regulation for the execution of electric facilities on property – definitions
REGULATION AEA 90364-3	Regulation for the execution of electric facilities on property – determination of general features of the facilities
REGULATION AEA 90364-4	Regulation for the execution of electric facilities on property – protections to preserve safety
REGULATION AEA 90364-5	Regulation for the execution of electric facilities on property – election and installation of electric materials
REGULATION AEA 90364-6	Regulation for the execution of electric facilities on property – verification of electric facilities (initial and periodicals) and its maintenance
REGULATION AEA 90706	Guide to the management of maintenance of facilities
REGULATION AEA 90364-7-712	Photovoltaic panels
REGULATION AEA 90364-7-710	Regulation for the execution of electric facilities on property – places for medical uses and external rooms
REGULATION AEA 90364-7-718	Regulation for the execution of electric facilities on property – places of public competition
REGULATION AEA 90364-7-770	Unifamiliar homes (until 63 A – classifications BA2 and BD1)
REGULATION AEA 90364-7-779 IRAM 36066	Particular rules for facilities on special places – section 779: modules of concentrated installation of minimum electrification
REGULATION AEA 90364-7-780	Regulation for the execution of electric facilities on property part 7: particular rules for facilities in special places section 780: electric facilities of automatization of buildings
REGULATION AEA 90790	Protection against electric atmospheric discharges on charge stations of liquid and gas fuel
REGULATION AEA 90865-1 IRAM 60865-1	Short circuit currents – calculation of the effects. Part 1 – definitions and methods of calculation
REGULATION AEA 90890-1	Method for the verification by calculation of the increase of temperature on boards BT. Part 1: natural ventilation
REGULATION AEA 90909-0	Short circuit currents on triphasic systems of alternative current – normative document. Calculation of currents
REGULATION AEA 90909-1	Short circuit currents on triphasic systems of alternative current – technical inform. Factors for the calculation
REGULATION AEA 91140	Protection against electric shocks. Common aspects to facilities and its components, materials and equipment
REGULATION AEA 90079-10-1	Explosive atmospheres. Part 10 – classification of áreas – sec. 1 – explosive gas atmospheres
REGULATION AEA 90079-10-2	Explosive atmospheres. Part 10 – classification of areas – sec. 2 – dust explosive atmosphere
REGULATION AEA 90079-14. AEA 90079-17	Explosive atmospheres. Part 14, project, selection and building of electric facilities. Explosive atmospheres. Part 17, inspection and maintenance of electric facilities.
REGULATION AEA 90364-8	Regulation for the execution of electric facilities on property – part 8 energetic efficiency on electric facilities of low tension. Section 1 – general requirements of energetic efficiency.
REGULATION AEA 91340-1	Regulation about electrostatic technical inform part 1 electrostatic phenomena – principles and measurements
REGULATION AEA 92305-1 IRAM 2184-1	Protection against thunders. Evaluation of risk.
REGULATION AEA 92305-3 IRAM 2184-3	Protection against thunders. Physical damage to structure and human risk.
REGULATION AEA 92305-4 IRAM 2184-4	Protection against thunders. Electric and electronic systems in structures.
REGULATION AEA 92305-11 IRAM 2184-11	Protection against thunders. Guide for the election of the systems of protection against thunders (SPCR).
REGULATION AEA 92559-1	Smart electric networks. Part 1 guide of concepts, benefits and challenges for its implementation
REGULATION AEA 92606	Regulation for the protection against the electric arc. Calculation of representative magnitudes of thermal effects and its protection
REGULATION AEA 95101	Regulation for external electric lines in general – underground facilities of energy and of telecommunications
REGULATION AEA 95150	Regulation for the execution of electric facilities of submission and measurement in low tension
REGULATION AEA 95201	Regulation of external air lines of low tension
REGULATION AEA 95301	Regulation of external air lines of medium and high tension
REGULATION AEA 95401	Regulation about transformation centers and submission in medium tension
REGULATION AEA 95402	Regulation for transformative stations
REGULATION AEA 95702	Regulation for the execution of works with tension in electric facilities higher than 1 kV
REGULATION AEA 95703	Regulation for the execution of electric facilities of public lighting
REGULATION AEA 95704	Regulation for the signaling of electrical facilities on public track. Includes the application guide
REGULATION AEA 95705	Regulation for the execution of works with tension on electrical facilities of low tension
MERCOSUL GMC RESOLUTION 18/98	Working plan of the safety commission of electrical products of SGT nº 3 “technical regulations”

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MERCOSUL RESOLUTION 42/01	**GMC**	Windows of energized functioning
MERCOSUL RESOLUTION 4/09	**GMC**	Cables and electrical conductors of low tension
MERCOSUL RESOLUTION 4/10	**GMC**	Light switchers for fixed electrical facilities

Source: Argentina. Elaborated by CGTI-EESP/FGV.

Table 26 - Standards of Electrical Appliances (Argentina)

NUMBER	TITLE
IRAM - 2004	Electrical copper conductors hard, for air power and put lines to land.
IRAM - 2011	Annealed copper wires. For electrical conductors.
IRAM - 2012	Method of verification of the mechanical characteristics of the insulation of conductors (rubber or substitutes).
IRAM-2021-2	Electric heaters for environments. Performance requirements.
IRAM - 2026	Electrical insulating materials. New insulating mineral oils for transformers and equipment of maneuver.
IRAM - 2028	Insulating mass of bituminous nature for wiring boxes.
IRAM - 2031	Method of verification of the finish of the fibrous cap of electrical conductors. Insulated with rubber or substitutes.
IRAM - 2034	Starters and regulators rheostats for electric motors.
IRAM - 2042	Electric thermostats.
IRAM - 2052	Plugs for electrical heating appliances. Bipolar, non-effective ground and nominal voltage of 220 V.
IRAM-2053-1	Identification of electrical terminals and terminals. General rules for marking with alpha-numeric notation.
IRAM-2053-2	Electrical conductors. Insulated and bare. Identification by numbers or colors.
IRAM - 2061	Distilled water to electric storage batteries.
IRAM - 2064	Connectors of electric heating appliances. Bipolar grounded for home use and effective nominal voltage of 220 V.
IRAM - 2065	Plugs for electrical heating appliances. Bipolar, with effective ground and nominal voltage of 220 V socket.
IRAM - 2076	Electrical connectors. General requirements.
IRAM - 2081	Multipliers series and shunts for indicators electrical instruments.
IRAM - 2082	Humidity Chamber grade B. For testing of materials and electrical appliances.
IRAM - 2089	Humidity Chamber grade A. For testing of materials and electrical appliances.
IRAM - 2090	Lead and alloys of lead for pods and electrical cables.
IRAM - 2093	Small power electric motor. Test methods.
IRAM - 2094	Single-phase asynchronous electric motors.
IRAM - 2101	AC voltage dielectric test equipment.
IRAM-2103-1	Solid Electric insulating materials. Determination of the dielectric. Trials at industrial frequencies.
IRAM-2103-2	Solid electric materials. Determination of the dielectric. Additional requirements for testing to DC voltage.
IRAM-2103-3	Solid Electric insulating materials. Dielectric tests. Additional requirements for impulse tests.
IRAM - 2105	Transformers for transport and distribution of electrical energy. Levels of insulation and dielectric tests.
IRAM-2107-1	Solid Electric insulating materials. Methods of test of cross resistance and the surface.
IRAM - 2109	Small power electric motor. Three-phase induction.
IRAM - 2114	Solid Electric insulating materials. Determinations of the permittivity (dielectric constant) and dissipation factor. Frequency industrial, audio and radio frequency, including VHF.
IRAM - 2117	Lead oxides for electric accumulators and lead to their obtaining.
IRAM-2118-2	Electric fans and their speed controllers. Performance requirements.
IRAM - 2119	Stationary electric accumulators. Lead-acid, type planted.
IRAM - 2125	Polyphase Induction Motors. General test methods.
IRAM - 2126	Small power electric motor. Dimensions.
IRAM - 2129	Small power electric motor. Universal and direct current.
IRAM-2141-3	Electric washing machine. Part 3 - Energy efficiency labelling.
IRAM - 2144	Registrars electric instruments.
IRAM - 2162	Indicators electric instruments, Board. Dimensions.
IRAM-2178-1	Cables insulated with dielectric solid extruded for rated voltages from 1 kV (Um = 1,2 kV) up to 33 kV (Um = 36 kV). Part 1 - Wire power, control, signalling and command for nominal voltages from 0.6/1 kV (Um = 1,2 kV).
IRAM-2178-2	Cables insulated with dielectric solid extruded for rated voltages from 1 kV (Um = 1,2 kV) up to 33 kV (Um = 36 kV). Part 2 - For nominal voltages of 3.3 kV power Cables (3.6 kV) up to 33 kV (36 kV).
IRAM - 2182	Diesel electric generators. Fundamental requirements.
IRAM-2184-4	The lightning protection. Part 4 - Electrical and electronic systems in structures.
IRAM - 2189	Ingots of aluminium for the manufacture of electrical conductors. Chemical composition.
IRAM - 2192	Electric induction motors. Main measures and ratings.
IRAM - 2195	Switchboards, control and command under metal roof. Dielectric tests.
IRAM - 2200	Switchboards, control and command under metal roof.
IRAM - 2212	Aluminum alloy conductors. For overhead power lines.
IRAM - 2217	Thermoplastic materials of synthetic rubber for coating of electrical cables with metallic sheath.
IRAM - 2219	Single embedding box for single-phase electric meters.
IRAM - 2239	Electrical extension cords for household and similar, shutters and no blinds.
IRAM-2281-1	Grounding of electrical systems. General considerations. Code of practice.
IRAM-2281-2	Grounding of electrical systems. Guide for measurement of magnitudes of grounding (resistance, resistivity, and gradients).

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IRAM-2281-3	Grounding of electrical systems. Installations with nominal value less than or equal to 1 kV. Part 3 - Code of practice.
IRAM-2281-4	Grounding of electrical systems. Installations with rated voltages of 1 kV. Part 4 - Code of practice.
IRAM-2281-8	Grounding of electrical systems. Part 8 - Grounding brackets and appliances for use electric in public with nominal value lower or equal to 1 kV. Code of practice.
IRAM - 2292	Safety of electrical and electronic equipment for domestic and similar use. Inspection and reception.
IRAM - 2296	Hollow insulators used in electrical equipment. Test methods.
IRAM-2307-1	Composed of poly (vinyl chloride) (PVC) for insulations and sheaths of electric cables.
IRAM - 2339	Solid Electric insulating materials. Method for the determination of levels of resistance and test of electrical routing in wet conditions.
IRAM - 2340	Electrical insulating liquids. Measurement of the relative permittivity and dielectric dissipation (tg range) in AC power factor and resistivity in direct current.
IRAM - 2341	Electrical insulating liquids. Determination of dielectric frequency. Test method.
IRAM-2359-1	Electric panels. Permanent current copper bars. Design.
IRAM-2359-2	Electric panels. Bars of aluminium for steady flow. Design.
IRAM - 2368	Connectors of electric heating appliances. Bipolar without grounded, for home use and rated voltage 220 V effective.
IRAM - 2370	Electrical and electronic equipment. Rating for your protection against electrical shock.
IRAM - 2376	Solid Electric insulating materials. Method for the determination of flammability by exposure to a source of ignition. (IEC 60707:1981, MOD)
IRAM-2378-1	Trials relating to the risks of fire in electrical appliances. Test method with filament and application guide.
IRAM-2378-2	Trials relating to the risks of fire in electrical appliances. Needle burner test method.
IRAM-2378-3	Trials relating to the risks of fire in electrical appliances. Poor contact with filaments heating test method.
IRAM - 2392	Appliances, portable tools and similar electrical appliances. Limits and methods of measurement of radio interference characteristics.
IRAM - 694	Bars and rods of aluminum alloy for electrical conductors.
IRAM - 698	Aluminium wire non-alloy for electrical conductors.
IRAM - 702	Of copper rod for electrical conductors.
IRAM-AADL J 2024	Photoelectric switches for exterior lighting. Definitions, General conditions and requirements.
IRAM-AADL J 2025	Photoelectric switches for exterior lighting. Test methods.
IRAM-AITA 1-F15-1	Incandescent (filament) lamps for motor vehicles. Part 1: Dimensional, electrical and luminous requirements.
IRAM-IAPG-IEC 79-11	Electrical materials for explosive gaseous atmospheres. Security intrinsic 'i'.
IRAM-IAPG-IEC 79-12	Electrical materials for explosive gaseous atmospheres. Classification of mixtures of gases or vapors of flammable substances with air, according to the maximum experimental safety interstitium and the minimum ignition current.
IRAM-IAPG-IEC 79-13	Electrical materials for explosive gaseous atmospheres. Construction and use of rooms or buildings protected by pressurization.
IRAM-IAPG-IEC 79-14	Electrical materials for explosive gaseous atmospheres. Electrical installations in hazardous areas (except mine).
IRAM-IAPG-IEC 79-15	Electrical materials for explosive gaseous atmospheres. Electrical materials with 'n' protection mode.
IRAM-IAPG-IEC 79-16	Electrical materials for explosive gaseous atmospheres. Artificial ventilation for the protection of rooms of analyzers.
IRAM-IAPG-IEC 79-17	Electrical materials for explosive gaseous atmospheres. Recommendations for inspection and maintenance of electrical installations in hazardous areas (does not apply to mines).
IRAM-IAPG-IEC 79-18	Electrical materials for explosive gaseous atmospheres. Encapsulation "m".
IRAM-IAPG-IEC 79-19	Electrical materials for explosive gaseous atmospheres. Repair and overhaul of equipment used in potentially explosive atmospheres (excluding mines and explosives).
IRAM-IAPG-IEC 79-2	Electrical materials for explosive gaseous atmospheres. Electrical materials with protection 'p' mode.
IRAM-IAPG-IEC 79-20	Electrical materials for explosive gaseous atmospheres. Data of gases and vapors related to the use of electrical materials.
IRAM-IAPG-IEC 79-3	Electrical materials for explosive gaseous atmospheres. Exploder for intrinsically safe circuits.
IRAM-IAPG-IEC 79-4	Electrical materials for explosive gaseous atmospheres. Test method for the determination of the ignition temperature.
IRAM-IAPG-IEC 79-5	Electrical materials for explosive gaseous atmospheres. Powder filling 'q'.
IRAM-IAPG-IEC 79-6	Electrical materials for explosive gaseous atmospheres. Oil immersion 'o'.
IRAM-IEC 1241-1-1	Electrical materials for use in the presence of combustible dust. Part 1: Electrical materials protected by wraps. Section 1: Specifications for materials.
IRAM-IEC 1241-1-2	Electrical materials for use in the presence of combustible dust. Part 1: Electrical materials protected by wraps. Section 2: Selection, installation and maintenance.
IRAM-IEC 1241-2-1	Electrical materials for use in the presence of combustible dusts. Part 2: Methods of test. Section 1: Methods for determining the minimum ignition temperature of dust.
IRAM-IEC 1241-2-2	Electrical materials for use in the presence of combustible dust. Part 2: Methods of test. Section 2: Method for the determination of the electrical resistivity of dust layers.
IRAM-IEC 1241-2-3	Electrical materials for use in the presence of combustible dusts. Part 2: Methods of test. Section 3: Method for the determination of the minimum energy of ignition of dust/air mixtures.

IRAM-IEC 1241-3	Electrical materials for use in the presence of combustible dusts. Part 3: Classification of areas where are or may be present combustible dusts.
IRAM-NM 300-6	Safety of toys. Part 6: Safety of electrical toys.
IRAM-NM 326	Non-destructive testing. Mounting piezoelectric acoustic emission, contact sensors. Procedure.

Source: IRAM. Elaborated by CGTI-EESP/FGV.

APPENDIX 2 – Vehicle

Table 27 - Regulation on Vehicles (Brazil)

NAME	THEME
LAW 13111/15	Obligation of the sellers of automotive vehicles to inform the buyer the value of the taxes applied on the sale and the regular situation of the vehicle
LAW 12977/14	Dismantling of land vehicles
LAW 9503/97	Brazilian traffic code
LAW 8723/93	Regulates the license for the use of the vehicle or motor configuration
ORDINANCE 315/12	Child restraints
INMETRO ORDINANCE 547	CO2 emissions – fuel control
INMETRO ORDINANCE 330/12	LPG tanks
INMETRO ORDINANCE 301/11	Certification of products (autoparts) by laboratory accredited by INMETRO
INMETRO ORDINANCE 139/11	Diesel smoke
INMETRO ORDINANCE 205/08	New tires destined to commercial, light commercial and towed vehicles
INMETRO ORDINANCE 165/08	New tires destined to passenger cars, including those of mixed use and towed
INMETRO ORDINANCE 8/11	CNG tanks
INMETRO ORDINANCE 30/04	Braking and brake linings
CONAMA RESOLUTION 433/11	Emissions (Euro IV and V) of heavy duty vehicles
CONAMA RESOLUTION 415/09	Emissions and emissions (Euro IV and V) of heavy duty vehicles
CONAMA RESOLUTION 403/08	Emissions and emissions (Euro IV and V) of heavy duty vehicles
CONAMA RESOLUTION 315/02	Emissions, diesel smoke, emissions (Euro IV and V) of heavy duty vehicles and CO2 emissions – fuel consumption
CONAMA RESOLUTION 282/01	Replacement of catalytic converters
CONAMA RESOLUTION 272/00	Emission levels for vehicles
CONAMA RESOLUTION 252/99	Emission levels for vehicles
CONAMA RESOLUTION 226/97	Diesel smoke and CO2 emissions – fuel consumption
CONAMA RESOLUTION 17/95	Permissible sound level
CONAMA RESOLUTION 16/95	Diesel smoke and CO2 emissions – fuel consumption
CONAMA RESOLUTION 15/95	CO2 emissions – fuel consumption
CONAMA RESOLUTION 18/86	Brazilian Program for the Control of Pollution by Motor Vehicles (PROCONVE)
CONTRAN RESOLUTION 644/16	Buses and coaches
CONTRAN RESOLUTION 630/16	Braking and strength of superstructure
CONTRAN RESOLUTION 629/16	Buses and coaches and strength of superstructure
CONTRAN RESOLUTION 595/16	Fuel tanks
CONTRAN RESOLUTION 593/16	Rear protective devices
CONTRAN RESOLUTION 559/15	Anti-theft and immobiliser
CONTRAN RESOLUTION 548/15	Headlamps (R2 and HS1)
CONTRAN RESOLUTION 519/15	Braking
CONTRAN RESOLUTION 485/14	Anti-theft and immobiliser
CONTRAN RESOLUTION 445/13	Buses and coaches and strength of superstructure
CONTRAN RESOLUTION 330/09	Anti-theft and immobiliser
CONTRAN RESOLUTION 316/09	Seat strength, seat belt anchorages, seat belts and restraint systems

CONTRAN RESOLUTION 254/07	Safety glazing
CONTRAN RESOLUTION 245/07	Anti-theft and immobilizer
CONTRAN RESOLUTION 234/07	Couplings and close-coupling device
CONTRAN RESOLUTION 227/07	Headlamps (H1, H2, H3, H4, HB3, HB4, H7 and/or H8, H9, HIR 1, HIR2 and/or H11, R2, HS1, sealed beam, asymmetrical passing beam, halogen sealed beam, filament lamps for use in approved lamp units and headlamps with gas-discharge light sources, gas-discharge light sources for use in approved gas-discharge lamp units), adaptative front-lighting systems, front fog lamps, rear fog lamps, reversing lamps, parking lamps
CONTRAN RESOLUTION 226/07	Indirect vision devices and retro reflectors
CONTRAN RESOLUTION 225/07	Direction indicators and identification of controls, tell-tales and indicators
CONTRAN RESOLUTION 221/07	Fuel tanks and frontal impact
CONTRAN RESOLUTION 220/07	Seat strength, head restraints and head restraints (combined with seats)
CONTRAN RESOLUTION 197/06	Couplings and close-coupling device
CONTRAN RESOLUTION 48/98	Seat belt anchorages
CONTRAN RESOLUTION 44/98	Head restraints (combined with seats)
CONTRAN RESOLUTION 37/98	Audible warning
CONTRAN RESOLUTION 35/98	Audible warning
CONTRAN RESOLUTION 686/87	Anti-theft, immobilizer and vehicle alarm system
CONTRAN RESOLUTION 675/86	Flammability
CONTRAN RESOLUTION 486/74	Fuel tanks
CONTRAN RESOLUTION 463/73	Fuel tanks, door latches and hinges, behavior of steering device under impact, seat strength and seat strength for buses and coaches
CONTRAN RESOLUTION 448/71	Vehicle alarm systems
SECEX ORDINANCE 23/11	Regulates the import of used cars
DENATRAN ORDINANCE 190/09	Local homologation and labelling
IBAMA ORDINANCE 86/96	Pollutant emission levels and noise levels for imported vehicles
MERCOSUL GMC RESOLUTION 31/94	Fuel tanks

Source: INMETRO, CONAMA, CONTRAN. Prepared by CCGI-EESP/FGV.

Table 28 - Standards on Vehicles (Brazil)

Standard
ABNT NBR 14375:2017 Road vehicles-Clutch system-Scale for hybridity vehicle assessment
ABNT NBR 14828:2017 Road vehicles-Safety procedures for maintenance on vehicles equipped with an air bag
ABNT NBR 14753:2017 Automotive Road Vehicles-Injection Valve-Inspection and Diagnosis in Otto Cycle Engines
ABNT NBR 15905:2017 Spark-ignition internal combustion engines-Monolithic aluminum alloy piston
ABNT NBR 13705:2016 Road vehicles-Concentrated additives is endothermic engine cooling, types A, B and C-Requirements and test methods
ABNT NBR 15598:2016 Light motor vehicles-Determination of unburned ethanol contained in the exhaust gas by gas chromatography-Test method
ABNT NBR 16567:2016 Light electric hybrid road vehicles-Measurement of exhaust emission and fuel and energy consumption-Test methods
ABNT NBR ISO 28741:2016 Automotive Road Vehicles-Spark Plugs and Their Head Seats-Basic Features and Dimensions
ABNT NBR ISO 6621-3:2009 Errata 1:2016 Internal combustion engines-Piston rings Part 3: Material specifications
ABNT NBR 16564:2016 Internal combustion engines-Elastomer rings for sealing cylinder liners mounted on the engine block-Specifications and test methods
ABNT NBR ISO 11451-1:2016 Road vehicles-Vehicle test methods for electrical disturbances caused by narrow-band electromagnetic energy emitted Part 1: General Principles and Terminology
ABNT NBR ISO 11565:2016 Road vehicles-Spark plugs-Requirements and test methods
ABNT NBR 16529:2016 Motorcycles and similar vehicles-Evaporative emission measurement
ABNT NBR 14261:2016 Road vehicles-Cooling solutions for endothermic engines, types A, B and C-Requirements and test methods
ABNT NBR 11410:2016 Road implements-Automatic coupling and spherical coupling for trucks and trailers-Requirements

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ABNT NBR 14752:2016 Automotive Road Vehicles-Electric Fuel Pump-Inspection and Diagnosis (Otto Cycle)
ABNT NBR 12026:2016 Lightweight road vehicles – Determination of the emission of aldehydes and ketones contained in the exhaust gas by liquid chromatography-DNPH Method
ABNT NBR 15940:2016 Lead-acid batteries for use in four or more-wheel motor vehicles-Specification and test methods
ABNT NBR 16532:2016 Road vehicles-Ignition cables-Maintenance, inspection and exchange (Otto cycle)
ABNT NBR 11927:2016 Determination of adhesion between vulcanized elastomers and metals
ABNT NBR ISO 6621-4:2016 Internal combustion engines-Piston rings Part 4: General Specifications
ABNT NBR ISO 6310:2016 Road vehicles-Brake linings-Compressive deformation test methods
ABNT NBR 14843:2016 Road vehicles-Fuel pressure regulator-Test method
ABNT NBR 15917:2016 Road Attachments-Pneumatic suspension for mechanical suspension of truck-tractor and towed vehicles applied in dangerous goods vehicles-Requirements
ABNT NBR 16427:2016 Chains, crowns and pinions of motorcycles, scooters, mopeds, tricycles and quadricycles-Dimensions and test methods
ABNT NBR 16481:2016 Radiators for cooling internal combustion engines by liquid-Test method of mechanical strength and durability for vehicles of categories M1 and N1
ABNT NBR 14096:2016 Fire-fighting vehicles-Requirements for performance, manufacturing and test methods
ABNT NBR 7540:2016 Control the direction of the energy absorber-test method for determination of characteristics
ABNT NBR 7540:2016 Control of the direction of the energy absorber-Test method for determination of characteristics
ABNT NBR 12858:2016 Gaseous and gaseous mixtures used in vehicle emission laboratory-Determination of concentration, minimum purity and contaminants
ABNT NBR 16449:2016 Road implements-Mechanical coupling between four-axle tractor-trailer and semi-trailer-Interchangeability
ABNT NBR 7335:2016 Road vehicles-Impact test instrumentation
ABNT NBR 15646:2016 Accessibility-Vehicle lift and vehicular access ramp for accessibility of persons with disabilities or reduced mobility, on passenger vehicles of categories M1, M2 and M3-Requirements
ABNT NBR 10966-6:2013 Amendment 1:2015 Road vehicles-Brake system Part 6: Test requirements for vehicles of categories M, N and the equipped with anti-locking system
ABNT NBR 10966-6:2015 Road vehicles-Brake system Part 6: Test requirements for vehicles of categories M, N and the equipped with anti-locking system
ABNT NBR 15934:2015 Compression-ignition internal combustion engines (Diesel)-Monolithic aluminum alloy piston
ABNT NBR 7471:2015 Road vehicles-Helmets and visors for drivers and passengers of motorcycles and similar vehicles-Performance requirements and test methods
ABNT NBR 7812:2015 Copper tubes, seamless, for conducting application fluids on road vehicles, tractors and the like
ABNT NBR 10966-1:2013 Amendment 1:2015 Road vehicles-Brake system Part 1: Uniform provisions concerning braking approval for vehicles of categories M, N and the
ABNT NBR 10966-1:2015 Road vehicles-Brake system Part 1: Uniform provisions concerning braking approval for vehicles of categories M, N and the
ABNT NBR 10966-2:2013 Amendment 1:2015 Road vehicles-Brake system Part 2: Braking and performance tests for vehicles of categories M, N and the
ABNT NBR 10966-2:2015 Road vehicles-Brake system Part 2: Braking and performance tests for vehicles of categories M, N
ABNT NBR 14599:2014 Errata 1:2015 Road implements-Safety requirements for solid waste collectors/compactors
ABNT NBR 9491:2015 Safety glasses for road vehicles-Requirements
ABNT NBR 9493:2015 Safety Glasses-Determination of impact resistance with phanton
ABNT NBR 9494:2015 Safety glass-Determination of impact resistance with ball
ABNT NBR 9497:2015 Safety glass-Determination of secondary image separation
ABNT NBR 9498:2015 Safety Glasses-Abrasion Test Method
ABNT NBR 9499:2015Safety Glasses-High Temperature Resistance Test
ABNT NBR 9501:2015Safety Glasses-Radiation Testing
ABNT NBR 9502:2015 Safety Glasses-Resistance to humidity test
ABNT NBR 9504:2015Safety Glasses-Determination of Optical Distortion
ABNT NBR 9503:2015 Safety glasses-determination of light transmittance
ABNT NBR 6606:2015 Motor road vehicles-Determination of range of manual controls
ABNT ISO/TR 8713:2015 Road vehicles propelled electricity-Vocabulary
ABNT NBR 9995:2015 Exhaust gas of diesel engines-determination of opacity in dynamometer cycle
ABNT NBR 6091:2015 Motor road vehicles – Anchorages of safety belts, ISOFIX anchorage system and ISOFIX top tether anchorage of — Location and tensile strength
ABNT NBR 14148:2015 Side guard for trucks and towed
ABNT NBR 6068:2015 Road vehicles-masses and dimensions of adults
ABNT NBR 7318:2015 Vulcanized elastomer for use in motor vehicles – determination of hardness
ABNT NBR 16402:2015 Road vehicles-automotive exhaust system requirements for the replacement market for category M and N vehicles with Otto cycle engine
ABNT NBR 6016:2015 Exhaust gas of Diesel engine-evaluation of soot content with the Ringelmann scale
ABNT NBR 6144:2015 Connectors for auto radios antennas-dimensions
ABNT NBR ISO 7637-1:2015 Motor road vehicles-electrical Disturbances by conduction and coupling Part 1: definitions and general considerations
ABNT NBR 16369:2015 Motorcycles and similar vehicles – Determination of hydrocarbons, carbon monoxide, nitrogen oxides and carbon dioxide in exhaust gas
ABNT NBR 16331:2014 Errata 1:2015 Traffic safety-plastic barrier pipe
ABNT NBR IEC 62660-2:2015 Lithium-ion secondary cells for propulsion of electric road vehicles Part 2: reliability testing and abuse
ABNT NBR 15725:2015 Adhesives-structural bonding system in automotive glass replacement-requirements and test methods

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ABNT NBR ISO 6622-2:2015 Internal combustion engines-piston rings Part 2: rectangular piston rings made of steel
ABNT NBR 16330:2014 Traffic safety — easels and barriers to road signaling types I, II and III
ABNT NBR 16331:2014 corrected version: 2015 Traffic safety-plastic barrier pipe
ABNT NBR 16320:2014 Motor road vehicles-steering indicator Flashlight-specification
ABNT NBR 16321:2014 Motor road vehicles — astern Lantern — specification
ABNT NBR 7337:2014 Motor road vehicles-safety-belt requirements and tests
ABNT NBR ISO 6621-5:2014 Internal combustion engines-piston rings Part 5: quality requirements
ABNT NBR 9078:2014 Motor road vehicles-main with normal bulb Headlight-specification
ABNT NBR 9183:2014 Road vehicles-automotive Headlamp with halogen H4 main light bulb-specification
ABNT NBR 9293:2014 Motor road vehicles-main with halogen incandescent lamp Headlight (H1-H2-H3)-specification
ABNT NBR 9296:2014 Motor road vehicles-bounding, Lantern and brake position-specification
ABNT NBR 14599:2014 corrected version: 2015 Road equipment-safety requirements for collectors-solid waste compactors
ABNT NBR IEC 62660-1:2014 Lithium-ion secondary cells for propulsion of electric road vehicles Part 1: performance test
ABNT NBR 6743:2014 Road equipment-trucks, tractors and buses-trucks-adaptation for installation of vehicular auxiliary axis
ABNT NBR 10312:2014 Errata 1:2014 Automotive light road vehicles-determination of resistance to displacement by rolling track-free deceleration and dynamometer simulation
ABNT NBR 10312:2014 corrected version: 2014 Automotive light road vehicles — determination of resistance to displacement by rolling track-free deceleration and dynamometer simulation
ABNT NBR ISO 17268:2014 Connection devices for refueling vehicles with gaseous hydrogen
ABNT NBR ISO 3795:2014 Road vehicles, tractors and agricultural and forestry machinery — determining the combustion behavior of interior materials
ABNT NBR 15830:2014 Motor road vehicles — suspension damper — classification, terminology and identification
ABNT NBR 13308:2014 Motor road vehicles — suspension damper — verification of performance and durability — test method
ABNT IEC/TR 60783:2014 Wiring and connectors of electric road vehicles
ABNT NBR 9492:2014 Safety glasses — breaking Test — security against shrapnel
ABNT NBR ISO 18669-1:2014 Internal combustion engines--piston pins Part 1: general specifications
ABNT NBR ISO 6623:2014 Internal combustion engines--piston rings--Rings scrapers made of cast iron
ABNT NBR ISO 6626-2:2014 Internal combustion engines--piston rings Part 2: oil control rings with coil spring and reduced height, made of cast iron
ABNT NBR 10966-3:2013 Motor road vehicles — brake System Part 3: measurement procedures of response time in vehicles equipped with pneumatic brake systems of categories M, N and O
ABNT NBR 10966-4:2013 Road vehicles-automotive brake System Part 4: provisions relating to energy sources and energy storage devices (energy tanks) for vehicles of categories M, N and O
ABNT NBR 10966-5:2013 otor road vehicles — brake System Part 5: specifications for specific conditions for spring braking systems hoarder (spring brake) for vehicles of categories M, N and O
ABNT NBR 10966-7:2013 Motor road vehicles — brake System Part 7: distribution of braking among the axles and requirements of compatibility between tractors and trailed vehicles of categories M, N and O
ABNT NBR 16231:2013 Uniform provisions concerning the filament lamps for use in lighting systems and/or signalling systems of self-propelled road vehicles and their towed
ABNT NBR IEC 62196-2:2013 Plugs, sockets, sockets for electric vehicle and electric vehicle fixed plugs — electric vehicle conductive Charging Part 2: dimensional Requirements of compatibility and interchangeability for AC accessories with pins and tubular contacts
ABNT NBR 16218:2013 Impact resistant safety glasses for road vehicles ballistic armor — Visual and optical Aspects — requirements and test methods
ABNT NBR 15914:2013 Lead-acid battery for use in motor vehicles of four or more wheels — requirements and symbology
ABNT NBR 16204-1:2013 Motor road vehicles — occupant protection — side-impact tests Part 1: General
ABNT NBR 16204-2:2013 Motor road vehicles — occupant protection — side-impact tests Part 2: procedure and performance requirements in side impact test with speed of impact barrier with an angle of 63° to the longitudinal axis of the vehicle
ABNT NBR 16204-3:2013 Motor road vehicles — occupant protection — side-impact tests Part 3: procedure and performance requirements in side impact test with the impact barrier perpendicular to the longitudinal axis of the vehicle
ABNT NBR 15300-1:2013 Motor road vehicles — occupant protection — frontal impact tests Part 1: performance requirements
ABNT NBR 15283:2013 Motor road vehicles — strength of the seats, their anchorages and head restraint
ABNT NBR IEC 62196-1:2013 Plugs, sockets, sockets for electric vehicle and electric vehicle fixed Plugs — conductive Charging for electric vehicles Part 1: General requirements
ABNT NBR 16187:2013 Road motor vehicles — procedure for the determination of the H points and R
ABNT NBR 14652:2013 Road equipment-Collector waste carrier — health services construction and inspection requirements
ABNT NBR IEC 61851-1:2013 Conductive charging system for electric vehicles Part 1: General requirements
ABNT NBR IEC 61851-21:2013 Conductive charging system for electric vehicles Part 21: electric vehicle Requirements for conductive connection to an a.c/d.c. supply
ABNT NBR IEC 61851-22:2013 Conductive charging system for electric vehicles Part 22: AC recharging station for electric vehicles
ABNT NBR 16176:2013 Air-cooled cylinder shirts (finned) for internal combustion engines mounted on the engine block
ABNT NBR 16171:2013 Motor road vehicles — Horns — procedures and test requirements for vehicles categories L
ABNT NBR 6750:2013 Errata 1:2013 Wheels for cars — verification of the durability and resistance
ABNT NBR 13909:2013 Wheels and rims road and agricultural vehicles — terminology

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ABNT NBR 6608:2013 Wheels and rims road vehicles — Dimensions and IDs
ABNT NBR 6750:2013 corrected version: 2013 Wheels for cars — verification of the durability and resistance
ABNT NBR 6752:2013 For aluminum alloy wheel for light commercial cars and SUVs — performance verification tests
ABNT NBR 15861:2013 Road equipment — vehicular Equipment used — identification number
ABNT NBR 14681:2013 Road equipment — light Trailers — security Chains
ABNT NBR 16141:2013 Road equipment — locking System and Tipper lifting — requirements
ABNT NBR 16142:2013 Road equipment — stairway to road tank vehicle
ABNT NBR 15875-2:2011 Amendment 1:2013 Motor road vehicles — energized Triggers Part 2: technical requirements in accordance with European Union Directive 74/60/EEC
ABNT NBR 15875-2:2013 Motor road vehicles-powered Triggers Part 2: technical requirements in accordance with the EU Directive 74/60/EEC
ABNT NBR 15875-4:2011 Amendment 1:2013 Road motor vehicles Actuators energized Part 4: technical requirements according to ECE R-21 of the United Nations
ABNT NBR 15875-4:2013 Motor road vehicles-powered Triggers Part 4: technical requirements according to ECE R-21 of the United Nations
ABNT NBR 16140:2013 Truck-tractor, truck and bus — Adaptation to the installation of the auto direcional or directional axis
ABNT NBR ISO 11452-5:2013 Road motor vehicles — component test methods for electrical disturbances caused by electromagnetic energy emitted in narrow band Part 5: Stripline
ABNT NBR 15457:2012 Road equipment — thermally insulated Body — thermal performance
ABNT NBR 16130:2012 Motor road vehicles — direction terminals, bars, link bars, and sets of axial bars — requirements and test methods applied to vehicles in categories M and N and categories (G) and (where applicable).
ABNT NBR 16131:2012 Motor road vehicles — direction terminals, bars, link bars, and sets of axial bars — terminology
ABNT NBR 16122:2012 Road equipment — coupling ball for housing trailers (trailers) and light trailers — Dimensions
ABNT NBR 15916:2012 Lead-acid batteries for use in motorcycles, motor tricycles and quadricycles — requirements and symbology
ABNT NBR 15941:2012 Lead-acid batteries for motorcycles, motor tricycles and quadricycles — specification and test methods
ABNT NBR 14324:2012 Road equipment — Tank — geometric Format
ABNT NBR 6601:2012 Automotive light road vehicles – Determination of hydrocarbons, carbon monoxide, nitrogen oxides, carbon dioxide and particulate matter in exhaust gas
ABNT NBR 9188:2012 Road equipment — vertical Support for semi-trailers — requirements
ABNT NBR 14958-1:2012 Road vehicles — automotive friction Material Part 1: requirements and test methods for disc brake pads for use on brakes of vehicles of categories M1, M2 and N1
ABNT NBR 14958-2:2012 Road vehicles — automotive friction Material Part 2: requirements and test methods for drum brake linings intended for use on brakes of vehicles of categories M1, M2 and N1
ABNT NBR 14958-3:2012 Road vehicles — automotive friction Material Part 3: requirements and test methods for disc brake pads for use on brakes of vehicles of categories M3, N2, N3, O3 and O4
ABNT NBR 14958-4:2012 Road vehicles — automotive friction Material Part 4: requirements and test methods for drum brake linings intended for use on brakes of vehicles of categories M3, N2, N3, O3 and O4
ABNT NBR 14958-5:2012 Road vehicles — automotive friction Material Part 5: requirements and test methods for brake linings and pads for use on vehicles of category L brakes
ABNT NBR 15634:2012 Motor road vehicles — analysis and determination of the exhaust gas according to the ESC and ELR cycles ETC
ABNT NBR ISO 18669-2:2010 Errata 1:2012 Internal combustion engines--piston pins Part 2: inspection measurement Principles
ABNT NBR ISO 6627:2012 Internal combustion engines--piston rings--for oil control rings Expander/spacer/segment
ABNT NBR 8689:2012 Automotive light road vehicles — test fuels — requirements
ABNT NBR 16068:2012 Motor road vehicles — uniform designations relating to tests of vehicles of category L1, L2, L3, L4 and L5 with regard to braking
ABNT NBR 11409:2012 For installation-clay in trailers and semi-trailers — Procedure
ABNT NBR 6971:2012 Traffic safety-metal guard rails – implementation
ABNT NBR 9762:2012 Road vehicle-Terminology
ABNT NBR 6970:2012 Traffic safety metal guard rails — hot-dip galvanized
ABNT NBR ISO 11155-2:2011 Road motor vehicles — air filters for passenger compartments Part 2: gas filtration test
ABNT ISO/TS 11155-1:2011 Road motor vehicles — air filters for passenger compartments Part 1: filtering of particulate material
ABNT IEC/PAS 62545:2011 Environmental information for electrical and electronic equipment
ABNT NBR 15988:2011 Motor road vehicles — spare Bades for automotive springs bundle — test methods, acceptance requirements and terminology
ABNT NBR 1512012:2011 Motor road vehicles — coil springs for automotive suspension — test methods and minimum quality requirements
ABNT NBR 7501:2011 Inland Transport of dangerous goods — terminology
ABNT NBR ISO 11451-4:2011 Road motor vehicles — vehicle test methods for electrical disturbances caused by narrowband radiated electromagnetic energy Part 4: current injection (BCI)
ABNT NBR 15208:2011 Airports — Auto Proper Vehicle for loading/unloading of people with disabilities or with reduced mobility — requirements
ABNT NBR 15759:2009 Amendment 1:2011 Motor road vehicles-inspection procedures and/or replacement of timing belts and accessories in internal combustion engine Otto and Diesel cycles
ABNT NBR 15759:2011 Motor road vehicles-inspection procedures and/or replacement of timing belts and accessories in internal combustion engine Otto and Diesel cycles
ABNT NBR 15875-2:2010 Amendment 1:2011 otor road vehicles-powered Triggers Part 4: technical requirements according to ECE R-21 of the United Nations

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ABNT NBR 15875-4:2010 Amendment 1:2011 Motor road vehicles-powered Triggers Part 4: technical requirements according to ECE R-21 of the United Nations
ABNT NBR ISO 22241-1:2011 Diesel engines — liquid automotive NOx reducing agent — ARLA 32 Part 1: quality requirements
ABNT NBR ISO 22241-2:2011 Diesel engines — liquid automotive NOx reducing agent — ARLA 32 Part 2: test methods
ABNT NBR ISO 22241-3:2011 Diesel engines — liquid automotive NOx reducing agent — ARLA 32 Part 3: handling, transport and storage
ABNT NBR ISO 22241-4:2011 Diesel engines — liquid automotive NOx reducing agent — ARLA 32 Part 4: Interface Re-up
ABNT NBR 5535:2011 Motor road vehicles — Horns — acoustic Requirements
ABNT NBR 5536:2011 Motor road vehicles — Horns — test methods
ABNT NBR 15875-2:2010 Errata 1:2011 Motor road vehicles-powered Triggers Part 4: technical requirements according to ECE R-21 of the United Nations
ABNT NBR 15875-4:2010 Errata 1:2011 Motor road vehicles-powered Triggers Part 4: technical requirements according to ECE R-21 of the United Nations
ABNT NBR 9292:2011 Motor road vehicles-hydraulic brakes, fluid types 3, 4 and 5 – requirements and test methods
ABNT NBR 11412:2011 Road equipment-towed vehicles-Terminology
ABNT NBR ISO 6626:2011 Internal combustion engines--piston rings — oil control rings with coil spring
ABNT NBR 11413:2011 Road equipment — weights and dimensions of road vehicles towed light
ABNT NBR 14022:2009 Amendment 1:2011 Accessibility in vehicles of urban features for the public transport of passengers
ABNT NBR 14022:2011 Accessibility in vehicles of urban features for the public transport of passengers
ABNT NBR 14879:2011 Road equipment —-solid waste compactor Collector — definition of the volume
ABNT NBR 15570:2009 Amendment 1:2011 Transportation-technical specifications for the manufacture of vehicles of urban collective transport characteristics of passengers
ABNT NBR 15570:2011 Transport — technical specifications for the manufacture of vehicles of urban collective transport characteristics of passengers
ABNT ISO/TS 16949:2010 Quality management systems-particular requirements for implementation of ABNT NBR ISO 9001:2008 for automotive production and relevant spare parts
ABNT NBR 13332:2010 Road equipment —-solid waste compactor Collector and its main components — terminology
ABNT NBR ISO 18669-2:2010 corrected version: 2012 Internal combustion engines--piston pins Part 2: inspection measurement Principles
ABNT NBR 12922:2010 Locomotive — the driver's Cabin — requirements
ABNT NBR 15875-1:2010 Motor road vehicles-powered Triggers Part 1: General requirements
ABNT NBR 15875-3:2010 Motor road vehicles-powered Triggers Part 3: technical requirements as FMVSS 118 of the U.S. Government
ABNT NBR ISO 6625:2010 Internal combustion engines-piston rings-oil control rings
ABNT NBR ISO 6624-1:2010 Internal combustion engines-piston rings Part 1: trapezoidal Rings made of cast iron
ABNT NBR ISO 6624-2:2010 Internal combustion engines-piston rings Part 2: semitrapezoidais Rings made of cast iron
ABNT NBR ISO 6624-3:2010 Internal combustion engines--piston rings Part 3: trapezoidal steel Rings
ABNT NBR ISO 5011:2010 Filtering equipment of the intake air for internal combustion engines and compressors — performance test
ABNT NBR 9500:2010 Road equipment – Vehicle door-container (VPC) — requirements
ABNT NBR 10972:2010 Automotive light road vehicles-measurement of the concentration of carbon monoxide in the exhaust gas idling-lab test
ABNT NBR 7475:2010 Road equipment — container locking device-requirements
ABNT NBR 15831:2010 Motor road vehicles — removal and reinstallation of engines
ABNT NBR 11481:2010 Automotive light road vehicles — measurement of evaporative emission
ABNT NBR 7024:2010 Automotive light road vehicles — measurement of the fuel consumption — test method
ABNT NBR ISO 16185:2010 Motor road vehicles – engine family for certification of heavy goods vehicles for exhaust gas emissions
ABNT NBR ISO 4020:2010 Motor road vehicles — diesel fuel filters — test methods
ABNT NBR 15787:2010 Motor road vehicles — mechanical Monkey — terminology and classification
ABNT NBR 15788:2010 Motor road vehicles — mechanical Monkey — test methods
ABNT NBR 6751:2009 Wheels and rims for trucks, buses and similar verification of the durability and resistance
ABNT NBR ISO 11530:2009 Motor road vehicles-hydraulic jacks-specifications
ABNT NBR 15760-1:2009 Automotive-maintenance road vehicles in transmission system Part 1: mechanical changes
ABNT NBR 15760-2:2009 Automotive-maintenance road vehicles in transmission system Part 2: automatic changes
ABNT NBR 15754:2009 Motor road vehicles-fuel electric pump for Otto-cycle engines-technical requirements
ABNT NBR 6066:2009 Road vehicle-vehicle identification number (VIN)
ABNT NBR 15703:2009 Motor road vehicles-fuel pump Set to Otto cycle engines-Terminology
ABNT NBR 15689:2009 Two-wheeled vehicles-motorcycle and moped-resistance for rifled steel wheel rims
ABNT NBR 15640-1:2009 Automotive-trim road vehicles for clutch disc-behavior of friction and wear characteristics Part 1: low energy
ABNT NBR 14022:2006 Amendment 1:2009 Accessibility in vehicles of urban features for the public transport of passengers
ABNT NBR 15570:2008 Amendment 1:2009 Transportation-technical specifications for the manufacture of vehicles of urban collective transport characteristics of passengers
ABNT NBR 13032:2008 Errata 1:2009 Road motor vehicles Grinding of reciprocating internal combustion engines
ABNT NBR 15672:2009 Automotive glass-requirements for windscreen repair-
ABNT NBR 15673:2009 Automotive glass-repair of windscreens-test methods
ABNT NBR ISO 6621-1:2009 Internal combustion engines-piston rings Part 1: Vocabulary

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ABNT NBR ISO 6621-2:2009 Internal combustion engines-piston rings Part 2: measurement Principles for inspection
ABNT NBR ISO 6621-3:2009 corrected version: 2016 Internal combustion engines-piston rings Part 3: material specifications
ABNT NBR 15652:2009 Road equipment-loading lift to be installed in motor vehicles for goods transport-safety requirements
ABNT NBR 10961:2009 Road equipment-truck, truck-tractor, bus, trailer and semi-trailer-vehicle Axle-requirements and test methods
ABNT NBR 13746:2008 For road transport tank-Tank built in glass fibre reinforced plastic (GRP)
ABNT NBR 13399:2008 Road equipment-Equipment-vehicular identification number
ABNT NBR 15640-2:2008 Automotive-trim road vehicles for clutch disc-behavior of friction and wear characteristics Part 2; Average energy
ABNT NBR 15640-3:2008 Automotive-trim road vehicles for clutch disc-characteristics behavior of friction and wear Part 3: high energy
ABNT NBR 13032:2008 corrected version: 2009 Road motor vehicles Grinding of reciprocating internal combustion engines
ABNT NBR ISO 22902-1:2008 Motor road vehicles-automotive multimedia Interface Part 1: General Technical Overview
ABNT NBR 15629:2008 Automotive-maintenance road vehicles in HAC systems
ABNT NBR ISO 7656:2008 Automotive commercial road vehicles-dimensional Codes
ABNT NBR NM ISO 11439:2008 Gas cylinders-high pressure cylinders for storage of natural gas as fuel, automotive vehicles
ABNT NBR ISO 12103-1:2008 Road motor vehicle-test Dust for filter evaluation Part 1: the Arizona test dust
ABNT NBR ISO 12103-2:2008 Motor road vehicles-test Dust for filter evaluation Part 2: test Dust from aluminum oxide
ABNT NBR ISO 21750:2008 Automotive-road vehicles increased security in conjunction with the monitoring of tire inflation pressure
ABNT NBR 15510:2008 Trailer and semi-trailer-adaptation for the installation of the autodirecional axis and directional system or autodirecional
ABNT NBR 14481:2008 Motor road vehicles-Diagnostics and maintenance in Otto-cycle engines
ABNT NBR 15563:2008 Road vehicles-automotive engine cooling System-diagnosis and maintenance
ABNT NBR ISO 4131:2008 Motor road vehicles-dimensional Codes for passenger cars
ABNT NBR ISO 3832:2008 Passenger cars-luggage-method of measuring the volume of reference
ABNT NBR 8349:2008 Inspection and evaluation of horizontal signaling in airports
ABNT NBR 14008:2007 Automotive light road vehicles – Determination of the deterioration factor of the greenhouse gas emissions during the accumulation of shooting
ABNT NBR 11353-1:2007 Road vehicles and motor vehicles-vehicular natural gas (VNG) Part 1: terminology
ABNT NBR 11353-2:2007 Road vehicles and motor vehicles-vehicular natural gas system Part 2: guns, indicators, mixers, feeders, injection and control
ABNT NBR 11353-3:2007 Road vehicles and motor vehicles-vehicular natural gas (VNG) Part 3: pressure reducers
ABNT NBR 11353-4:2007 Road vehicles and motor vehicles-vehicular natural gas system Part 4: cylinder, valves, ventilation systems and high pressure line
ABNT NBR 11353-5:2007 Road vehicles and motor vehicles-vehicular natural gas (VNG) Part 5: in General
ABNT NBR 11353-6:2007 Road vehicles and motor vehicles-vehicular natural gas system Part 6: installation
ABNT NBR ISO 4130:2007 Motor road vehicles-three-dimensional reference system and reference marks-definitions
ABNT NBR ISO 16844-1:2007 Motor road vehicles-tachograph systems Part 1: electrical connectors
ABNT NBR ISO 16844-3:2007 Motor road vehicles-tachograph systems Part 3: motion sensor Interface
ABNT NBR ISO 16844-4:2007 Motor road vehicles-tachograph systems Part 4: Interface CAN (Controller Area Network)
ABNT NBR ISO 16844-5:2007 Motor road vehicles-tachograph SystemsPart 5: Interface CAN hold
ABNT NBR ISO 16844-6:2007 Motor road vehicles-tachograph systems Part 6: Diagnostics
ABNT NBR ISO 16844-7:2007 Motor road vehicles-tachograph systems Part 7: parameters
ABNT NBR 14582:2007 Winch-vehicular-construction requirements help
ABNT NBR 6067:2007 Motor road vehicles, its towed and combined-classification, terminology and definitions
ABNT NBR 15266-10:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 10: determination of the deviation of the diameters of the circles print speeds
ABNT NBR 15266-11:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 11: determination of concentricity of the circumferences of the print speeds
ABNT NBR 15266-12:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 12: Resistance to immersion
ABNT NBR 15266-13:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test method Part 13: high temperature resistance
ABNT NBR 15266-14:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 14: the light Stability
ABNT NBR 15266-15:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 15: resistance of tape to disk Union of seven days
ABNT NBR 15266-16:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 16: determination of cutting ribbons of touch Union of seven-day discs
ABNT NBR 15266-2:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test method Part 2: evaluation of the basis weight
ABNT NBR 15266-4:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 4: determination of the curl
ABNT NBR 15266-5:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test methods Part 5: black layer resistance action time registry
ABNT NBR 15266-6:2005 Errata 1:2007 Motor road vehicles-tachograph Disc-test method Part 6: evaluation of the performance of the registry under temperature
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ABNT NBR 15471-1:2007 Motor road vehicles-auto tire Gauge Part 1: components, functions and terminology
ABNT NBR 15471-2:2007 Motor road vehicles-auto tire Gauge Part 2: test methods
ABNT NBR 15471-3:2007 Motor road vehicles-auto tire Gauge Part 3: technical requirements
ABNT NBR 15455-1:2006 Passenger cars-connections for car radios Part 1: dimensions and General requirements
ABNT NBR 15455-2:2006 Passenger cars-connections for car radios Part 2: performance requirements
ABNT NBR ISO 11452-2:2006 Motor road vehicles-test methods for components for electrical disturbances caused by electromagnetic energy emitted in narrow band Part 2: armored Enclosure with absorbing
ABNT NBR ISO 8092-1:2006 Motor road vehicles-connections for embedded electrical wiring harnesses Part 1: Tabs for unipolar connections-dimensions and specific requirements
ABNT NBR ISO 8092-3:2006 Motor road vehicles-connections for embedded electrical wiring harnesses Part 3: Tabs for Multipole connections-dimensions and specific requirements
ABNT NBR ISO 8092-4:2006 Motor road vehicles-connections for embedded electrical wiring harnesses Part 4: PIN for unipolar and multipolar connections-dimensions and specific requirements
ABNT NBR 15447:2006 Motor road vehicles-Auto-radio-measurement of effective audio power in Watts RMS
ABNT NBR ISO 3732:2006 Road vehicles-connectors for the electrical connection between tractors and traction vehicles-vehicles-seven-pin connectors 12 type S (Supplement) for vehicles with 12 V nominal voltage
ABNT NBR 15207:2005 Amendment 1:2006 Airports-Ambulances-Requirements
ABNT NBR 15207:2006 Airports-Ambulances-Requirements
ABNT NBR ISO 612:2006 Motor road vehicles-dimensions of motor vehicles and towed vehicles-terms and definitions
ABNT NBR ISO 6311:2006 Road vehicles-automotive brake Linings-internal resistance to shear friction material-test procedure
ABNT NBR ISO 11841-1:2006 Motor road vehicles and internal combustion engines-filter Vocabulary Part 1: definitions of filters and filter components
ABNT NBR ISO 10599-1:2006 Auto-radio antenna Coaxial Connectors Part 1: dimensions
ABNT NBR ISO 10599-2:2006 Auto-radio antenna Coaxial Connectors Part 2: characteristic Values, performance requirements and tests
ABNT NBR ISO 8092-2:2006 Motor road vehicles-connections for embedded electrical wiring harnesses Part 2: definitions, test methods and general performance requirements
ABNT NBR 12070:2006 Clutch plateau-verification of resistance to centrifugal force-test method
ABNT NBR NM ISO 11406:2006 Commercial road vehicles-mechanical Coupling between "unit with rear-mounted hitch and draw bar trailers-Interchangeability
ABNT NBR 5483:2006 Acoustics-measurement of noise emitted by horns installed in self-propelled road vehicles-engineering Method
ABNT NBR ISO 1176:2006 Motor road vehicles-Masses-Vocabulary and codes
ABNT NBR 14844:2006 Motor road vehicles-endothermic engine coolant-practical advice
ABNT NBR 13776:2006 Motor road vehicles, its towed and combined-
ABNT NBR ISO 11451-2:2006 Motor road vehicles-vehicle test methods for electrical disturbances caused by electromagnetic energy emitted in narrow band Part 2: external radiation sources to the vehicle
ABNT NBR NM ISO 4086:2006 Road vehicles-90 King Pin for semi-trailers-Interchangeability
ABNT NBR 12683:2005 Road vehicles-automotive brake systems-dicso brakes-check for leaks, seals, functionality, strength, presence of gases released by the piston covering and corrosion
ABNT NBR 15320:2005 Accessibility to the disabled person in road transport
ABNT NBR 15300-2:2005 Road vehicles-automotive occupant protection-frontal impact tests Part 2: frontal impact test procedure with 100% overlap
ABNT NBR 15300-3:2005 Road vehicles-automotive occupant protection-frontal impact tests Part 3: frontal impact test procedure with 40% overlap
ABNT NBR 15265:2005 Road vehicles-disc-diagram-Requirements
ABNT NBR 15266-1:2005 Motor road vehicles-tachograph Disc-test methods Part 1: determination of moisture stretching
ABNT NBR 15266-10:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test methods Part 10: determination of the deviation of the diameters of the circles print speeds
ABNT NBR 15266-11:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test methods Part 11: determination of concentricity of the circumferences of the print speeds
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ABNT NBR 15266-5:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test methods Part 5: black layer resistance action time registry
ABNT NBR 15266-6:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test method Part 6: evaluation of the performance of the registry under temperature
ABNT NBR 15266-7:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test method Part 7: Resistance of adhesion
ABNT NBR 15266-8:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test methods Part 8: visual assessment

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ABNT NBR 15266-9:2005 corrected version: 2007 Motor road vehicles-tachograph Disc-test method Part 9: determination of rotational print offset
ABNT NBR 15240:2005 Motor road vehicles-behaviour of the structure of the passenger compartment-requirements for rear impact tests
ABNT NBR 15241:2005 Motor road vehicles-fuel system-requirements for rear impact tests
ABNT NBR 15222:2005 Motor road vehicles-instant and unchangeable Recorder of speed and time (tachograph) fitted with disc-diagram
ABNT NBR 15209:2005 For tank transport of anhydrous hydrofluoric acid (100%) in bulk
ABNT NBR ISO 7642:2005 Trailers-housing (trailers) and light trailers-Trailers of categories the [1] [2] and with inécia brakes-brake test method in the test Workbench
ABNT NBR 15180:2004 Motor road vehicles-vehicle identification number (VIN)-re-recorded version
ABNT NBR 15148:2004 Automotive clutch System road vehicles-noise Evaluation
ABNT NBR ISO 10486:2004 Passenger cars-car radio identification number (CRIN)
ABNT NBR NM ISO 3842:2004 Road vehicle-fifth wheel-Interchangeability
ABNT NBR ISO 7643:2003 Road vehicles-Trailers of housing (trailers) and light trailers-Trailers of category O [1] [2] and with inertia brakes-linear test method of brake controls
ABNT NBR 14980:2003 Errata 1:2003 Tank for transport of bulk liquid products intended for human or animal consumption requirements
ABNT NBR 14980:2003 corrected version: 2003 Tank for transport of bulk liquid products intended for human or animal consumption requirements
ABNT NBR 14907:2002 Errata 1:2003 Anti-intrusion protection front for motor vehicles with a maximum total mass above 3.5 t-requirements and test methods
ABNT NBR 14970-1:2003 Accessibility in motor vehicles Part 1: driving Requirements
ABNT NBR 14970-2:2003 Accessibility in motor vehicles Part 2: guidelines for clinical evaluation of driver in reduced mobility
ABNT NBR 14970-3:2003 Accessibility in motor vehicles Part 3: guidelines for evaluation of the handling of the driver with reduced mobility in motor vehicle suitable
ABNT NBR NM ISO 1726:2003Road vehicles-mechanical Coupling between tractor and semi-trailer truck-Interchangeability
ABNT NBR NM ISO 8717:2003 Commercial road vehicles-fifth wheel-endurance Tests
ABNT NBR 14889:2002 Errata 1:2003 Motor road vehicles in maintenance-inspection, diagnosis, repair and/or replacement in Diesel cycle engines regulator
ABNT NBR 14906:2002 Road vehicles-automotive brake System-where the tests type I and type II or IIA are not required for brakes of towed vehicles and alternative testing
ABNT NBR 14907:2002 corrected version: 2003 Anti-intrusion protection front for motor vehicles with a maximum total mass above 3.5 t-requirements and test methods
ABNT NBR 14902:2002 Two-wheeled vehicles-Motorcycles-technical terms
ABNT NBR 14889:2002 corrected version: 2003 Motor road vehicles in maintenance-inspection, diagnosis, repair and/or replacement in Diesel cycle engines regulator
ABNT NBR 14893:2002 Two-wheeled vehicles Moped-technical terms
ABNT NBR 14845:2002 Automotive-Motor road vehicles-Test
ABNT NBR 14846:2002 Road vehicles-automotive alternator and voltage regulator-Essay
ABNT NBR 14794:2002 Road vehicles-automotive brake Trim-Determination of the coefficient of friction and wear of disk brakes pads on test bench using constant braking force moment
ABNT NBR 5537:2002 Road vehicles-automotive brake Trim-verification of shear strength between the garrison and the metal support for disk brakes pads and drum brake shoes
ABNT NBR 14783:2001 Motor road vehicles-clutch-system evaluation of trepidation
ABNT NBR 14777:2001 Motor road vehicles in maintenance-removal and installation of glass
ABNT NBR 14778:2001 Motor road vehicles in maintenance-inspection, diagnosis, repair and/or replacement brake system
ABNT NBR 14779:2001 Motor road vehicles in maintenance-inspection, diagnosis, repair and/or replacement in steering system
ABNT NBR 14780:2001 Motor road vehicles in maintenance-inspection, diagnosis, repair and/or replacement in suspension system
ABNT NBR 14781:2001 Motor road vehicles in maintenance-inspection, diagnosis, repair and/or replacement exhaust system
ABNT NBR 14754:2001 Road vehicles-automotive oxygen Sensor-maintenance tests
ABNT NBR 14755:2001 Motor road vehicles-air mass Sensor-maintenance tests
ABNT NBR 9495:2001 Motor road vehicles-servoacionador hydraulic brake check
ABNT NBR 14734:2001 Road vehicles-automotive engine cooling System-Terminology
ABNT NBR 5478:2001 Motor road vehicles-Smoke emitted by diesel engine-Correlation units and limit curve
ABNT NBR 14729:2001 Road vehicles-brake-System requirements for the tests on vehicles equipped with inertia brake
ABNT NBR 13037:2001 Road vehicles-automotive exhaust Gas emitted by diesel engine at free acceleration-determination of opacity
ABNT NBR 7027:2001 Motor road vehicles-Smoke emitted by diesel engine-determination of opacity or the degree of blackening under constant
ABNT NBR NM ISO 337:2001 Road vehicles-50 King Pin for semi-trailers-basic dimensions of mounting and interchangeability
ABNT NBR NM ISO 8716:2001 Commercial road vehicles-King Pin for fifth wheel-endurance Tests
ABNT NBR 14624:2000 Vehicle technical inspection-coding of inspection items
ABNT NBR 14600:2000 Road vehicles-automotive clutch and brake Guanição-determination of acetone soluble constituents
ABNT NBR 14601:2000 Road vehicles-automotive clutch and brake Trim-determination of loss on ignition, ash and moisture content
ABNT NBR 9594:2000 Automotive-trim road vehicles-clutch fastening materials, diameter of 3 mm to 10 mm-dimensions and material
ABNT NBR 14593:2000 Road vehicles-automotive clutch system-skating verification
ABNT NBR 9300:2000 Road vehicles-automotive clutch Plateau-verification of the durability test bench
ABNT NBR 14561:2000 Vehicles to attend to medical emergencies and rescue
ABNT NBR NM 178:2000 Automobile-Radiators-Terminology

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ABNT NBR 14489:2000 corrected version: 2001 Diesel engine-analysis and determination of gases and particulate matter emitted by the diesel engine cycles-cycle of 13 points
ABNT NBR 14482:2000 Otto cycle road vehicles-starting battery replacement
ABNT NBR 9714:2000 Self-propelled road vehicle noise on condition that stopped
ABNT NBR 9080:1999 Clutch disk-verification of resistance to centrifugal force
ABNT NBR 14040-5:1998 Errata 1:1999 Vehicle safety inspection-light and heavy vehicles Part 5: lighting
ABNT NBR 14335:1999 Radiators-performance characteristics-technical terms
ABNT NBR 14040-8:1998 Errata 1:1999 Vehicle safety inspection-light and heavy vehicles Part 8: axles and suspension
ABNT NBR 14284:1999 Road vehicles-Bodywork-repair and painting of components
ABNT NBR 14040-3:1998 Errata 1:1999 Vehicle safety inspection-light and heavy vehicles Part 3: equipment required and prohibited
ABNT NBR 14180-1:1998 Vehicle safety inspection-Motorcycles and the like Part 1: basic guidelines
ABNT NBR 14180-10:1998 Vehicle safety inspection-Motorcycles and the like Part 10: complementary systems and components
ABNT NBR 14180-11:1998 Vehicle safety inspection-Motorcycles and the like Part 11: vehicle safety inspection station
ABNT NBR 14180-12:1998 Vehicle safety inspection-Motorcycles and the like Part 12: enabling vehicular safety inspectors
ABNT NBR 14180-2:1998 Vehicle safety inspection-Motorcycles and the like Part 2: identification
ABNT NBR 14180-3:1998 Vehicle safety inspection-Motorcycles and the like Part 3: equipment required and prohibited
ABNT NBR 14180-4:1998 Vehicle safety inspection-Motorcycles and the like Part 4: signaling
ABNT NBR 14180-5:1998 Vehicle safety inspection-Motorcycles and the like Part 5: lighting
ABNT NBR 14180-6:1998 Vehicle safety inspection-Motorcycles and the like Part 6: Brakes
ABNT NBR 14180-7:1998 Vehicle safety inspection-Motorcycles and the like Part 7: Direction
ABNT NBR 14180-8:1998 Vehicle safety inspection-Motorcycles and the like Part 8: axles and suspension
ABNT NBR 14180-9:1998 Vehicle safety inspection-Motorcycles and the like Part 9: tyres and wheels
ABNT NBR 10166:1998 Clutch plateau-measurement of functional parameters
ABNT NBR 10810:1998 Clutch disc-Determination of the moment of prominence
ABNT NBR 5544:1998 Clutch and brake linings-determination of relative density
ABNT NBR 7813:1998 Clutch and brake linings-type organic friction Material-verify the characteristics of friction and wear Test FAST
ABNT NBR 8970:1998 Clutch disk trim-Requirements
ABNT NBR ISO 3853:1998 Road vehicles-mechanical coupling device of a semitrailer tractor trailers-townhouse-(trailers) and light trailers-mechanical strength test
ABNT NBR 14040-1:1998 Vehicle safety inspection-light and heavy vehicles Part 1: basic guidelines
ABNT NBR 14040-10:1998 Vehicle safety inspection-light and heavy vehicles Part 10: complementary systems and components
ABNT NBR 14040-11:1998 Vehicle safety inspection-light and heavy vehicles Part 11: vehicle safety inspection station
ABNT NBR 14040-12:1998 Vehicle safety inspection-light and heavy vehicles Part 12-enabling vehicular safety inspectors
ABNT NBR 14040-2:1998 Vehicle safety inspection-light and heavy vehicles Part 2: identification
ABNT NBR 14040-3:1998 corrected version: 1999 Vehicle safety inspection-light and heavy vehicles Part 3: equipment required and prohibited
ABNT NBR 14040-4:1998 Vehicle safety inspection-light and heavy vehicles Part 4: signaling
ABNT NBR 14040-5:1998 corrected version: 1999 Vehicle safety inspection-light and heavy vehicles Part 5: lighting
ABNT NBR 14040-6:1998 Vehicle safety inspection-light and heavy vehicles Part 6: Brakes
ABNT NBR 14040-7:1998 Vehicle safety inspection-light and heavy vehicles Part 7: Direction
ABNT NBR 14040-8:1998 corrected version: 1999 Vehicle safety inspection-light and heavy vehicles Part 8: axles and suspension
ABNT NBR 14040-9:1998 Vehicle safety inspection-light and heavy vehicles Part 9: tyres and wheels
ABNT NBR ISO 1585:1996 Road vehicles-engine test Code-net Power effective
ABNT NBR 10452:1996 Transport of livestock-Procedure
ABNT NBR 6948:1996 Rubber gasket for hydraulic brakes-precipitation verification after soaking in liquid for brake
ABNT NBR 7317:1996 Rubber gaskets for hydraulic brakes-verification of change after immersion in brake fluid
ABNT NBR 13539:1995 Infrared Analyzer of carbon monoxide (CO), hydrocarbons (HC) and carbon dioxide (CO_2) contained in the exhaust gas of automotive light road vehicles
ABNT NBR 13540:1995 Infrared Analyzer of carbon monoxide (CO), hydrocarbons (HC) and carbon dioxide (CO_2) contained in the exhaust gas of automotive light road vehicles-Tests
ABNT NBR 13477:1995 Flexible hoses for hydraulic brakes for road vehicles
ABNT NBR 13478:1995 Flexible hoses for hydraulic brakes for road vehicles-Tests
ABNT NBR 7321:1995 Hydraulic oil filter-determination of pressure drop characteristics of flow
ABNT NBR 13367:1995 Rubber gaskets for hydraulic brakes master cylinders-determination of structural strength-test method
ABNT NBR 6143:1995 Disc brake pad-determination of friction and wear through the test bench Krauss
ABNT NBR 6050:1995 Clutch
ABNT NBR 13102:1994 Reflective surfaces applied to motor road vehicles-measurement of specular gloss-test method
ABNT NBR 13123:1994 Reflective surfaces applied to motor road vehicles-specification
ABNT NBR 8359:1994 Locks and hinges of the side doors of motor road vehicles – Determination of the characteristics-test method
ABNT NBR 8358:1994 Locks and hinges of the side doors of motor road vehicles-specification
ABNT NBR 12898:1993 Report of traffic accident (RAT)-Procedure
ABNT NBR 6052:1993 Flange of the fuel level sensor, gasket and fuel tank flange-mounting shapes and basic dimensions
ABNT NBR 13042:1993 Manufacture of vehicle-alarm Procedure
ABNT NBR 12897:1993 Use of the opacimeter for medication of the soot content of Diesel engine-light absorption method-Procedure
ABNT NBR 12895:1993 Check the performance of the service brakes linings for road vehicles, in test bench inertial type (for brake dynamometer)-Procedure
ABNT NBR 5541:1993 Brake trim-verify the characteristics of friction and wear

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ABNT NBR 7329:1993 Hydraulic oil filter-Determination of the integrity of the filter element
ABNT NBR 12813:1993 Extraction of samples of hydraulic fluid from one system into operation, particulate contamination analysis-Procedure
ABNT NBR 12685:1992 Lighting Lantern rear license plate of motor road vehicles-specification
ABNT NBR 6609:1992 Friction levels of friction materials for brake linings
ABNT NBR 12146:1992 Feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the tightness and performance-test method
ABNT NBR 12149:1992 -Reducer vaporizer for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the operation-test method
ABNT NBR 12153:1992 Fuel feeder for feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the operation-test method
ABNT NBR 12515:1992 Graphic symbols for systems and components of hydraulic and pneumatic brakes-Symbolism
ABNT NBR 12530:1992 Symbols of the dimensions of road vehicles, cargo and special automotive mixed Symbols
ABNT NBR 12556:1992 External and internal dimensions of road vehicles, cargo and special automotive mixed Terminology
ABNT NBR 12557:1992 Road vehicles-automotive controls, indicators and optical instruments or acoustic-Terminology
ABNT NBR 12562:1992 Long range auxiliary Lighthouse-specification
ABNT NBR 11893:1991 Feed components of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11894:1991 Fuel filter for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11895:1991 -Reducer vaporizer for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11896:1991 Solenoid valve for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 11897:1991 Fuel feeder for feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-specification
ABNT NBR 12147:1991 Fuel filter for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklift trucks-inspection of tightness test method
ABNT NBR 12148:1991 -Reducer vaporizer for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklift trucks-inspection of tightness test method
ABNT NBR 12150:1991 Solenoid valve for the feeding of reciprocating internal combustion engines for liquefied petroleum gas oil, for exclusive use in forklifts-verification of the tightness of the valve body-test method
ABNT NBR 12151:1991 Solenoid valve for the feeding of reciprocating internal combustion engines for liquefied petroleum gas, for exclusive use in forklifts-checking the operation-test method
ABNT NBR 11866:1991 Rubber sealing ring for cylinders of the disk brakes-specification
ABNT NBR 11868:1991 Round wire of carbon steel, drawn for the manufacture of wheels-specification
ABNT NBR 12101:1991 Rubber sealing ring for cylinders of the disk brakes-Determination of characteristics-test method
ABNT NBR 5534:1991 Description of the requirements for the location and identification of controls lighting cars and vans
ABNT NBR 6602:1991 Clutch-evaluation on capacity of ramp work stream
ABNT NBR 5520:1991 Brake linings-determination of hardness "Gogan" of friction materials
ABNT NBR 12013:1990 Automotive light road vehicles-measurement of the concentration of carbon monoxide in the exhaust gas, idling (field test)-test method
ABNT NBR 11407:1990 Vulcanized elastomer-determination of changes of the physical properties, the effect of liquid-immersion test method
ABNT NBR 11800:1990 Retrorrefletores for road vehicles-test method
ABNT NBR 5531:1990 Road vehicles-shooting
ABNT NBR 6056:1990 Positioning of the locus of the driver's eyes in relation to road vehicle
ABNT NBR 6060:1990 Locus of the driver's eyes in self-propelled road vehicles-dimensions
ABNT NBR 11408:1990 Road vehicles-determination of burning velocity of the inner-coating materials test method
ABNT NBR 11472:1990 Plastic fuel tank for self-propelled road vehicles-specification
ABNT NBR 11954:1990 Determination of the coefficient of friction between the windshield and the cleaning of the pick blade-test method
ABNT NBR 6047:1990 Automotive-Engine road vehicles
ABNT NBR 11216:1990 Identification of connections of pneumatic brake systems, engines of road vehicles-Procedure
ABNT NBR 7026:1990 Exhaust gas emitted by Diesel engine-measuring soot with Sampler for filter element
ABNT NBR 10965:1989 Warning triangle-specification
ABNT NBR 5521:1989 Windshield wiper of cars and vans-verification of durability
ABNT NBR 10853:1989 Indicators of temperature and electric meters fuel-level Specification
ABNT NBR 9712:1989 Heat transfer limitation of the brake drum for tire-specification
ABNT NBR 9500:1986 Errata 1:1989 Project minimum requirements for road vehicle door-container-Procedure
ABNT NBR 10962:1989 Brake trim-verification of resistance of glue between the friction surfaces and work due to corrosion-test method
ABNT NBR 10753:1988 Brake trim-evaluation of characteristics of friction material in test bench inertial type (dynamometer) for brakes of cars and vans of mixed use-test method
ABNT NBR 5533:1988 Motor road vehicles bodywork and chassis frame
ABNT NBR 5108:1987 Terminals with electrical connections by screw clamps for insulated cables-dimensions and tolerances
ABNT NBR 6058:1987 Use of two-dimensional device for positioning of occupants in road vehicles
ABNT NBR 5556:1986 Symbols for identification of controls, indicators and pilot lights of road vehicles and road machines, automotive, industrial and agricultural tractors
ABNT NBR 5505:1984 Friction material to the brake lining of road vehicles, industrial and similar verification of stability, expansion and growth
ABNT NBR 8360:1984 Vulcanized elastomer-accelerated aging in ozone Chamber-static test-test method

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ABNT NBR 8833:1983 Determination of the conformity of vehicles with the established standards for leakage-issuance Procedure
ABNT NBR 7014:1981 Horns for motor road vehicles
ABNT NBR 7023:1981 Direction-self-propelled road vehicles
ABNT NBR 6018:1980 Low voltage terminals for ignition coil
ABNT NBR 5929:1978 Alternative vehicular internal combustion engines to ethanol
ABNT NBR 5552:1977 Rubber gaskets for hydraulic brakes
ABNT NBR 5922:1977 Steel tubes for fuel injection in diesel engines for use in vehicles, tractors and similar
ABNT NBR 5443:1977 Double-wall steel tubes for fluid conduction

Source: ABNT. Prepared by CCGI-EESP/FGV.

Table 29 - Vehicles Regulation (Argentina)

NAME	THEME
LAW 24449	Regulates traffic in Argentina
DECREE 779/95	Regulates law 24449
RESOLUTION 247/05	Attributes to the National Institute of Industrial Technology the competence to verify the compliance with legal requirements for the management of the requests for granting the License for Model Configuration (LCM).
RESOLUTION 97/14	Approves the requirements and procedure for registration to the National Registry of Autoparts Testing Laboratories
INTI DIRECTING COUNCIL RESOLUTION 10/14	Approves the procedure for recognition of testing/measurement laboratories for the automotive and auto parts industry to incorporate to the "Network of Laboratories for the Automotive Industry" (RELIAU)
LAW 26363	Creates the National Road Safety Agency
PROVISION 166/10	Implements in all zero kilometer vehicles the double airbag, the anti-lock braking system and the headrest for all seats adjacent to the doors (side)
PROVISION 494/10	Implements the central headrest, visual and acoustic warning device for the driver's safety belt and automatic lighting
PROVISION 272/11	Implements the frontal and rear impact test and the child restraint system
DISPOSITION 408/10	Establishes terms for the implementation of the automatic low-beam lighting system on motor vehicles that would be incorporated into the Argentine automotive park
RESOLUTION 91/01	Regulates the replacement market for auto parts for automotive vehicles
DECREE 13/15	Appoints the Secretariat of Environmental Control and Monitoring as the competent authority in the contamination control
RESOLUTION 1464/15	Implements the limits and procedures of emissions certification

Source: Ministerio de Producción. Prepared by CCGI-EESP/FGV.

Table 30 -Vehicles Standards (Argentina)

NAME	TITLE
IRAM-AITA 8-A1	Road vehicles. Wheels for trucks, buses, and towed vehicles. Requirements and test methods.
IRAM - 10271	Commercial road vehicles. Mechanical coupling devices. Wear limits.
IRAM - 12542	Tempered glass, safety, road transport vehicles. Methods of determination of defects.
IRAM - 12536	Flat and curved, safety, tempered, glass for land transport vehicles. Test method for determining the resistance to impact.
IRAM - 12554	Safety glass, tempered, flat and curved, for terrestrial transport vehicles. Fragmentation test method.
IRAM - 12546	Safety glass tempered for terrestrial transport vehicles.
IRAM - 12564	Land transport vehicle safety glasses. Method for the determination of the light transmission.
IRAM - 12571	Lamellar safety glass for land transport vehicles. Test method for impact resistance.
IRAM - 12570	Lamellar safety glass for land transport vehicles. Test method for moisture resistance.
IRAM - 8407	Industrial vehicles. Symbols for the tell-tales, indicators and controls.
IRAM - 8411	Industrial vehicles. Safety requirements for their construction and operation.
IRAM - 8410	Industrial vehicles. The braking performance.
IRAM - 8406	Industrial vehicles. Definitions and terminology.
IRAM - 8401	Industrial vehicles. Front forklift. Counterbalanced.
IRAM - 16030	Vehicles of medical transport and its equipment. Ground ambulances. Requirements.
IRAM-AITA 13-J7	Road vehicles. Symbols for controls, indicators and witnesses.
IRAM-AITA 1-N10B1	Road vehicles. Wiper system. Part 1 - Requirements and test methods.
IRAM-NM-ISO 3842	Road vehicles. Hitch plate. Interchangeability.
IRAM - 10251	Road vehicles. Bolt the hitch plate. Strength tests.
IRAM-NM-ISO 4086	Road vehicles. 90 fifth wheel hitch PIN. Interchangeability.
IRAM-AITA 11-B3	Road vehicles. Address ends, axial joints and joints from suspension. Requirements and test methods.
IRAM-AITA 21069-1 ISO	Road vehicles. Test of brake systems of vehicles with total maximum authorized mass greater 3,5 t using roller brake testers. Part 1 - Air brake systems.
IRAM-AITA 10274-1	Road vehicles. Energy efficiency. Part 1 - Measurement of emissions of CO2 and fuel economy.
IRAM-AITA 6-G2	Road vehicles. Diaphragms for air brake chambers. Requirements and test methods.

IRAM-AITA 10275	Road vehicles. Names and categories.
IRAM-AITA 6-C2	Road vehicles. Sets lining brake, disc or drum, replacement, for motor vehicles and their trailers. Requirements and test methods.
IRAM-AITA 6-E4	Road vehicles. Hydraulic master cylinder for brake and clutch. Requirements and test methods.
IRAM-AITA 11-A2	Road vehicles. Boxes of steering rack and pinion. Part 2: Methods of test.
IRAM-AITA 11-A1	Road vehicles. Boxes of steering rack and pinion. Part 1: Requirements.
IRAM-AITA 6-G3-2	Road vehicles. Vacuum pumps (depressants) to over-run. Part 2: Methods of test.
IRAM-AITA 6-G3-1	Road vehicles. Vacuum pumps (depressants) to over-run. Part 1: Requirements.
IRAM-AITA 4-D2	Road vehicles. Conventional telescopic hydraulic dampers. Requirements and test methods.
IRAM-AITA 4-D3	Road vehicles. Structural dampers (McPherson). Requirements and test methods.
IRAM - 10269	Commercial road vehicles. Location of electrical and pneumatic connections between tractor vehicles and towed.
IRAM - 10268	Commercial road vehicles. Hose coiled for the connection of the pneumatic between tractor vehicle and trailer brake system. Requirements and test methods.
IRAM - 10262	Commercial road vehicles. Hitch plate. Requirements and test methods.
IRAM - 10272	Commercial road vehicles. The hitch plate backing plate. Requirements and test methods.
IRAM - 10252	Commercial road vehicles. Drawbar eye. Requirements and test methods.
IRAM - 10253	Commercial road vehicles. 50 mm of drawbar eye. Requirements and interchangeability.
IRAM-AITA 10261	Commercial road vehicles. Tow hook. Requirements.
IRAM - 10258	Commercial road vehicles. Axes. Requirements and test methods.
IRAM-AITA 10260	Commercial road vehicles. Rear (bumper) protection devices. Requirements and test methods.
IRAM - 10259	Commercial road vehicles. Mechanical coupling devices. Marking.
IRAM-AITA 10276	Commercial road vehicles. Lateral protection devices. Requirements.
IRAM - 10255	Commercial road vehicles. Coupling devices and rigid eyelets. Strength tests.
IRAM - 10256	Commercial road vehicles. Mechanical device for coupling articulated traction bars. Strength tests.
IRAM - 10263	Commercial road vehicles. Vertical bracket Assembly of semi-trailers. Requirements and test methods.
IRAM - 10265	Commercial road vehicles. Connectors for the electrical connection between tractor vehicles and towed. 7-pin type connector 24 (supplementary) S for vehicles with a rated voltage of 24 V.-requirements and test methods.
IRAM - 10264	Commercial road vehicles. Connectors for the electrical connection between tractor vehicles and towed. 7-pin type connector 24 N (normal) for vehicles with a rated voltage of 24 V.-requirements and test methods.
IRAM - 10266	Commercial road vehicles. Connectors for the electrical connection between tractor vehicles and towed. 15-pin connector for vehicles with nominal voltage of 24 V.-requirements and test methods.
IRAM - 10267	Commercial road vehicles. Brake pneumatic between tractor vehicle and trailer connectors. Requirements and test methods.
IRAM - 10257	Commercial road vehicles. Mechanical coupling between towing device vehicle's coupling in the rear and with drawbar trailers. Interchangeability.
IRAM - 10254	Commercial road vehicles. Drawbar coupling. Interchangeability.
IRAM-NM-ISO 337	Road vehicles. 50 fifth wheel coupling pin. Mounting and interchangeability characteristics and basic measures.
IRAM-NM-ISO 8717	Commercial road vehicles. Hitch plate. Strength tests.
IRAM-AITA 1-N10B3	Motor vehicles. Systems wipers for automobiles and light trucks. Test methods.
IRAM-AITA 1-N10B2	Motor vehicles. Systems wipers for automobiles and light trucks. Inspection and reception.
IRAM-AITA 1-N1	Motor vehicles. System washer, for cars and trucks.
IRAM-AITA 6-H2	Motor vehicles. Liquids for hydraulic brake and clutch systems. Test methods.
IRAM-AITA 6-H10	Motor vehicles. Liquids for hydraulic brake and clutch systems. Inspection and reception.
IRAM-AITA 6-H5	Motor vehicles. Fluid for hydraulic brake and clutch systems. Type 5.1.
IRAM-AITA 6-H4	Motor vehicles. Fluid for hydraulic brake and clutch systems. Type 4.
IRAM-AITA 6-H3	Motor vehicles. Fluid for hydraulic brake and clutch systems. Type 3.
IRAM-AITA 6-A2-1	Motor vehicles. Campaign-hydraulic brake wheel cylinders. Requirements.
IRAM-AITA 6-A2-3	Motor vehicles. Campaign-hydraulic brake wheel cylinders. Test methods.
IRAM-AITA 6-A2-2	Motor vehicles. Campaign-hydraulic brake wheel cylinders. Merchandise inspection and reception.
IRAM-AITA 6-E4-2	Motor vehicles. Master cylinder for hydraulic brakes. Inspection and reception.
IRAM-AITA 1-K15-2	Motor vehicles. Anchorages for safety belts. Part 2: on vehicles without anchor factory.
IRAM-AITA 1-K15-1	Motor vehicles. Anchorages for safety belts. Part 1: on vehicles with factory Rke anchors.
IRAM-AITA 4-D2-2	Motor vehicles. Telescopic shock absorbers. Inspection and reception.
IRAM-AITA 0-B3	Motor vehicles, trailers and semiacoplados. Definition of dimensions.
IRAM-AITA 0-B1	Commercial motor vehicles, trailers and semiacoplados. General definitions.
IRAM-AITA 3680 - 1	On Board of motor vehicles (SRI) child restraint systems. Part 1 - Definitions and classification.
IRAM-AITA 3680 - 3	Child restraint (SRI) on Board of motor vehicle systems. Part 3 - LATCH System. Requirements and test methods.
IRAM-AITA 3680 - 2	Child restraint (SRI) on Board of motor vehicle systems. Part 2 - ISOFIX system and universal, semi-universal, restricted and specific categories. Requirements and test methods.
IRAM - 3927	Safety in lifting equipment. Hydraulic articulated jib cranes mounted on vehicles or on surface. Constructive characteristics, operation, inspection, testing and maintenance.
IRAM - 3926	Safety in lifting equipment. Lifting and rotating aerial devices mounted on vehicles (gidroelevators), to position personal.

IRAM - 11076	Wheels for commercial vehicles. Measures.
IRAM - 10051	Ramps for the entry and exit of persons with reduced mobility to vehicles for the transport of passengers with a capacity of more than nine seats.
IRAM - 10052	Platform lifts for the entry and exit of people in wheelchairs to vehicles for the transport of passengers with a capacity of more than nine seats.
IRAM-2008-2	Rotating electrical machines. Methods of test for the determination of losses and performance, excluding machines for electric traction vehicles.
IRAM - 2185	Rotating electrical machines of traction. To be used in the railways, vehicles and four-wheel-drive systems.
IRAM-FA L 7010	Railway material. Coil springs suspension for vehicles.
IRAM-FA L 7019	Material feroviario. Bars for the manufacture of springs for suspension for vehicles.
IRAM-AITA 1-F15-2	Incandescent (filament) lamps for motor vehicles. Part 2: Performance requirements and test conditions.
IRAM-AITA 1-F15-1	Incandescent (filament) lamps for motor vehicles. Part 1: Dimensional, electrical and luminous requirements.
IRAM-FA L 2055	Incandescent electric lamps for railway vehicles.
IRAM-FA L 7025	Wheels for railway vehicles.
IRAM - 4260	Instruments for measuring the speed of motor vehicles.
IRAM - 3895	Protective clothing for racing drivers. Protection against heat and fire. Performance requirements and test methods.
IRAM-IAPG TO 6863	Natural gas. Compressed natural gas (CNG) used as a fuel for motor vehicles. Quality parameters.
IRAM-FA L 7007	Central screw Coupler. For towed vehicles.
IRAM-FA L 7020	Axes for towed vehicles.
IRAM-FA L 12578	Double glazed sealed for railway vehicles with air conditioning.
IRAM-3641-1	Seat belts for use in motor vehicles. Requirements and test methods.
IRAM-3641-2	Seat belts for use in motor vehicles. Inspection and reception.
IRAM-IAS U 500 255	Hot vehicle rolled high strength steel sheets.
IRAM-AITA 0-B2	Loads in commercial motor vehicles, trailers and semiacoplados. General definitions.
IRAM-AITA 9-C	Acoustic. Measurement of noise emitted by vehicles in acceleration. Engineering method.
IRAM-AITA 9-C1	Acoustic. Measurement of noise emitted by motor vehicles in use, detained. Verification method.

APPENDIX 3 - Cosmetics

Table 31 - Regulation on cosmetics (Brazil)

NAME	THEME
DECREE 8077/13	Regulates law 6360/76
LAW 6360/76	Basic rules for personal hygiene, perfumery and cosmetics products
ANVISA ORDINANCE 131/16	Labeling for SUS
ANVISA ORDINANCE 83/16	Internalization of Mercosul regulation
ANVISA ORDINANCE 69/16	Internalization of Mercosul regulation
ANVISA ORDINANCE 15/15	Internalization of Mercosul regulation
ANVISA ORDINANCE 7/15	Internalization of Mercosul regulation
ANVISA ORDINANCE 48/13	Internalization of Mercosul regulation
ANVISA ORDINANCE 19/13	Internalization of Mercosul regulation
ANVISA ORDINANCE 15/13	Internalization of Mercosul regulation
ANVISA ORDINANCE 44/12	Internalization of Mercosul regulation
ANVISA ORDINANCE 30/12	Internalization of Mercosul regulation
ANVISA ORDINANCE 29/12	Internalization of Mercosul regulation
ANVISA ORDINANCE 3/12	Internalization of Mercosul regulation
ANVISA ORDINANCE 54/11	Time extension
ANVISA ORDINANCE 38/11	Internalization of Mercosul regulation
ANVISA ORDINANCE 36/09	Formaldehide
ANVISA ORDINANCE 92/08	Deregulation (Degrees 1 and 2)
ANVISA ORDINANCE 176/06	Internalization of Mercosul regulation
ANVISA ORDINANCE 172/06	Time extension
ANVISA ORDINANCE 78/06	Time extension
ANVISA ORDINANCE 332/05	Cosmetic vigilance system
ANVISA ORDINANCE 108/05	Time extension
ANVISA ORDINANCE 13/03	Toothbrushes
ANVISA ORDINANCE 254/02	Inclusion of www.anvisa.gov.br website
ANVISA ORDINANCE 79/00	Definition of PHPC
ANVISA ORDINANCE 74/00	Training program on good governance for auditors and inspectors
ANVISA ORDINANCE 10/99	Pacifiers and other items
ANVISA RESOLUTION 481/99	Microbiological control of PHPC
ANVISA ORDINANCE 296/98	Adoption of Mercosul classification system
ANVISA ORDINANCE 295/98	
ANVISA ORDINANCE 97/96	Toothbrushes
INMETRO ORDINANCE 228/05	Evaluation Regulation of Social Responsibility Management System
INMETRO ORDINANCE 108/05	Rules for toys under the Brazilian System for Conformity Assessment (SBAC)
INMETRO ORDINANCE 197/02	Revises the technical metrological regulation establishing the minimum conditions thermometers used in the determination of the temperature of petroleum have to meet as much as their liquid derivatives
INMETRO ORDINANCE 146/01	Creates a Technical Metrological Regulation that establishes the conditions portable and non-portable ethylometers for evidentiary purposes have to meet
INMETRO ORDINANCE 105/01	Pre-measured cosmetics and toilet products
INMETRO ORDINANCE 69/01	Provisions for PHPC goods in the following states: solid, semi-solid, gel, solid and liquid form; and which are physically characterized by lack of fluidity
INMETRO ORDINANCE 100/00	Establishes requirements for the liquid-flow glass thermometers, internal scale and total immersion type EIL and EIC
INMETRO ORDINANCE 126/99	Establishes criteria for commercialization, indication of the net content and methodology of verification of the liquid content of soap and bar soap
INMETRO ORDINANCE 87/99	Establishes the conditions the packaging of soap and bar soap products commercialized in the domestic market have to meet
MERCOSUL GMC RESOLUTION 7/05	Classification of personal hygiene products, cosmetics and perfumes
MERCOSUL GMC RESOLUTION 36/04	Compulsory Labelling General for Personal Care Products, Cosmetics and Perfumes
MERCOSUL GMC RESOLUTION 26/04	Specific technical requirements for toiletries, cosmetics and perfumes
MERCOSUL GMC RESOLUTION 36/99	Specific labelling for personal care products, cosmetics and perfumes
MERCOSUL GMC RESOLUTION 24/95	Requirements for the registration of Mercosul and extra-zone cosmetic products and for business entities registration holders and importers
MERCOSUL GMC RESOLUTION 110/94	Definition of cosmetic products

Source: ANVISA, INMETRO, MERCOSUL. Prepared by CCGI-EESP/ FGV (May 2017).

Table 32 - ABNT Standards on Personal Hygiene, Perfumery and Cosmetics (Brazil)

STANDARD	THEME
ABNT NBR 16483:2016	Beauty salon — people skills who work in beauty salons
ABNT NBR 16383:2015	Beauty salon-requirements of good practice in the provision of services
ABNT NBR 16283:2015	Beauty salon-Terminology

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ABNT NBR ISO 21149:2008	Cosmetics-microbiology-detection and Count of aerobic mesophilic bacteria
ABNT NBR ISO 21150:2008	Cosmetics-microbiology-detection of Escherichia coli
ABNT NBR ISO 22717:2008	Cosmetics-microbiology-detection of Pseudomonas aeruginosa
ABNT NBR ISO 22718:2008	Cosmetics-microbiology-detection of Staphylococcus aureus
ABNT NBR ISO 21148:2008	Cosmetics-microbiology-general instructions for microbiological research

Source: ABNT. Prepared by CCGI-EESP/ FGV (May 2017).

Table 33 - Regulation on cosmetics, hygienic products and perfumery (Argentina)

NAME	THEME
ANMAT RESOLUTION 2016/93	Regulates cosmetics and hygiene goods subject to the intervention of ANMAT
ANMAT DISPOSITION 2723/97	Approves the Unique Form of authorization for the importation of medicine, cosmetic products and hygienic products, reactive of diagnosis of use "in vitro" and/or disposable material, apparatus and equipment of medical and dental use
ANMAT DISPOSITION 1109/99	Conditions techniques for the qualifications that are required and eligibility requirements of such applications, in relation to the production or importation of cosmetic products for personal hygiene and perfume
ANMAT DISPOSITION 1402/08	Pharmaceuticals, personal hygiene, cosmetics and perfumes approving procedures
ANMAT DISPOSITION 1107/09	Rule that one must adjust companies producing, importing, exporting and packing of products of personal hygiene, cosmetics and Perfumes
ANMAT DISPOSITION 11276/16	Prohibit the use, marketing, import and export of the substance pure gamma butyrolactone (GBL) for the reasons set out in recital of the present
ANMAT DISPOSITION 13831/16	Banned products using antibacterial registered in ANMAT. Products of personal hygiene, cosmetics and perfumes are these national and imported, the substances listed in annex I, which is part of this provision
ANMAT DISPOSITION 13832/15	All physical and/or legal person performing import, export, production, manufacture, fractionation, marketing and/or deposit, within national jurisdiction or destined for interprovincial trade, of substances listed in the annex of the this provision, as well as also for medicinal or pharmaceutical specialities containing them, must register with the DVSSCE of the INAME to obtain a special certification for the management of these substances
ANMAT DISPOSITION 7529/13	Established that the substances formaldehyde and paraformaldehyde only may be used in personal hygiene products, cosmetics and perfumes under the conditions and detailed use restrictions
ANMAT DISPOSITION 7230/12	Grant term for companies that manufacture and importing of personal hygiene products, cosmetics and perfumes to proceed with adjustments for the fulfilment of the provision ANMAT No. 957/2012
ANMAT DISPOSITION 6544/12	It establishes the list of substances for limited use observed at the national level for personal hygiene products, cosmetics and perfumes
ANMAT RESOLUTION 327/12	Establishment requirements of registration and authorization for the marketing of repellents for human use in the national territory
ANMAT DISPOSITION 959/12 (WITH THE MODIFICATIONS OF THE DISPOSITION 5812/12)	Adopting the electronic management system with digital signature for the application for automatic admission of products of personal hygiene, cosmetics and perfumes of annex I, categorized according the ANMAT No. 345/06 available
ANMAT DISPOSITION 685/09	Establish that admission of personal hygiene products, cosmetics and perfumes of grade I must be requested and processed exclusively in electronic form, prior to the marketing of them
ANMAT DISPOSITION 374/06	Measures taken on labeling to follow personal hygiene products, cosmetics and perfumes. Glossary of definitions
ANMAT DISPOSITION 5572/05	Prohibit the use use of lead acetate in cosmetic products from the entry into force of this provision. Prohibit the marketing of cosmetic products containing in its formulation lead acetate, as of January 31, 2006. Companies producing and/or importing must withdraw from the market the existing containers according to the date indicated in the preceding article and proceed to their destruction
ANMAT DISPOSITION 6830/01	The Disposition set forth that will be considered cosmetic products those protective solar which meet the definition established by article 2 ° (former M.S. & A.S.) resolution No. 155/98
ANMAT DISPOSITION 1112/99	Limitations that apply to the use of certain raw materials that can be used in Personal hygiene, cosmetics and perfume products are making national or imported
ANMAT DISPOSITION 1108/99	Technical standards for the products of personal hygiene, cosmetics and Perfumes-automatic admission
MSYAS FORMER RESOLUTION 155/98	Update of regulations related to the personal hygiene cosmetic products and Perfumes, and activities inherent to them
MERCOSUL GMC RESOLUTION 62/2014	Mercosul technical regulation about the list of substances that cannot be utilized on products of personal hygiene, cosmetics and perfumes.
MERCOSUL GMC RESOLUTION 16/2012	Mercosul technical regulation about the list of color substances allowed to products of personal hygiene, cosmetics and perfumes
MERCOSUL GMC RESOLUTION 24/2011	Mercosul technical regulation about the list of substances that products of personal hygiene, cosmetics and perfumes must not contain, except on conditions and with the restrictions established
MERCOSUL GMC RESOLUTION 19/2011	Mercosul technical regulation of good practices of production for products of personal hygiene, cosmetics and perfumes
MERCOSUL GMC RESOLUTION 8/2011	Mercosul technical regulation about sun protectors on cosmetics
MERCOSUL GMC RESOLUTION 7/2011	Mercosul technical regulation about the list of substances of conservative action allowed for products of personal hygiene, cosmetics and perfumes
MERCOSUL GMC RESOLUTION 48/2010	List of substances of cosmetic use

MERCOSUL RESOLUTION 46/2010	**GMC**	Mercosul technical regulation about the list of substances that products of personal hygiene, cosmetics and perfumes must not contain, except on the conditions and with the restrictions established
MERCOSUL RESOLUTION 38/2009	**GMC**	List of color substances allowed for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 51/2008	**GMC**	Criteria and mechanism for the update of Mercosul lists of substances in products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 49/2008	**GMC**	Criteria for the subscription of simplification agreements of procedures of sanitary control of products of personal hygiene, cosmetics and perfumes grade 1 produced in Mercosul
MERCOSUL RESOLUTION 26/2006	**GMC**	Contracting of outsourcing for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 25/2005	**GMC**	Update of the resolution GMC nº 71/00 – Mercosul technical regulation "List of ultraviolet filters allowed for personal hygiene products, cosmetics and perfumes"
MERCOSUL RESOLUTION 19/2005	**GMC**	Program of cosmetic vigilance, on the area of personal hygiene products, cosmetics and perfumes
MERCOSUL RESOLUTION 7/2005	**GMC**	Mercosul technical regulation "Classification of products of personal hygiene, cosmetics and perfumes"
MERCOSUL RESOLUTION 5/2005	**GMC**	Mercosul technical regulation "Authorization of functioning / habilitation of companies of products of personal hygiene, cosmetics and perfumes, its modifications and eliminations/cancellations"
MERCOSUL RESOLUTION 36/2004	**GMC**	Mercosul technical regulation about general compulsory labelling for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 26/2004	**GMC**	Specific technical requisites for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 48/2002	**GMC**	Mercosul technical regulation about the list of substances that products of personal hygiene, cosmetics and perfumes must not contain, except on the conditions and with the established restrictions
MERCOSUL RESOLUTION 26/2002	**GMC**	Mercosul technical regulation about sun protectors in cosmetics
MERCOSUL RESOLUTION 71/2000	**GMC**	Update of res. GMC nº 8/99 – Mercosul technical regulation "List of ultraviolet filters, allowed to personal hygiene products, cosmetics and perfumes"
MERCOSUL RESOLUTION 50/2000	**GMC**	Mercosul technical regulation for the quantitative indication of cosmetics
MERCOSUL RESOLUTION 49/2000	**GMC**	Mercosul technical regulation about the control of liquid content for the quantitative indication of cosmetic and hygienic products and traded in nominal amounts from 5g/ml to 20g/ml
MERCOSUL RESOLUTION 47/1999	**GMC**	Program of training of inspectors on good practices of production and control for the industry of hygiene products, cosmetics and perfumes
MERCOSUL RESOLUTION 36/1999	**GMC**	Technical regulation about specific labelling for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 8/1999	**GMC**	Update of res. GMC nº 25/95 "List of ultraviolet filters, allowed for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 51/1998	**GMC**	Parameters of microbiological control for products of personal hygiene, cosmetics and perfumes
MERCOSUL RESOLUTION 41/1996	**GMC**	Name for ingredients utilized in products of personal hygiene, cosmetics and perfumes of Mercosul origin and extra zone for use on registry between State parties
MERCOSUL RESOLUTION 28/1995	**GMC**	List of substances that cannot be utilized on the formulation of cosmetic products
MERCOSUL RESOLUTION 27/1995	**GMC**	List of conservative agents allowed for use in hygiene products, perfumes and cosmetics
MERCOSUL RESOLUTION 25/1995	**GMC**	List of ultraviolet filters, allowed for use on hygiene products, perfumes and cosmetics
MERCOSUL RESOLUTION 24/1995	**GMC**	Requisites for the registry of Mercosul and extra zone cosmetic products and for habilitation of representing companies that detain the registry on the receiving State party and importers
MERCOSUL RESOLUTION 110/1994	**GMC**	Definition of cosmetic products

Source: ANMAT. Elaborated by CCGI-EESP/FGV

Table 34 - Standards on Cosmetic (Argentina)

NAME	TITLE	STATE
IRAM-ISO 21148	Cosmetics. Microbiology. General instructions for microbiological examination.	In force.
IRAM - 25536	Products for personal hygiene, cosmetics and perfumes. Test method for microbiological control.	In force.
IRAM-37022-1	Cosmetics. Good practices of manufacture of cosmetic products. Directives for the design, construction specifications, operating conditions and maintenance of manufacturing areas.	In force.
IRAM-37022-2	Cosmetics. Good practices of manufacture of cosmetic products. Directives relating to the adequacy, clothing and hygiene of personnel from the area of manufacturing.	In force.
IRAM-37022-3	Cosmetics. Good practices of manufacture of cosmetic products. Directives for the design, maintenance and cleaning of the area of manufacturing equipment.	In force.
IRAM-37022-4	Cosmetics. Good practices of manufacture of cosmetic products. Guidelines for the documentation and registration of manufacturing activities.	In force.
IRAM-37022-5	Cosmetics. Good practices of manufacture of cosmetic products. Guidelines for the areas of storage and forwarding.	In force.

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IRAM-37022-6	Cosmetics. Good practices of manufacture of cosmetic products. Directives to elaborate.	In force.
IRAM-37022-7	Cosmetics. Good practices of manufacture of cosmetic products. Filling, packaging and packaging directives.	In force.
IRAM - 37028	Cosmetics. Guide to application of methods for the study of the stability.	In force.

Source: IRAM. Elaborated by CCGI-EESP/FGV.

APPENDIX 4 - Machinery and Mechanical Equipment

Table 35 - Regulation on Machinery and mechanical Equipment (Brazil)

NAME	THEME
LAW 123/06	Exceptions to NR 12 for small and micro enterprises (SMEs)
ILO CONVENTION 119	Protection of machinery
LAW 6514/77	Safe work environment for workers in the machinery sector
DECREE 5452/43	Consolidation of the labor laws
ORDINANCE 509/16	In case of a conflict between the items of annexes and the items of general parts of the norm, the requisites in the annex prevail
ORDINANCE 211/15	Manual of machinery and mechanical appliances produced or imported since the validity of the norm
ORDINANCE 857/15	Exemption of compliance with technical safety requirements foreseen in NR 12
ORDINANCE 1893/13	Changes NR 12
ORDINANCE 23/11	Import of used machinery and used parts of machinery
ORDINANCE 197/10	Creates the National Thematic Tripartite Commission – CNTT of NR 12 with the objective of accompanying the implementation of the new NR 12 regulation
INMETRO ORDINANCE 577/15	Refrigerators, freezers and other refrigerating or freezing equipment
INMETRO ORDINANCE 165/15	Vehicle platform list
INMETRO ORDINANCE 164/15	Vehicle platform lift. Other lifting, handling, loading; unloading machinery elevators
INMETRO ORDINANCE 547/14	Catalytic converter body
INMETRO ORDINANCE 472/14	Parts and accessories of the motor vehicles of headings 87.01 to 87.05
INMETRO ORDINANCE 406/14	Taps, cocks, valves and similar appliances for pipes
INMETRO ORDINANCE 343/14	Powders fire extinguishers / Mechanical appliances for projecting/dispersing
INMETRO ORDINANCE 255/14	Steam or other vapor generating boilers
INMETRO ORDINANCE 123/14	Parts and accessories of vehicles of headings 87.11 to 87.13
INMETRO ORDINANCE 50/14	Silencers (mufflers) and exhaust pipes
INMETRO ORDINANCE 45/14	Parts and accessories for motor cycles
INMETRO ORDINANCE 18/14	Child devices
INMETRO ORDINANCE 442/13	Child devices
INMETRO ORDINANCE 410/13	Air conditioning machines comprising a motor-driven fan and elements for changing the temperature and humidity, incl. those machines in which the humidity cannot be separately regulated; parts thereof
INMETRO ORDINANCE 642/12	Vehicle platform
INMETRO ORDINANCE 588/12	Vehicle platform
INMETRO ORDINANCE 301/12	Systems and equipment for water heating using solar energy
INMETRO ORDINANCE 182/12	Instantaneous/storage gas water heaters
INMETRO MINISTERIAL ACT 7/12	Systems and equipment for water heating using solar energy
INMETRO ORDINANCE 486/10	Fire extinguishers and parts of fire extinguishers, spray guns and sprayers
INMETRO ORDINANCE 18/04	Parts; accessories for adp machines; units
INMETRO ORDINANCE 261/02	Non-automatic weighing instruments
INMETRO ORDINANCE 171/02	High pressure cylinders for methane gas storage
IBAMA ORDINANCE 6/15	Vehicles, tractors; mechanical appliances for agricultural machinery, etc.
CONTRAN RESOLUTION 641/16	Vehicles (Electronic stability control - ESC)
CONTRAN RESOLUTION 593/16	Bumpers and parts, for motor vehicles
CONTRAN RESOLUTION 567/15	Vehicles (stability control system)
NR 36	Safety and health on work in slaughter companies and processing of meat and meat products
NR 34	Conditions and work environment in the industry of construction, repair and ship dismantling

NR 33	Safety and health on work in confined spaces
NR 32	Safety and health on work in health services
NR 31	Safety and health on work in agriculture, livestock, forestry, forest exploration and aquaculture
NR 30	Safety and health on waterway work
NR 29	Safety and health on port work
NR 28	Oversight and penalties
NR 23	Protection against fires
NR 22	Safety and occupational health in mining
NR 20	Safety and health in the work with flammable and combustible
NR 19	Explosives
NR 18	Conditions and working environment in the construction industry
NR 17	Ergonomics
NR 13	Boilers and pressure vessels
NR 12	Safety at work in machines and equipment
NR 11	Transportation, movement, storage and handling of materials
NR 5	Internal commission of prevention of accidents – CIPA
NR 4	Specialized services in safety and work medicine engineering
NR 3	Embargo or ban
NR 2	Previous inspection
NR 1	General provisions
TECHNICAL NOTE DSST/SIT 179/16	Application of national standards (ABNT), international technical standards (ISO and IEC) and harmonized European standards
TECHNICAL NOTE 48/16	Alters NR 12

Source: INMETRO e MTE. Prepared by CCGI-EESP/FGV.

Table 36 - Mechanical Machinery Standards (Brazil)

STANDARDS
ABNT NBR 16579:2017 Hydraulic presses-Safety requirements
ABNT NBR ISO 7500-1:2016 Metallic materials – Calibration and verification of static uniaxial testing machines Part 1: tensile/compression test-calibration and verification of measurement system of the force
ABNT NBR 16557:2016 Bakery machines-Mass rolling machines-Safety and hygiene requirements
ABNT NBR 15456:2016 Storage of flammable and combustible liquids – Construction and testing of line voltages
ABNT NBR 6412:2016 Ed 3:2016 Hydraulic turbines — Approval of models
ABNT NBR 6412:2016 Amendment 1:2016 Hydraulic turbines-Reception of models
ABNT NBR 16357:2016 Seamless steel cylinder, for the manufacture of portable fire extinguishers and on wheels with load up to 10 kg of CO2 — Requirements and test methods
ABNT NBR 13865:2016 Bakery machines —Rods with roller length greater than or equal to 400 mm — Safety and hygiene requirements
ABNT NBR 16542:2016 Bakery machines — Flour mills — Safety and hygiene requirements
ABNT NBR 16543:2016 Bakery machines — Sliceries — Safety and hygiene requirements
ABNT NBR 15734:2016 Bakery machinery — Dough mixers — Safety and hygiene requirements
ABNT NBR 16535-1:2016 Roller bearings-Accessories Part 1: mounting bushings and plugs of disassembly for bearings of tapered bore
ABNT NBR 16535-2:2016 Roller bearings-Accessories Part 2: dimensions of fastening nuts and locking devices
ABNT NBR 14250:2016 Pressure regulators for gas cylinders used in welding, cutting and allied processes-requirements and test methods
ABNT NBR 11327:2016 Requirements for use of pulleys with motor operator
ABNT NBR 16496:2016 Measurement of water and gas-metering service provider for residential and commercial buildings-Requirements
ABNT NBR 10147:2016 Escalators and crawlers — Inspection and acceptance testing, periodic and routine
ABNT NBR 11093:2016 hort stem for broaching-Specifications
ABNT NBR 16455:2016 Pressure vessels-methodology for non-intrusive inspection
ABNT NBR ISO 15241:2016 Roller bearings — Symbols for physical quantities
ABNT NBR 15406:2016 V belts for agricultural machinery-Requirements
ABNT NBR ISO 5167-3:2016 Fluid flow measurement by differential pressure devices inserted into the penstocks of circular cross-section Part 3: nozzles and Venturi nozzles
ABNT NBR 13536:2016 Safety of machinery — Plastic and rubber injection molding machine
ABNT NBR 8854:2016 Surface defects in screws — Procedure
ABNT NBR 10976:2016 Locking washers with external nail — Dimensions
ABNT NBR 9581:2016 Hydraulic turbines and turbine pumps accumulation — verification of the cavitation erosion
ABNT NBR 11326:2016 Lifting equipment and cargo handling-hook-forged rod set-dimensions
ABNT NBR 16463-1:2016 Cranes Part 1: requirements for the preparation of instruction manuals
ABNT NBR 16463-2:2016 Cranes Part 2: Identification
ABNT NBR ISO 8528-7:2014 Errata 1:2016 Alternating current generators driven by reciprocating internal combustion engines Part 7: declarations techniques for specification and design
ABNT NBR 16579:2017 Hydraulic presses-safety requirements
ABNT NBR ISO 7500-1:2016 Metallic materials – calibration and verification of static uniaxial testing machines Part 1: tensile/compression test-calibration and verification of measurement system of the force

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ABNT NBR 16557:2016 Bakery machines-mass rolling machines-safety and hygiene requirements
ABNT NBR 15456:2016 Storage of flammable and combustible liquids – Construction and testing of line voltages
ABNT NBR 6412:2016 Ed 3:2016 Hydraulic turbines — approval of models
ABNT NBR 6412:2016 Amendment 1:2016 Hydraulic turbines-reception of models
ABNT NBR 16357:2016 Seamless steel cylinder, for the manufacture of portable fire extinguishers and on wheels with load up to 10 kg of CO2 — requirements and test methods
ABNT NBR 13865:2016 Bakery machines — Rods with roller length greater than or equal to 400 mm — safety and hygiene requirements
ABNT NBR 16542:2016 Bakery machines — flour mills — safety and hygiene requirements
ABNT NBR 16543:2016 Bakery machines — Slicing — safety and hygiene requirements
ABNT NBR 15734:2016 Bakery machinery — dough mixers — safety and hygiene requirements
ABNT NBR 16535-1:2016 Roller bearings-accessories Part 1: mounting Bushings and plugs of disassembly for bearings of tapered bore
ABNT NBR 16535-2:2016 Roller bearings-accessories Part 2: dimensions of fastening nuts and locking devices
ABNT NBR 14250:2016 Pressure regulators for gas cylinders used in welding, cutting and Allied processes-requirements and test methods
ABNT NBR 11327:2016 Requirements for use of pulleys with motor operator
ABNT NBR 16496:2016 Measurement of water and gas-metering service provider for residential and commercial buildings-Requirements
ABNT NBR 10147:2016 Escalators and crawlers — inspection and acceptance testing, periodic and routine
ABNT NBR 11093:2016 Short stem with 7:24 cone for broaching-specifications
ABNT NBR 16455:2016 Pressure vessels-methodology for non-intrusive inspection
ABNT NBR ISO 15241:2016 Roller bearings — symbols for physical quantities
ABNT NBR 15406:2016 V belts for agricultural machinery-Requirements
ABNT NBR ISO 5167-3:2016 Fluid flow measurement by differential pressure devices inserted into the penstocks of circular cross-section Part 3: nozzles and Venturi nozzles
ABNT NBR 13536:2016 Safety of machinery — plastic and rubber injection molding machine
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ABNT NBR 10976:2016 Locking washers with external nail — Dimensions
ABNT NBR 9581:2016 Hydraulic turbines and turbine pumps accumulation — verification of the cavitation erosion
ABNT NBR 11326:2016 Lifting equipment and cargo handling-hook-forged rod set-dimensions
ABNT NBR 16463-1:2016 Cranes Part 1: requirements for the preparation of instruction manuals
ABNT NBR 16463-2:2016 Cranes Part 2: Identification
ABNT NBR ISO 8528-7:2014 Errata 1:2016 Alternating current generators driven by reciprocating internal combustion engines Part 7: declarations techniques for specification and design
ABNT NBR 16127:2015 Plain bearings-thin-walled Bearings with or without flange-Tolerance, design features and test methods (ISO 3548-1:2014, MOD)
ABNT NBR ISO 6892-1:2013 Errata 1:2015 Metallic materials — Tensile Testing Part 1: Method of test at ambient temperature
ABNT NBR ISO 9809-1:2014 Errata 1:2015 Gas cylinders-seamless steel cylinders, gases-design, construction and tests Part 1: Quenched and tempered steel cylinders with tensile strength less than 1 100 MPa
ABNT NBR 16348:2015 Conveyor belts with tarpaulins, textile products in bulk-dimensions, specifications and markings
ABNT NBR 16017:2015 Plain bearings-multilayer Materials for thin-walled plain bearings
ABNT NBR 16128:2015 Plain bearings-Aluminum alloys for solid bearings
ABNT NBR 6110:2015 Continuous conveyors — Belt conveyors — Widths and lengths of conveyor belts
ABNT NBR 14610:2015 Temperature indicator with sensor-Calibration by comparison
ABNT NBR ISO 8528-1:2014 Alternating current generators, driven by reciprocating internal combustion engines Part 1: application, features and performance
ABNT NBR ISO 8528-10:2014 Alternating current generators driven by reciprocating internal combustion engines Part 10: measurement of environmental noise by the surrounding surface
ABNT NBR ISO 8528-12:2014 Alternating current generators driven by reciprocating internal combustion engines Part 12: power source for safety services
ABNT NBR ISO 8528-2:2014 Alternating current generators driven by reciprocating internal combustion engines Part 2: engines
ABNT NBR ISO 8528-3:2014 Alternating current generators driven by reciprocating internal combustion engines Part 3: generators for generating sets
ABNT NBR ISO 8528-4:2014 Alternating current generators driven by reciprocating internal combustion engines Part 4: switching and control equipment
ABNT NBR ISO 8528-5:2014 Alternating current generators driven by reciprocating internal combustion engines Part 5: generators
ABNT NBR ISO 8528-6:2014 Alternating current generators driven by reciprocating internal combustion engines Part 6: test methods
ABNT NBR ISO 8528-7:2014 corrected version: 2016 Alternating current generators driven by reciprocating internal combustion engines Part 7: declarations techniques for specification and design
ABNT NBR ISO 8528-8:2014 Alternating current generators driven by reciprocating internal combustion engines Part 8: requirements and testing for low power generating groups
ABNT NBR ISO 8528-9:2014 Alternating current generators driven by reciprocating internal combustion engines Part 9: measurement and evaluation of mechanical vibration
ABNT NBR 16329:2014 Stationary mixers — Safety requirements
ABNT NBR 5891:2014 Rounding decimal numbering rules

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ABNT NBR 16324:2014 Chain hoists with manual override — Requirements and test methods
ABNT NBR ISO 4649:2014 Rubber, vulcanized or thermoplastic-Determination of abrasion resistance by using a rotating cylindrical drum device
ABNT NBR 16318:2014 Measurement of liquid flow in closed conduits-Volumetric liquid collection method in measuring tank
ABNT NBR 8011:2014 Continuous conveyors-Belt conveyors-Capacity calculation
ABNT NBR 12550:2014 Thermometry-Terminology
ABNT NBR 10124:2014 Instrument for measurement and control-measuring tape-Fiber ribbon requirements
ABNT NBR 6172:2014 Continuous conveyors-Conveyor belts-Drums-Dimensions
ABNT NBR ISO 1119:2014 Geometrical product specifications (GPS) — A series of angles and cones of cone-shape/fusiform
ABNT NBR 15473:2014 Storage of flammable and combustible liquids-Post vehicle dealer (services)-Manufacturing and performance of additional filter for line voltages (metering pump)
ABNT NBR ISO 5941:2014 Compressors, pneumatic tools and machines-Preferred pressures
ABNT NBR 12727:2014 Diaphragm type gas meter, for residential installations-Requirements and test methods
ABNT NBR ISO 10100:2014 Hydraulic fluid systems-Cylinders-Acceptance tests
ABNT NBR 15827:2014 Industrial valves for exploration, production, refining and transport of oil products — Design requirements and testing of prototype
ABNT NBR 16301:2014 Specification and acceptance of heating furnaces, heat treatment and thermochemical processes of metals
ABNT NBR 15538:2014 Water meters — Tests for evaluation of efficiency
ABNT NBR 16133:2012 Errata 1:2014 Bakery machines-Accessories-Baking sheets and pans
ABNT NBR 15015:2014 Storage of flammable and combustible liquids — Floating ball valve
ABNT NBR 15138:2014 Storage of flammable and combustible liquids — Unloading sealed device
ABNT NBR 16275:2014 Continuous conveyors — Belt conveyors cleaning system — Method of obtaining reference value for assessing the efficiency of scrapers
ABNT NBR 15139:2014 Storage of flammable and combustible liquids — Non-return valve installed at suction lines
ABNT NBR ISO 9809-1:2014 corrected version: 2015 Gas cylinders – Seamless steel cylinders, gases — Design, construction and tests Part 1: Quenched and tempered steel cylinders with tensile strength less than 1 100 MPa
ABNT NBR ISO 9809-3:2014 Gas cylinders – Seamless steel cylinders, gases — Design, construction and tests Part 3: normalized steel cylinders
ABNT NBR ISO 9809-2:2014 Gas cylinders – Seamless steel cylinders, gases — Design, construction and tests Part 2: Quenched and tempered steel cylinders with tensile strength greater than or equal to 1 100 MPa
ABNT NBR 8205:2014 Continuous conveyors – Belt conveyors — Calculation of strength and power
ABNT NBR 8163:2014 Continuous conveyors — Belt conveyors – Conveyor belts thickness and your toppings
ABNT NBR ISO 23125:2013 Machine tools — Safety
ABNT NBR 15177:2013 Poly V belts — Requirements
ABNT NBR ISO 12100:2013 Safety of machinery — General principles of design — assessment and reduction of risks
ABNT NBR 8194:2013 Water meters — Standardization
ABNT NBR ISO 9386-1:2013 Motorized lifting platforms for persons with reduced mobility — Safety requirements, dimensions and functional operation Part 1: vertical lift platforms
ABNT NBR ISO 148-1:2013 Metallic materials-Charpy pendulum impact test Part 1: test method
ABNT NBR ISO 148-2:2013 Metallic materials-Charpy pendulum impact test Part 2: verification of testing machines
ABNT NBR ISO 13855:2013 Safety of machinery — Positioning of protective equipment with reference to the approach of human body parts
ABNT NBR 16197:2013 Errata 1:2013 Calculation of rolling paths in elastic solid basis for lifting and handling of loads — Procedure
ABNT NBR 12240:2013 Metallic materials – Calibration of static torque measuring devices
ABNT NBR ISO 6892-2:2013 Metallic materials — Tensile testing Part 2: test method for high temperature
ABNT NBR ISO 9513:2013 Metallic materials – Calibration of strain gage systems used in axially round trials
ABNT NBR 16022:2013 Plain bearings — Thin-walled bearings — Measurement of the height of the back of the sleeve — Application of standard plug
ABNT NBR ISO 3548-3:2013 Plain bearings — Thin-walled bearings with or without flange Part 3: measurement of peripheral length
ABNT NBR 16198:2013 Measurement of fluid flow in closed conduits — Methods using ultrasonic flowmeter for transit time — General guidelines for the selection, installation and use
ABNT NBR 14712:2013 Electric and hydraulic lifts — Freight elevators, lifts and elevators of gurney — Safety requirements for construction and installation
ABNT NBR 16035-5:2013 Boilers and pressure vessels – Minimum requirements for the construction Part 5: pressure vessels not subject to call-European standard
ABNT NBR 15082:2013 Narrow V-belts metric — Requirements
ABNT NBR 16197:2013 corrected version: 2013 Calculation of rolling paths in elastic solid basis for lifting and handling of loads — Procedure
ABNT NBR 14105-1:2013 Errata 1:2013 Pressure gauges Part 1: analog gauges with elastic element sensor manufacturing requirements, grading, testing and use
ABNT NBR 16035-4:2013 Boilers and pressure vessels — Minimum requirements for construction Part 4: according to ASME Code, Section VIII, Division 2
ABNT NBR 16107:2012 Errata 1:2013 Conversion factor of gas volume
ABNT NBR 14153:2013 Safety of machinery — Parts of safety-related control systems — General principles for design

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ABNT NBR 16169:2013 Continuous conveyors, belt conveyors — Methodology for dynamic test of fence in rolls of belt conveyors in mud tank
ABNT NBR 16200:2013 Construction elevators for persons and materials with vertically guided cabin-safety requirements for construction and installation
ABNT NBR ISO 6892-1:2013 corrected version: 2015 Metallic materials — Tensile testing Part 1: method of test at ambient temperature
ABNT NBR ISO 463:2013 Geometric specifications of products (GPS) — Dimensional measuring instruments — Metrological characteristics and mechanical comparator clock project
ABNT NBR 14105-1:2013 corrected version: 2013 Pressure gauges Part 1: analog gauges with elastic element sensor manufacturing requirements, grading, testing and use
ABNT NBR ISO 8573-1:2013 Compressed air — Contaminants and purity classes
ABNT NBR 16100:2012 Amendment 1:2013 Retaining rings for holes — Rectangular section — Specification
ABNT NBR 16100:2013 Retaining rings for holes — Rectangular Section — Specification
ABNT NBR 13861:2013 Continuous conveyors — Belt conveyors — Storage, packaging and handling of conveyor belts
ABNT NBR 15070:2013 Double "V" belts (hexagonal) classics — Requirements
ABNT NBR 9711:2013 Industrial hoses — Terminology
ABNT NBR ISO 376:2012 Errata 1:2013 Metallic materials – Calibration of force measuring instruments used for the verification of testing machines uni axially round
ABNT NBR 16147:2013 Lifting equipment and cargo handling — Commissioning — Specification
ABNT NBR 16144:2013 Plain bearings — Thin-walled bearings — Tolerances and design features for the micro-filament of the inner diameter of the sleeve
ABNT NBR 5854:2013 Simple pressure washers with folded edges or straight — Shapes and dimensions
ABNT NBR 13770:2013 Thermocouple-Calibration by comparison with standard instrument
ABNT NBR 16139:2013 Conveyor belts — Procedure for dynamic test for rollers — Test method
ABNT NBR 16133:2012 corrected version: 2014 Bakery machines — Accessories — Baking sheets and pans
ABNT NBR 16035-2:2012 Ed 2 Boilers and pressure vessels — Minimum requirements for construction Part 2: according to ASME Code, Section I
ABNT NBR 16035-3:2012 Ed 2 Boilers and pressure vessels — Minimum requirements for construction Part 3: according to ASME Code, Section VIII, Division 1
ABNT NBR 16035-1:2012 Ed 2 Boilers and pressure vessels — Minimum requirements for construction Part 1: general
ABNT NBR 10123:2012 Measuring and control instrument — Steel tape measuring tape — Requirements
ABNT NBR ISO 7183:2012 Compressed air dryers — Specifications and tests
ABNT NBR 16107:2012 corrected version: 2013 Conversion factor of gas volume
ABNT NBR ISO 19973-1:2012 Pneumatic systems-Determination of confidence in components by means of tests Part 1: general procedures
ABNT NBR ISO 19973-2:2012 Pneumatic systems-Determination of confidence in components by means of tests Part 2: directional control valves
ABNT NBR 10143:2012 Air compressors — Classification
ABNT NBR 10144:2012 Air compressor — Terminology
ABNT NBR 16084:2012 Measurement of fluid flow in closed conduits — Guidance for the selection, installation and use of Coriolis meters (measurement of mass flow rate, density and volumetric)
ABNT NBR 16083:2012 Maintenance of lifts, escalators and crawlers — Requirements for maintenance instructions
ABNT NBR ISO 1217:2012 Positive displacement compressors — Acceptance tests
ABNT NBR ISO 4414:2012 Pneumatic power transmission — General and safety requirements for systems and components
ABNT NBR 15003:2012 V-belts for light duty — Requirements
ABNT NBR 14963:2012 Classical V-belts-Requirements
ABNT NBR 15002:2012 Narrow V-belts-Requirements
ABNT NBR ISO 9386-2:2012 Motorized lifting platforms for persons with reduced mobility — Safety requirements, dimensions and functional operation Part 2: stairway lifts for users seated, standing and wheelchair-bound, moving on an inclined plane
ABNT NBR 8197:2012 Metallic materials – Calibration of force measuring instruments of general use
ABNT NBR ISO 376:2012 corrected version: 2013 Metallic materials – Calibration of force measuring instruments used for the verification of testing machines uni axially round
ABNT NBR 16042:2012 Electric passenger lifts — Safety requirements for the construction and installation of lifts without machine room
ABNT NBR 16043-1:2012 Measurement of water flow in closed conduits under load — Meters for hot and cold drinking water Part 1: specifications
ABNT NBR 16043-2:2012 Measurement of water flow in closed conduits under load — Meters for hot and cold drinking water Part 2: installation requirements
ABNT NBR 16043-3:2012 Measurement of water flow in closed conduits under load — Meters for hot and cold drinking water Part 3: test methods and equipment
ABNT NBR 16020:2011 Electronic measurement of liquids — Flow computers
ABNT NBR ISO 4378-1:2011 Plain bearings -Terms, definitions, classification and symbols Part 1: design, materials and their properties
ABNT NBR ISO 4384-2:2011 Plain bearings-Metal hardness testing of sliding Part 2: solid material
ABNT NBR ISO 10099:2011 Pneumatic systems-Cylinders – Final examination and acceptance criteria

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ABNT NBR 15972:2011 Plain bearings — Copper alloys — Copper alloys processed mechanically to flat solid bearings (ISO 4382-2:1991, MOD)
ABNT NBR 15970:2011 Glass liquid thermometer — Calibration
ABNT NBR 15962:2011 Hoses, rubber, for grit blasting — Requirements
ABNT NBR 15959:2011 Rubber hoses for welding, cutting and related processes — Requirements
ABNT NBR 15958:2011 Safety requirements for design of load-lifting equipment
ABNT NBR ISO 12301:2011 Plain bearings-techniques of quality control and inspection of quality characteristics of geometric and material
ABNT NBR ISO 5167-2:2011 Fluid flow measurement for pressure differential devices inserted in circular cross-section penstocks Part 2: orifice plates
ABNT NBR 5866:2011 Pressure washers for screws with cylindrical head-Dimensions
ABNT NBR 5868:2011 Metric trapezoidal screw ISO
ABNT NBR 5876:2011 Threads-Terminology
ABNT NBR 10065:2011 Fasteners of stainless steel and corrosion-resistant steel − Specification
ABNT NBR 6669:2011 Chipboard screws — Requirements
ABNT NBR 5875:2011 Bolts, nuts and fittings – Terminology
ABNT NBR 10081:2010 Calculation of pipe thread gauges where the fence is not made by the doughnut — Procedures
ABNT NBR 10112:2010 Cylindrical head screw with hexagon socket-product grade A – Dimensions
ABNT NBR 10043:2010 Cross-slotted screw-Penetration calibrator, shapes and dimensions
ABNT NBR ISO 4379:2010 Plain bearings — Copper alloy bushings
ABNT NBR 10087:2010 Hex head bolt and partially threaded product grade C — Dimensions
ABNT NBR 10108:2010 Fasteners-mechanical properties of headless screws and other threaded fasteners similar elements not subject to tensile stresses — Specification
ABNT NBR ISO 12128:2010 Plain bearings — Holes, channels and lubrication scholarships — Dimensions, types, description and your application in sliding bushings
ABNT NBR ISO 4382-1:2010 Plain bearings-Copper alloys Part 1: cast copper alloys for bearings of solid and multilayer thick wall
ABNT NBR 10040:2010 Chipboard screws with head bowed and crossed — Dimensions
ABNT NBR 10106:2010 Acceptance inspection of fasteners — Procedure
ABNT NBR 10114:2010 Rounded socket head cap screw slotted — Degree of the product — Requirements and description
ABNT NBR 5926:2010 Pre-assembled spring washers on bolts — Requirements
ABNT NBR ISO 3548-2:2010 Plain bearings-Thin-walled bearings with or without flange Part 2: measurement of the wall thickness and the thickness of the flange
ABNT NBR ISO 12302:2010 Plain bearings-Characteristics of quality-Statistical process control (SPC)
ABNT NBR ISO 12308:2010 Plain bearings-Quality assured-definitions, applications and testing
ABNT NBR ISO 3547-1:2010 Plain bearings — Shaped bushings Part 1: dimensions
ABNT NBR ISO 3547-2:2010 Plain bearings — Shaped bushings Part 2: test data to external and internal diameters
ABNT NBR ISO 3547-3:2010 Plain bearings — Shaped bushings Part 3: holes, and dents lubrication channels
ABNT NBR ISO 3547-4:2010 Plain bearings — Shaped bushings Part 4: materials
ABNT NBR ISO 3547-5:2010 Plain bearings — Shaped bushings Part 5: external diameter check
ABNT NBR ISO 3547-6:2010 Plain bearings — Shaped bushings Part 6: check the internal diameter
ABNT NBR ISO 3547-7:2010 Plain bearings — Shaped bushings Part 7: measurement of wall thickness of thin-wall anchors
ABNT NBR 10113:2010 Slotted socket head cap screw – Product – Degree requirements and description
ABNT NBR 10115:2010 Slotted countersunk head screw-Product grade A – Requirements and description
ABNT NBR 5869:2010 Threaded ends and spare parts of screws – Shapes and dimensions
ABNT NBR 8133:2010 Pipe thread where the fence is not made by the thread-Designation, dimensions and tolerances
ABNT NBR 9595:2010 Fasteners-chipboard screws – Application, choose basic bore diameters and in passing
ABNT NBR 9981:2010 Hex bolt of high strength for structural use-Dimensions
ABNT NBR 10041:2010 Fasteners-Screws self tapping screw with countersunk head and cross-slot-Dimensions
ABNT NBR 10089:2010 Screws — Body length and the threaded part
ABNT NBR 10107:2010 Hex head bolts and thread total-product grade C-Dimensions and tolerances
ABNT NBR 10116:2010 Screw with countersunk head-bowed and crack — Degree of the product — Requirements and description
ABNT NBR 5870:2010 Screw outputs – Shapes and dimensions
ABNT NBR 8091:2010 Tapered threaded pin — Dimensions
ABNT NBR 9583:2010 Auto screwdriver screws with cylindrical head and crack — Dimensions
ABNT NBR 9586:2010 Auto screwdriver screws with countersunk head-bowed and crack — Dimensions
ABNT NBR 9980:2010 Round-head screw, for use as a ladder of electric power transmission line – Requirements and description
ABNT NBR 10042:2010 Fasteners — Chipboard screws with countersunk head bowed and crossed — Dimensions
ABNT NBR ISO 8434-3:2010 Metallic tube connections for fluid transmission and use in general Part 3: flat face connectors with o-ring seal
ABNT NBR ISO 8434-2:2010 Metallic tube connections for fluid transmission and general use Part 2: rounded to 37° connectors
ABNT NBR 9983:2010 Use in washer hex bolt high structural resistance-Dimensions and material-Standardization
ABNT NBR 8244:2010 Left-hand thread spools of warp-Profiles and dimensions

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ABNT NBR 12274:2010 Inspection in steel cylinders, seamless, for gases
ABNT NBR NM ISO 6506-1:2010 Errata 1:2010 Metallic materials-Brinell hardness test Part 1: test method (ISO 6506-1:2005, IDT)
ABNT NBR NM ISO 6506-2:2010 Errata 1:2010 Metallic materials-Brinell hardness test Part 2: verification and calibration of testing machines (ISO 6506-2:2005, IDT)
ABNT NBR NM ISO 6507-1:2008 Errata 1:2010 Metallic materials-Vickers hardness test Part 1: test method
ABNT NBR NM ISO 6508-2:2008 Errata 1:2010 Metallic materials-Hardness test Rockwell Part 2: verification and calibration of testing machines (scales A, B, C, D, E, F, G, H, K, N, T)
ABNT NBR ISO 10360-1:2010 Geometrical products specification (GPS)-Approval tests and periodic verification of coordinate measuring machines (MMC) Part 1: vocabulary
ABNT NBR ISO 10360-3:2010 Geometrical products specification (GPS)-Approval tests and periodic verification of coordinate measuring machines (MMC) Part 3: MMC with the axis of the turntable as fourth axis
ABNT NBR ISO 10360-4:2010 Geometrical products specification (GPS)-Approval tests and periodic verification of coordinate measuring machines (MMC) Part 4: MMC used in measurement in scanning mode
ABNT NBR 12176:2010 Gas cylinders-Identification of the content
ABNT NBR 15055:2004 Errata 1:2010 Globe valves, angle and bronze-retention-Requirements
ABNT NBR 15869:2010 Rubber hoses for abrasive pulp — Requirements
ABNT NBR ISO 4706:2010 Gas cylinders – Refillable cylinders, steel, seamed — Test pressure less than or equal to 60 bar
ABNT NBR 15855:2010 Gas measurement by ultrasonic type gauges multipath
ABNT NBR NM ISO 6506-1:2010 Metallic materials-Brinell hardness test Part 1: test method (ISO 6506-1:2005, IDT)
ABNT NBR NM ISO 6506-2:2010 Metallic materials-Brinell hardness test Part 2: verification and calibration of testing machines (ISO 6506-2:2005, IDT)
ABNT NBR NM ISO 6506-3:2010 Metallic materials-Brinell hardness test Part 3: calibration of reference blocks (ISO 6506-3:2005, IDT)
ABNT NBR NM ISO 6506-4:2010 Metallic materials-Brinell hardness test Part 4: tables of hardness values (ISO 6506-4:2005, IDT)
ABNT NBR ISO 8434-1:2010 Metallic tube connections for fluid transmission and general use Part 1: taper connectors of 24°
ABNT NBR 15597:2010 Safety requirements for the construction and installation of lifts-Existing lifts-Requirements for improving the safety of electric passenger lifts and elevators-passenger electric loads
ABNT NBR 15854:2010 Ice point bath — Preparation, preservation and use as a reference temperature
ABNT NBR ISO 14159:2010 Safety of machinery — Hygiene requirements for the design of machines
ABNT NBR ISO 15242-1:2010 Roller bearings — Vibration measurement methods Part 1: Fundamentals
ABNT NBR ISO 15242-2:2010 Roller bearings – Measuring methods of vibration Part 2: radial ball bearings with cylindrical bore and outside surface
ABNT NBR ISO 15242-3:2010 Roller bearings — Vibration measurement methods Part 3: radial spherical roller bearings selfcomers and tapered bearings with cylindrical bore and outside surface
ABNT NBR ISO 15242-4:2010 Roller bearings — Vibration measurement methods Part 4: radial cylindrical roller bearings with cylindrical bore and outside surface
ABNT NBR ISO 281:2010 Roller bearings — Dynamic load capacity and estimated useful life
ABNT NBR 8883:2008 Errata 1:2010 Calculation and manufacture of floodgate
ABNT NBR 15806:2010 Building remote measurement systems and centralized water and gas consumption
ABNT NBR 6678:2010 Continuous conveyors, conveyor belts — Rollers — Design, selection and standardization
ABNT NBR 15768:2009 Butterfly valve of nodular cast iron for sanitation
ABNT NBR ISO 14743:2009 Pneumatic power transmission system — Instant type thermoplastic pipe connections
ABNT NBR ISO 5175:2009 Equipment used in welding and cutting processes and related processes in gas-safety devices for combustible gases and oxygen or compressed air-General specifications, requirements and testing
ABNT NBR 12892:2009 Single-family or restricted-use lifts to the person with reduced mobility-Safety requirements for construction and installation
ABNT NBR 15005:2009 Storage of flammable and combustible liquids-Underground fuel storage system (SASC)-Anti-overflow valve
ABNT NBR 15706:2009 Storage of flammable and combustible liquids-Swivel joint for supply hose
ABNT NBR ISO 4185:2009 Liquid flow measurement in ducts closed-Gravimetric method
ABNT NBR 6390:1995 Errata 1:2009 Chains of transmission, accuracy, and with short step and corresponding sprockets-Dimensions
ABNT NBR 13742:2009 Continuous conveyors-Belt conveyors-Safety procedures
ABNT NBR 13862:2009 Continuous conveyors-Belt conveyors-Safety requirements for design
ABNT NBR ISO 15878:2008 Equipment for highway maintenance and construction-Asphalt pavers-Terminology and commercial specifications
ABNT NBR NM ISO 6508-1:2008 Metallic materials-Hardness test Rockwell Part 1: test method (scales A, B, C, D, E, F, G, H, K, N, T)
ABNT NBR NM ISO 6508-2:2008 Metallic materials-Hardness test Rockwell Part 2: verification and calibration of testing machines (scales A, B, C, D, E, F, G, H, K, N, T)
ABNT NBR NM ISO 6508-3:2008 Metallic materials-Hardness test Rockwell Part 3: calibration of reference blocks (scales A, B, C, D, E, E, F, G, H, K, N, T)
ABNT NBR ISO 3274:2008 Geometrical product specifications (GPS)-Roughness: profile-Nominal characteristics of instruments by touch (palpation tips)
ABNT NBR ISO 4288:2008 Geometrical product specifications (GPS)-Roughness: profile-Rules and procedures for the evaluation of roughness

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ABNT NBR 11725:2008 Connections and threads for gas cylinders valves
ABNT NBR 13774:2008 Cables of compensation or thermocouple extension-Tolerances and identification
ABNT NBR ISO 15644:2008 Equipment for highway maintenance and construction-Distributors of aggregates-Terminology and commercial specifications
ABNT NBR 13930:2008 Mechanical presses-Safety requirements
ABNT NBR 13771:2008 Cable or thermocouple extension compensation-Calibration by comparison with standard instrument
ABNT NBR 13772:2008 Resistance thermometer calibration by comparison with the reference resistance thermometer
ABNT NBR 13773:2008 Industrial platinum resistance thermometer-Requirements and testing
ABNT NBR 13863:2008 Preparation and use of reference junction for thermocouple calibration
ABNT NBR NM ISO 6507-1:2008 Metallic materials-Vickers hardness test Part 1: test method
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ABNT NBR NM ISO 6507-3:2008 Metallic materials-Vickers hardness test Part 3: calibration of reference boulders
ABNT NBR NM ISO 6507-4:2008 Metallic materials-Vickers hardness test Part 4: tables of hardness values
ABNT NBR ISO 11623:2008 Transportable gas cylinders-Periodic inspection and testing of composite gas cylinder
ABNT NBR ISO 15643:2008 Equipment for highway maintenance and construction-Distributors/sprinklers of bituminous binder-Terminology and commercial specifications
ABNT NBR 8883:2008 corrected version: 2010 Calculation and manufacture of floodgate
ABNT NBR ISO 16528-1:2008 corrected version: 2015 Boilers and pressure vessels Part 1: performance requirements
ABNT NBR ISO 16528-2:2008 Boilers and pressure vessels Part 2: procedures for full attendance of **ABNT NBR** ISO 16528-1
ABNT NBR NM ISO 11439:2008 Gas cylinders-high pressure cylinders for storage of natural gas as fuel, automotive vehicles
ABNT NBR ISO 9300:2008 Gas flow measurement for critical flow Venturi nozzles
ABNT NBR 11758:2008 Extractor liquid industrial machine for textile articles
ABNT NBR ISO 5167-1:2008 Fluid flow measurement by differential pressure devices inserted in circular cross-section penstocks Part 1: General principles and requirements
ABNT NBR 15547:2007 Continuous conveyors, belt conveyors-textile belts-permanent Amendments
ABNT NBR ISO 15642:2007 Equipment for highway maintenance and construction-plants for asphalt mixtures-terminology and commercial specifications
ABNT NBR ISO 15645:2007 Equipment for construction and maintenance of Highways-road milling machine-terminology and commercial specifications
ABNT NBR ISO 15689:2007 Equipment for construction and maintenance of highways-Sprinklers of powder binder-terminology and commercial specifications
ABNT NBR 15869:2010 Rubber hoses for abrasive pulp — requirements
ABNT NBR ISO 4706:2010 Gas cylinders – Refillable cylinders, steel, seamed — test pressure less than or equal to 60 bar
ABNT NBR 15855:2010 Gas measurement by ultrasonic type gauges multipath
ABNT NBR NM ISO 6506-1:2010 Metallic materials-Brinell hardness test Part 1: test method (ISO 6506-1:2005, IDT)
ABNT NBR NM ISO 6506-2:2010 Metallic materials-Brinell hardness test Part 2: verification and calibration of testing machines (ISO 6506-2:2005, IDT)
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ABNT NBR NM ISO 6506-4:2010 Metallic materials-Brinell hardness test Part 4: tables of hardness values (ISO 6506-4:2005, IDT)
ABNT NBR ISO 8434-1:2010 Metallic tube connections for fluid transmission and general use Part 1: taper Connectors of 24°
ABNT NBR 15597:2010 Safety requirements for the construction and installation of lifts-existing Lifts-requirements for improving the safety of electric passenger lifts and elevators-passenger electric loads
ABNT NBR 15854:2010 Ice point bath — Preparation, preservation and use as a reference temperature
ABNT NBR ISO 14159:2010 Safety of machinery — hygiene requirements for the design of machines
ABNT NBR ISO 15242-1:2010 Roller bearings — vibration measurement methods Part 1: Fundamentals
ABNT NBR ISO 15242-2:2010 Roller bearings – measuring Methods of vibration Part 2: radial ball bearings with cylindrical bore and outside surface
ABNT NBR ISO 15242-3:2010 Roller bearings — vibration measurement methods Part 3: radial spherical roller Bearings selfcomers and tapered bearings with cylindrical bore and outside surface
ABNT NBR ISO 15242-4:2010 Roller bearings — vibration measurement methods Part 4: radial cylindrical roller bearings with cylindrical bore and outside surface
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ABNT NBR 15768:2009 Butterfly valve of nodular cast iron for sanitation
ABNT NBR ISO 14743:2009 Pneumatic power transmission system — instant type thermoplastic pipe Connections
ABNT NBR ISO 5175:2009 Equipment used in welding and cutting processes and related processes in gas-safety devices for combustible gases and oxygen or compressed air-general specifications, requirements and testing
ABNT NBR 12892:2009 Single-family or restricted-use lifts to the person with reduced mobility-safety requirements for construction and installation
ABNT NBR 15005:2009 Storage of flammable and combustible liquids-underground fuel storage system (SASC)-Anti-overflow valve

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ABNT NBR 15706:2009 Storage of flammable and combustible liquids-swivel joint for supply hose
ABNT NBR ISO 4185:2009 Liquid flow measurement in ducts closed-gravimetric Method
ABNT NBR 6390:1995 Errata 1:2009 Chains of transmission, accuracy, and with short step and corresponding sprockets-dimensions
ABNT NBR 13742:2009 Continuous conveyors-belt conveyors-safety procedures
ABNT NBR 13862:2009 Continuous conveyors-belt conveyors-safety requirements for design
ABNT NBR ISO 15878:2008 Equipment for highway maintenance and construction-asphalt pavers-terminology and commercial specifications
ABNT NBR NM ISO 6508-1:2008 Metallic materials-hardness test Rockwell Part 1: test method (scales A, B, C, D, E, F, G, H, K, N, T)
ABNT NBR NM ISO 6508-2:2008 Metallic materials-hardness test Rockwell Part 2: verification and calibration of testing machines (scales A, B, C, D, E, F, G, H, K, N, T)
ABNT NBR NM ISO 6508-3:2008 Metallic materials-hardness test Rockwell Part 3: calibration of reference blocks (scales A, B, C, D, E, E, F, G, H, K, N, T)
ABNT NBR ISO 3274:2008 Geometrical product specifications (GPS)-Roughness: profile-nominal Characteristics of instruments by touch (palpation tips)
ABNT NBR ISO 4288:2008 Geometrical product specifications (GPS)-Roughness: profile-rules and procedures for the evaluation of roughness
ABNT NBR 11725:2008 Connections and threads for gas cylinders valves
ABNT NBR 13774:2008 Cables of compensation or thermocouple extension-Tolerances and identification
ABNT NBR ISO 15644:2008 Equipment for highway maintenance and construction-Distributors of aggregates-terminology and commercial specifications
ABNT NBR 13930:2008 Mechanical presses-safety requirements
ABNT NBR 13771:2008 Cable or thermocouple extension compensation-Calibration by comparison with standard instrument
ABNT NBR 13772:2008 Resistance thermometer calibration by comparison with the reference resistance thermometer
ABNT NBR 13773:2008 Industrial platinum resistance thermometer-Requirements and testing
ABNT NBR 13863:2008 Preparation and use of reference junction for thermocouple calibration
ABNT NBR NM ISO 6507-1:2008 Metallic materials-Vickers hardness test Part 1: test method
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ABNT NBR NM ISO 6507-3:2008 Metallic materials-Vickers hardness test Part 3: calibration of reference boulders
ABNT NBR NM ISO 6507-4:2008 Metallic materials-Vickers hardness test Part 4: tables of hardness values
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ABNT NBR ISO 15643:2008 Equipment for highway maintenance and construction-distributors/sprinklers of bituminous binder-terminology and commercial specifications
ABNT NBR 8883:2008 corrected version: 2010 Calculation and manufacture of floodgate
ABNT NBR ISO 16528-1:2008 corrected version: 2015 Boilers and pressure vessels Part 1: performance requirements
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ABNT NBR NM ISO 11439:2008 Gas cylinders-high pressure cylinders for storage of natural gas as fuel, automotive vehicles
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ABNT NBR 11758:2008 Extractor liquid industrial machine for textile articles
ABNT NBR ISO 5167-1:2008 Fluid flow measurement by differential pressure devices inserted in circular cross-section penstocks Part 1: General principles and requirements
ABNT NBR 15547:2007 Continuous conveyors, belt conveyors-textile belts-permanent Amendments
ABNT NBR ISO 15642:2007 Equipment for highway maintenance and construction-plants for asphalt mixtures-terminology and commercial specifications
ABNT NBR ISO 15645:2007 quipment for construction and maintenance of Highways-road milling machine-terminology and commercial specifications
ABNT NBR ISO 15689:2007 Equipment for construction and maintenance of highways-Sprinklers of powder binder-terminology and commercial specifications
ABNT NBR ISO 16039:2007 Equipment for highway maintenance and construction-concrete pavers-definitions and commercial specifications
ABNT NBR NM 313:2007 Passenger lifts-safety requirements for construction and installation-particular requirements for accessibility of people, including people with disabilities
ABNT NBR 15474:2007 Storage of flammable and combustible liquids-construction and performance of automatic nozzles for use in supply units
ABNT NBR 15417:2007 Pressure vessels-Safety Inspection Service
ABNT NBR 15427:2006 Storage of flammable and combustible liquids-safety valve of the hose
ABNT NBR 15416:2006 ubber hoses for suction and discharge of liquid fuels-Requirements
ABNT NBR 15347:2006 Rubber hoses for steam-Requirements
ABNT NBR ISO 9902-1:2005 Textile machinery-noise test code Part 1: common requirements
ABNT NBR ISO 9902-2:2005 Textile machinery-noise test code Part 2: preparation to spinning and spinning
ABNT NBR ISO 9902-3:2005 Textile machinery-noise test code Part 3: non-woven fabric machines
ABNT NBR ISO 9902-4:2005 Textile machinery-noise test codes Part 4: yarn processing machines and the manufacture of rope and codoaria article
ABNT NBR ISO 9902-5:2005 Textile machinery-noise test codes Part 5: weaving and knitting preparation
ABNT NBR ISO 9902-6:2005 Textile machinery-noise test codes Part 6: fabric manufacturing Machinery

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ABNT NBR ISO 9902-7:2005 Textile machinery-noise test code Part 7: dyeing and finishing Machinery
ABNT NBR NM 207:1999 2:2005 Errata Electric passenger lifts-safety requirements for construction and installation
ABNT NBR 15178:2004 Rubber hoses for water suction and discharge requirements
ABNT NBR ISO 261:2004 ISO general purpose metric screw thread-general plan
ABNT NBR ISO 262:2004 ISO general purpose metric screw-diameters selection for screws and nuts
ABNT NBR ISO 68-1:2004 ISO general purpose metric screw thread-basic profile Part 1: metric screw Thread
ABNT NBR ISO 724:2004 ISO general purpose metric screw thread-basic dimensions
ABNT NBR ISO 965-2:2004 ISO general-purpose metric-Tolerances Part 2: dimensional Limits for internal and external threads for general use-medium quality
ABNT NBR ISO 965-3:2004 ISO general-purpose metric-Tolerances Part 3: Clearances for building threads
ABNT NBR ISO 965-4:2004 ISO general-purpose metric-Tolerances Part 4: size limits for external threads for hot-dip galvanized, for assemblies with internal threads with tolerance position H or G after galvanizing
ABNT NBR ISO 965-5:2004 ISO general-purpose metric-Tolerances Part 5: limits for internal thread Dimensions hot-dip galvanized, for assemblies with external threads with tolerance position h before galvanizing
ABNT NBR 14005:1997 Errata 1:2004 Speed meter for cold water, of 15 m ³/h up to 1 500 m ³/h nominal flow
ABNT NBR NM ISO 10791-8:2004 Test conditions for machining centers Part 8: evaluation of the performance of the three coordinate plans outline
ABNT NBR NM ISO 10791-9:2004 Test conditions for machining centers Part 9: evaluation of operation times in trade of tool and pallet Exchange
ABNT NBR 15117:2004 Valves-cast iron drawer with threaded and flanged ends-Requirements
ABNT NBR 15125:2004 Rubber hoses for water and air Requirements
ABNT NBR 15107:2004 Elastomers and plastics machines-shredders-Machines-safety requirements for blade granulators
ABNT NBR ISO 1502:2004 ISO general purpose metric screw thread-Calibrators and calibration
ABNT NBR NM ISO 1984-1:2004 Test conditions for milling machines with manually controlled fixed height table-accuracy test Part 1: machines with horizontal spindle tree
ABNT NBR 15083:2004 -Globe and angle valves, cast iron with flanged and threaded ends-Requirements
ABNT NBR ISO 1478:2004 Self-tapping thread
ABNT NBR 15055:2004 corrected version: 2010 , Globe valves, angle and bronze-retention Requirements
ABNT NBR 15049:2004 Chemical adhesion bolt installed on concrete or masonry elements-determination of structural performance
ABNT NBR NM 290-1:2004 Plain cylindrical plug gauge body "does not pass" for holes with nominal diameter from 1 mm to 40 mm, for general use and in precision mechanics
ABNT NBR NM 290-2:2004 Body of spherical end buffer calibrator "don't matter", for nominal diameter holes above 40 mm up to 500 mm
ABNT NBR NM 290-3:2004 Body of cylindrical flat Cap sectioned calibrator "don't matter", for nominal diameter holes up to 120 mm to 200 mm
ABNT NBR NM 290-4:2004 Body of cylindrical flat Cap sectioned calibrator "don't matter", for holes with nominal diameters above 40 mm to 120 mm
ABNT NBR NM 290-5:2004 lain cylindrical plug gauge body "don't matter", for nominal diameter holes above 40 mm up to 250 mm, for use in precision mechanics
ABNT NBR NM ISO 10791-5:2004 Test conditions for machining centers Part 5: accuracy and repeatability of pallet positioning door parts
ABNT NBR NM ISO 10791-6:2004 Test conditions for machining centers Part 6: accuracy of advances, speeds and interpolations
ABNT NBR NM ISO 230-3:2004 Test code for machine tools Part 3: determination of thermal effects
ABNT NBR NM ISO 13853:2003 Safety of machinery-safety distances to prevent access to danger zones by the lower limbs
ABNT NBR 14968:2003 Errata 1:2003 Valve-drawer of nodular cast iron with rubber wedge-Requirements
ABNT NBR 10285:2003 Industrial valves-Terminology
ABNT NBR NM 282-1:2003 Plain cylindrical plug gauge body "passes", for nominal diameter of holes 1 mm to 40 mm, for use in General and precision mechanics
ABNT NBR NM 282-2:2003 Plain cylindrical plug gauge body "passes", for nominal diameter holes up to 40 mm to 120 mm
ABNT NBR NM 282-3:2003 Body of cylindrical flat Cap sectioned calibrator "passes", for nominal diameter holes up to 120 mm to 200 mm
ABNT NBR NM 282-4:2003 Plain cylindrical plug gauge body "passes", for nominal diameter holes above 40 mm up to 250 mm, for use in precision mechanics
ABNT NBR 14978:2003 Electronic measurement of gas-flow computers
ABNT NBR 14967:2003 Industrial hoses-test methods
ABNT NBR 14968:2003 corrected version: 2003 Valve-drawer of nodular cast iron with rubber wedge-Requirements
ABNT NBR ISO 12132:2003 Sliding bearings-assured quality of thin-wall sleeve design FMEA
ABNT NBR 14957:2003 Technical drawing-knurled representation
ABNT NBR NM 283:2003 Smooth cylindrical ring gauge "passes" and standard flat cylindrical ring for adjusting with nominal diameter from 1 mm to 315 mm for general use and for adjustment of pneumatic devices for measurement of length
ABNT NBR NM 284:2003 Smooth cylindrical ring gauge "passes" and standard flat cylindrical ring for adjusting with nominal diameter from 1 mm to 315 mm for use in precision mechanics
ABNT NBR NM 285:2003 Smooth cylindrical ring gauge "is nothing but" with nominal diameter from 1 mm to 315 mm

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ABNT NBR NM 286:2003 Smooth cylindrical ring gauge "is nothing but" with nominal diameter from 1 mm to 315 mm for use in precision mechanics
ABNT NBR NM ISO 10791-2:2003 Test conditions for machining centers Part 2: geometric Tests for machines with vertical tree axis or with universal heads with primary vertical axis rotation (Z axis-vertical)
ABNT NBR NM ISO 10791-3:2003 Test conditions for machining centers Part 3: geometric Tests for machines with integrated universal heads and indexed or continuous (Z axis-vertical)
ABNT NBR NM ISO 13852:2003 Safety of machinery-safety distances to prevent access to danger zones by upper limbs
ABNT NBR NM ISO 13854:2003 Safety of machinery-minimum Gaps to avoid crushing of parts of the human body
ABNT NBR 14918:2002 Mechanical post installed bolt in concrete-performance assessment
ABNT NBR ISO 4287:2002 Geometrical product specifications (GPS)-Roughness: Method of profile-terms, definitions and parameters of roughness
ABNT NBR 13767:2002 Meat picks-safety requirements
ABNT NBR ISO 12179:2002 Geometrical product specifications (GPS)-Roughness-profile-Calibration method of measuring instruments by touch (palpation socket)
ABNT NBR NM 256:2002 Optical plans
ABNT NBR NM 257:2002 Optical Parallels
ABNT NBR NM 258:2002 V-Prism for inspection
ABNT NBR NM 260:2002 Height meter-features and metrological requirements
ABNT NBR NM 267:2002 Hydraulic passenger lifts-safety requirements for construction and installation
ABNT NBR NM 272:2002 Safety of machinery-Guards-General requirements for the design and construction of fixed and movable guards
ABNT NBR NM 273:2002 Safety of machinery-interlocking Devices associated with guards-principles for design and selection
ABNT NBR NM ISO 10791-1:2002 Test conditions for machining centers Part 1: geometric Tests to machines with horizontal tree and axle with aftermarket heads (Z-axis horizontal)
ABNT NBR NM ISO 230-4:2002 Test code for machine tools Part 4: circular Tests for machine tools with numerical control
ABNT NBR NM 279:2002 Measuring instruments-graduated Rules-steel features and metrological requirements
ABNT NBR 14827:2002 Anchors installed in concrete or masonry elements-determination of tensile strength and shear
ABNT NBR 14831:2002 Hydraulic hoses-requirements and test methods
ABNT NBR 14801:2002 Measurement of gas flow in closed conduits-turbine type Meters-and further testing
ABNT NBR ISO 9951:2002 Measurement of gas flow in closed conduits-turbine type Meters
ABNT NBR 14782:2001 Temperature indicator for resistance thermometer calibration by comparison, using signal generator
ABNT NBR 14699:2001 Technical drawing-symbol Representation applied to geometric tolerances-proportions and dimensions
ABNT NBR 14700:2001 Technical drawing-local representation of hardness measurement
ABNT NBR 14670:2001 Thermocouple temperature indicator-Calibration by comparison using signal generator
ABNT NBR 8018:2001 Metric tapered external and internal parallel matching your
ABNT NBR 14646:2001 Geometric tolerances-maximum requirements and minimum material requirements
ABNT NBR ISO 2768-1:2001 General tolerances Part 1: tolerances for linear and angular dimensions without individual tolerance indication
ABNT NBR ISO 2768-2:2001 General tolerances Part 2: geometric tolerances for elements without indication of individual tolerance
ABNT NBR 14611:2000 Technical drawing-metal structures-simplified Representation
ABNT NBR NM 215:2000 Standard blocks
ABNT NBR NM 216:2000 Callipers and depth callipers-features and metrological requirements
ABNT NBR ISO 9104:2000 Measurement of fluid flow in closed conduits-methods for performance evaluation of electromagnetic flow meters for liquids
ABNT NBR 13142:1999 Technical drawing-copy folding
ABNT NBR 13272:1999 Technical drawing-drawing up of the lists of items
ABNT NBR 13273:1999 Technical drawing-reference to items
ABNT NBR NM 195:1999 Escalator and conveyor belts-safety requirements for construction and installation
ABNT NBR NM 196-10:1999 Elevators passenger and freight elevator guides for cars and counterweights-Profile T
ABNT NBR NM 214:1999 Flat steel strips
ABNT NBR NM ISO 10791-4:1999 Educational conditions for machining centers Part 4: accuracy and repeatability of positioning of linear and rotary axes
ABNT NBR NM ISO 10791-7:1999 Test conditions for machining centers Part 7: test finished part accuracy
ABNT NBR NM ISO 230-1:1999 Test code for machine tools Part 1: geometric accuracy of machine tool operating with no load or finishing conditions
ABNT NBR NM ISO 230-2:1999 Test code for machine tools Part 2: determination of accuracy and repeatability of positioning of axes of machine tool numerical control
ABNT NBR NM 207:1999 Electric passenger lifts-safety requirements for construction and installation
ABNT NBR NM 212:1999 corrected version: 2002 Main meters of cold drinking water up to 15 m ³/h
ABNT NBR ISO 6525:1999 Sliding bearings-abutment ring type Washers made from Strip-dimensions and tolerances
ABNT NBR ISO 6817:1999 Measurement of liquid flow in closed conduits-conductive Method using electromagnetic flowmeters
ABNT NBR 14364:1999 Elevators and escalators-Inspectors of elevators and escalators-qualification

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ABNT NBR 12771:1999 Thermocouples-Reference Tables
ABNT NBR 14326:1999 Fasteners-actuated Tools for payload, for application of concrete steel pins, masonry or structural steel-Methods, types and characteristics
ABNT NBR 14327:1999 Hydraulic lubrication nipples
ABNT NBR ISO 6526:1999 Sliding bearings-Semi-washers bimetallic stamped-characteristics and tolerances
ABNT NBR 14271:1999 Errata 1:1999 Fastener-fixing bolt for payload-specification
ABNT NBR 14267:1999 Fasteners-threaded Parts with coatings of hot-dip zinc-specification
ABNT NBR 14268:1999 Fastener-chipboard screws for concrete and masonry-specification
ABNT NBR 14269:1999 Fasteners-Nails of tempered steel for fixing in concrete and masonry-specification
ABNT NBR 14270:1999 Fasteners-plastic expansion Plugs-specification
ABNT NBR 14271:1999 corrected version: 1999 Fastener-fixing bolt for payload-specification
ABNT NBR 14245:1998 Machines for leather and shoes-technical manuals-Structuring of content
ABNT NBR NM 152:1998 Measuring instruments and systems of bias-Levels
ABNT NBR NM 153:1998 Tilt measurement systems-cylindrical tubes with bubbles-dimensions and requirements
ABNT NBR NM 154:1998 Tilt measurement systems-Electronic Systems-types and requirements
ABNT NBR NM 155:1998 Numerical control of machines-nomenclature of coordinate system and movements
ABNT NBR NM ISO 2972:1998 Numerical control of machines-Symbols
ABNT NBR 14191-1:1998 Safety of machinery-reduction of risks to health resulting from hazardous substances emitted by machinery Part 1: principles and specifications for machinery manufacturers
ABNT NBR 14171:1998 Industrial gas oven-safety requirements
ABNT NBR 10126:1987 Errata 2:1998 Dimensioning on technical drawing-Procedure
ABNT NBR 14152:1998 Safety of machinery-two-hand control devices — functional aspects and principles for project
ABNT NBR 14154:1998 Safety of machinery — prevention of unexpected departure
ABNT NBR 14097:1998 Mineral insulation thermocouple
ABNT NBR 12430:1998 Valve-drawer of nodular cast iron
ABNT NBR NM 103:1998 Granite Desempenos
ABNT NBR NM 104:1998 Cast iron Desempenos
ABNT NBR NM 80:1998 Wired ruler
ABNT NBR NM 81:1998 Steel brackets 90°
ABNT NBR NM ISO 1:1997 Standard reference temperature for industrial measurements of length
ABNT NBR NM ISO 3611:1997 Micrometer for external measurements
ABNT NBR 14005:1997 corrected version: 2004 peed meter for cold water, of 15 m ³/h up to 1 500 m ³/h nominal flow
ABNT NBR 13996:1997 Blow moulding machines intended for the production of hollow thermoplastic articles-safety requirements for design and construction
ABNT NBR 13970:1997 Safety of machinery-temperatures of accessible surfaces-ergonomics Data to establish temperature limit values for hot surfaces
ABNT NBR 8009:1997 Single-Jet water meter for cold water to 15.0 m ³/h nominal flow-Terminology
ABNT NBR 13881:1997 Bimetallic thermometers-manufacturing Recommendations and use Terminology, safety and calibration
ABNT NBR 12228:1997 Stationary tank for the storage of highly chilled gas-periodic inspection
ABNT NBR 6409:1997 Geometric tolerances-Tolerances of form, orientation, position, and beat-Generalities, symbols, definitions and directions in drawing
ABNT NBR ISO 8526-1:1997 Modular units for machine tool pallet truck door parts Part 1: pallet-holders with nominal dimension up to 800 mm
ABNT NBR ISO 8526-2:1997 Modular units for machine tools pallet truck door parts Part 2: pallet-holders with nominal dimension greater than 800 mm
ABNT NBR 13780:1997 Thin-walled half bearing with or without flange-Tolerance, design features, test data
ABNT NBR 13757:1996 Injection moulding machines for plastics and elastomers-Terminology
ABNT NBR 13759:1996 Safety of machinery-emergency stop equipment, functional aspects-principles for design
ABNT NBR 13264:1995 Guide columns for door-dies-shapes and dimensions-Standardization
ABNT NBR 13265:1995 Bushing-Guide to columns-shapes and dimensions-Standardization
ABNT NBR 13266:1995 Puller-shape and dimensions-Standardization
ABNT NBR 13267:1995 xtender tools-shapes and dimensions-Standardization
ABNT NBR 13268:1995 Nose-to-tree with Morse cones and metric-shapes and dimensions
ABNT NBR 13269:1995 Tree-nose shapes and dimensions-Standardization
ABNT NBR 13270:1995 losing shape and dimensions-Standardization
ABNT NBR 13271:1995 Clamping screw-shape and dimensions-Standardization
ABNT NBR 13232:1994 Threaded bolts with cross-Rod fixed Forms and dimensions-Standardization
ABNT NBR 13233:1994 hreaded bolts with cross-Rod mobile-shapes and dimensions-Standardization
ABNT NBR 13234:1994 Pressure disk-shapes and dimensions-Standardization
ABNT NBR 13243:1994 Steel cylinders for compressed gases-hydrostatic test the water shirt-test method
ABNT NBR 13225:1994 Measurement of fluid flow in penstocks using orifice plates and nozzles in special settings (with drain holes in pipes with diameters of less than 50 mm, such as input and output devices, and other settings)-specification

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ABNT NBR 13196:1994 Pressure gauges for compressed gases used in welding, cutting and Allied processes-specifications
ABNT NBR 13197:1994 Pneumatic systems-Cylinders-acceptance tests
ABNT NBR 13198:1994 neumatic directional control valve five-way-coding system for specification of the re-patterning valve functions
ABNT NBR 13200:1994 Calculation of the volume of gas stored in high pressure cylinder
ABNT NBR 13181:1994 Security router-Procedure
ABNT NBR 13183:1994 nspection and testing of seamless aluminum alloy for gases-Procedure
ABNT NBR 8402:1994 Implementation of character for writing in technical drawing-Procedure
ABNT NBR 11312:1993 Numerical control of machinery-Terminology
ABNT NBR 12952:1993 Inspection of valves, cast steel and forged steel, petrochemical industry-Procedure
ABNT NBR 6178:1993 Industrial laundry
ABNT NBR 12985:1993 External hex plugs, heavy type, with cylindrical thread-dimensions and characteristics-Standardization
ABNT NBR 13004:1993 Self-aligning, concave and conical washers-shapes and dimensions-Standardization
ABNT NBR 13043:1993 Welding-numbers and names Standardization processes
ABNT NBR 12913:1993 Seal faces for threaded ends and her holes-shapes and dimensions-Standardization
ABNT NBR 12955:1993 Countersunk and recesses for screws and nuts-shapes and Dimensions-Standardization
ABNT NBR 12987:1993 Hexagon socket plugs with cylindrical thread-dimensions and characteristics-Standardization
ABNT NBR 12811:1993 Check for pipe thread gauges where the fence is made by thread-Procedure
ABNT NBR 6675:1993 Installation of air conditioners for domestic use (type monobloc or modular)
ABNT NBR 12954:1993 Pins locators-shapes and dimensions-Standardization
ABNT NBR 10277:1993 Mounting clamp for tools with drag-shapes and dimensions-Standardization
ABNT NBR 10278:1993 Mounting clamp for tools with and without drag square-shapes and dimensions-Standardization
ABNT NBR 12746:1993 Pneumatic directional control valve five-way-subplate dimensions without electrical connector-Standardization
ABNT NBR 12689:1992 Flat head screw (countersunk) with Hexagon socket-product Grade A-Dimensions-Standardization
ABNT NBR 12690:1992 Truss head screws with Hexagon socket-level of product sizes and specifications-Standardization
ABNT NBR 9584:1992 Chipboard screws with hex-head sizes and specifications-Standardization
ABNT NBR 12656:1992 Flat washers to the bolts and nuts, metric thread, for general use-products degrees and C-Standardization
ABNT NBR 12660:1992 Beveled flat washers-normal Series-300 class Hardness HV-Product grade A-Standardization
ABNT NBR 12680:1992 Coupling dimensions for fastening elements-coupling measures-Standardization
ABNT NBR 11749:1992 Cylinder valves for compressed gases-specification
ABNT NBR 12158:1992 Woodworking machines-circular saw-radial Tests for verification of accuracy-test method
ABNT NBR 12159:1992 Woodworking machines-circular saw with and without Mobile-table Tests for verification of accuracy-test method
ABNT NBR 12288:1992 Simplified representation of Centre holes in technical drawing-Procedure
ABNT NBR 12510:1992 Flat cylinders valves for medical gases-PIN system of security indicators-Standardization
ABNT NBR 12560:1992 Diaphragm metering pumps-specification
ABNT NBR 12596:1992 Dimensioning of hydraulic balance for small hydropower plants (SHP)-Procedure
ABNT NBR 12602:1992 Pneumatic cylinders with removable mounting rod, series 1100 kPa (10bar)-32 mm piston diameters to 320 mm-mounting Dimensions-Standardization
ABNT NBR 11375:1992 Errata 1:1992 Drum for steel cord-Standardization
ABNT NBR 12157:1991 Woodworking machines-Planing of two, three or four sides-precision verification tests-test method
ABNT NBR 12507:1991 Nose cone tree-centring and fixing flange bayonet systems-accessories-dimensions
ABNT NBR 12555:1991 Heat exchangers-Terminology
ABNT NBR 11701:1991 Threads-types and applications-Classification
ABNT NBR 12502:1991 Guide Bush type quick-change drilling and exchangeable and accessories-dimensions-Standardization
ABNT NBR 12296:1991 Design of penstocks for small hydropower plants (SHP)-Procedure
ABNT NBR 8855:1991 Mechanical properties of fasteners bolts and prisoners-specification
ABNT NBR 11808:1991 Mechanical surface aerator brush type-specification
ABNT NBR 12463:1990 Pressure washers-jagged shapes and dimensions-Standardization
ABNT NBR 12464:1990 Serrated washers-shapes and dimensions-Standardization
ABNT NBR 11403:1990 Flanged Hexagon socket screw-light series-Standardization
ABNT NBR 11404:1990 Flanged Hexagon socket screw-heavy-duty range-Standardization
ABNT NBR 11394:1990 Hexagon nuts low Degrees of product A and B-dimensions-Standardization
ABNT NBR 11396:1990 Hexagon nuts low Castle-Degrees of product A and B-dimensions-Standardization
ABNT NBR 11309:1990 Tracer height meter-specification
ABNT NBR 10126:1987 Errata 1:1990 Dimensioning on technical drawing-Procedure
ABNT NBR 11184:1990 Mechanical vertical surface aerator type high rotation-specification
ABNT NBR 11200:1990 corrected version: 1996 Hex head screw, with full-product A and B grades, with thin thread-dimensions-Standardization
ABNT NBR 11207:1990 Hex head screw, with total thread-Degrees of product A and B-dimensions-Standardization
ABNT NBR 11145:1990 Spring representation in technial drawing-Procedure
ABNT NBR 11311:1990 Verification of accuracy of woodworking machines surfacers-Procedure

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ABNT NBR 10982:1990 Electric lifts-operation and signaling devices-Standardization
ABNT NBR 11086:1990 7:24 cone rod for tools and fasteners-dimensions-Standardization
ABNT NBR 11087:1990 Cutter-holder shaft nut-Standardization
ABNT NBR 11203:1990 Grub screw, with Hexagon socket and flat Tip-Product Grade A-Dimensions-Standardization
ABNT NBR 11204:1990 Grub screw, with Hexagon socket and end-product Grade A-Dimensions-Standardization
ABNT NBR 11205:1990 Grub screw, with Hexagon socket and conical Tip-Product Grade A-Dimensions-Standardization
ABNT NBR 11206:1990 Grub screw, with Hexagon socket and hollow point-product Grade A-Dimensions-Standardization
ABNT NBR 11214:1990 Verification of the compatibility of materials of filtering elements with the fluid power hydraulic systems-Procedure
ABNT NBR 11183:1990 Mechanical vertical surface aerator type of low-specification
ABNT NBR 11211:1990 Castle hex nut 1 type, grade A and B products-Standardization
ABNT NBR 10980:1989 Pulley-dimensions and materials-Standardization
ABNT NBR 11375:1989 corrected version: 1992 Drum for steel cord-Standardization
ABNT NBR 10977:1989 Fluid flow meter-Terminology
ABNT NBR 10981:1989 Chain hoists with motor operator-specification
ABNT NBR 10902:1989 Cutter-holder shaft with keyway for longitudinal and transverse cylindrical milling cutter-dimensions-Standardization
ABNT NBR 10903:1989 Security lock hook forged stem nut-dimensions and materials-Standardization
ABNT NBR 10582:1988 Sheet presentation to technical drawing-Procedure
ABNT NBR 10092:1987 Low socket head cap screw with Hexagon socket-dimensions and mechanical characteristics-Standardization
ABNT NBR 10126:1987 corrected version: 1998 Dimensioning on technical drawing-Procedure
ABNT NBR 10133:1987 Large hydraulic valves-Terminology
ABNT NBR 10140:1987 Hydraulic and pneumatic systems-nominal Pressures-Standardization
ABNT NBR 10068:1987 Drawing sheet-layout and dimensions-Standardization
ABNT NBR 10070:1987 Forged Rod hooks for lifting nd moving loads-dimensions and mechanical properties-Standardization
ABNT NBR 8400:1984 Errata 3:1987 Calculation of equipment for lifting and moving loads-Procedure
ABNT NBR 9585:1986 Chipboard screws with countersunk head and crack-dimensions-Standardization
ABNT NBR 12231:1986 Periodic inspection of stationary tanks used for packaging and storage of carbon dioxide (CO)-Procedure
ABNT NBR 8896:1985 raphic symbols for hydraulic and pneumatic systems and components-basic and functional Symbols-Symbolism
ABNT NBR 8897:1985 Graphic symbols for hydraulic and pneumatic components and systems energy transformations-Symbolism
ABNT NBR 8898:1985 Graphic symbols for hydraulic and pneumatic components and systems-distribution and energy regulator-Symbolism
ABNT NBR 8400:1984 corrected version: 1987 Calculation of equipment for lifting and moving loads-Procedure
ABNT NBR 8403:1984 Application of lines in drawings-linetypes-Widths of the lines-Procedure
ABNT NBR 8404:1984 Indication of the State of surfaces in technical drawings-Procedure
ABNT NBR 6406:1980 Calibrators-constructive characteristics, tolerances

Source: ABNT. Elaborated by CCGI-EESP/FGV.

Table 37 - Regulation on Machinery (Argentina)

NAME	THEME
LAW 19587	Regulates hygiene and safety at work
LAW 1843/99	Provides rules for the circulation of agricultural machines and the transport of grass roll
RESOLUTION 3542/92	Regulates the registry of machines
LAW 9585/84	Creates the provincial registry of tractors, combine harvesters and automotive agricultural implements
LAW 22254/80	Dissolves the mechanical industries of the State
LAW I – NUMBER 4	Creates the department of rural mechanics
LAW 1884/50	Regulates the use of mechanical equipment on public works
RESOLUTION 595/99	Regulates the intervention of the Argentine Association of Producers of Machines, Accessories and Similar Goods on the assessment of goods

Source: Argentina. Elaborated by CCGI-EESP/FGV.

Table 38 - Machinery Standards (Argentina)

NAME	TITLE
IRAM - 1219	Paints for marine use. Paints enamel synthetic bright, motors and machine roomsi - *Pinturas para uso marino. Pinturas esmalte sintéticas brillantes, para motores y salas de máquina.*.
IRAM-2008-2	Rotating electrical machines. Methods of test for the determination of losses and performance, excluding machines for electric traction vehicles. - *Máquinas eléctricas rotativas. Métodos de ensayo para la determinación de las pérdidas y del rendimiento, excluyendo las máquinas para vehículos de tracción eléctrica.*

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IRAM - 2019	Orders and offers of rotating electrical machines and transformers.- *Pedidos y ofertas de máquinas eléctricas rotativas y transformadores.*
IRAM - 2131	Carbon brushes for electrical machines. Test methods. - *Escobillas para máquinas eléctricas. Métodos de ensayo.*
IRAM - 2139	Prismatic brushes for electrical machines. - *Escobillas prismáticas para máquinas eléctricas.*
IRAM - 2145	Welding arc machines. With transformer in air. - *Máquinas de soldar a arco. Con transformador en aire.*
IRAM - 2150	Synchronous machines. Trials of the dielectric - *Máquinas sincrónicas. Ensayos del dieléctrico*.
IRAM - 2151	Synchronous machines. Global warming essay. - *Máquinas sincrónicas. Ensayo de calentamiento*
IRAM - 2152	Synchronous machines. Performance and regulation. - *Máquinas sincrónicas. Rendimiento y regulación.*
IRAM - 2153	Synchronous machines. Determination of characteristic magnitudes - *Máquinas sincrónicas. Determinación de magnitudes características*.
IRAM - 2154	Synchronous machines. Method for the determination of the characteristic moments - *Máquinas sincrónicas. Método de determinación de los momentos característicos*.
IRAM - 2185	Rotating electrical machines of traction. To be used in the railways, vehicles and four-wheel-drive systems - *Máquinas eléctricas rotativas de tracción. Para ser utilizadas en ferrocarriles, vehículos y sistemas de tracción*.
IRAM - 2223	Rotating electrical machines. Definitions - *Máquinas eléctricas rotativas. Definiciones*
IRAM - 2244	Electrical machines presses with increased safety - *Maquinas eléctricas rotativas con seguridad aumentada*.
IRAM - 2259	Rotating electrical machines. Noise limits - *Máquinas eléctricas rotativas. Límites de ruido*.
IRAM - 2260	Rotating electrical machines. Symbols for the forms of construction and mounting arrangements - *Máquinas eléctricas rotativas. Símbolos para las formas de construcción y las disposiciones de montaje*.
IRAM - 3027	Strips of cotton for typewriters and calculating machines - *Cintas de algodón para máquinas de escribir y máquinas de calcular*.
IRAM - 3028	Carbon paper for typewriters - *Papel carbónico para máquinas de escribir*.
IRAM - 3030	Inks for obliteradoras machines and metal seals. Blue and black colors - *Tintas para máquinas obliteradoras y para sellos de metal. Colores azul y negro*.
IRAM - 3037	Tape of polyamide for typewriters and calculating machines - *Cintas de poliamida para máquinas de escribir y máquinas de calcular*.
IRAM - 3574	Machinery safety protections. For plastic and rubber injection moulding machines - *Protecciones de seguridad en maquinarias. Máquinas de moldeo por inyección para material plástico y caucho*.
IRAM - 3578	Machinery safety protections - *Protecciones de seguridad en maquinarias*.
IRAM-3681-11	Electric elevators. Part 11 - Safety for the construction and installation of lifts without machine room - *Ascensores eléctricos de pasajeros. Parte 11 - Seguridad para la construcción e instalación de ascensores sin sala de máquinas*.
IRAM-4119-1	Agricultural and forestry machinery acoustic. Method for the determination of the sound level. Part 1: on the position of the operator - *Maquinaria agrícola y forestal, Acústica. Método de determinación del nivel sonoro. Parte 1: En el puesto del operador*.
IRAM-4119-2	Agricultural and forestry machinery acoustic. Method for the determination of the sound level. Part 2: Out of the position of the operator - *Maquinaria agrícola y forestal, Acústica. Método de determinación del nivel sonoro. Parte 2: Fuera del puesto del operador*
IRAM - 5031	Heights of trees of machines shafts - *Alturas de ejes de árboles de máquinas* .
IRAM - 5041	Machine tools for working metals with release of chips. Nomenclature and reception conditions - *Máquinas herramientas para trabajar metales con desprendimiento de virutas. Nomenclatura y condiciones de recepción*.
IRAM - 5080	Bits with square shank. For hand-operated machines - *Brocas helicoidales con vástago cuadrado. Para máquinas de accionamiento a mano.*.
IRAM - 5084	Short males for machine or by hand, with whitworth thread thick and thin. Manufacturing in the threaded part tolerances. *Machos cortos para máquina o a mano, con rosca whitworth gruesa y fina. Tolerancias de fabricación en la parte roscada.*
IRAM - 5087	Short males for machine or hand unified coarse and fine thread. Manufacturing in the threaded part tolerance - *Machos cortos para máquina o a mano con rosca unificada gruesa y fina. Tolerancia de fabricación en la parte roscada*
IRAM - 5089	Machine tool. Mechanical presses. Safety requirements - *Máquinas herramienta. Prensas mecánicas. Requisitos de seguridad.*
IRAM - 5091	High speed steel extracorta series cylindrical shank bits. For automatic and semi-automatic machines - *Brocas helicoidales de acero rápido con vástago cilíndrico serie extracorta. Para máquinas automáticas y semiautomáticas.*
IRAM - 5124	Males die, short. Machine thread and thread by hand. General measures - *Machos de roscar, cortos. De roscar a máquina y de roscar a mano. Medidas generales.*
IRAM - 5125	T-slots, for machine tools - *Ranuras T, para máquinas herramientas*.
IRAM - 5130	T screws for machine tools - *Tornillos T para máquinas herramientas*.
IRAM - 5131	T nuts for machine tools - *Tuercas T para máquinas herramientas*.
IRAM - 5137	Machine with conical shank reamers - *Escariadores de máquina con vástago cónico.*
IRAM - 5163	Tweezers and conical pods, for machine tools - *Pinzas y vainas cónicas, para máquinas herramientas*.
IRAM - 5188	Males die long, thread-tapping machine. General measures - *Machos de roscar largos, de roscar a máquina. Medidas generales.*
IRAM - 5212	Bolts for tillage machines. ISO metric thread. Enough quality - *Bulones para máquinas de labranza. Rosca métrica ISO. Calidad basta.*.
IRAM - 5256	Axes and buckets slotted for machine tools. Four slots - *Ejes y cubos ranurados para máquinas herramientas. Cuatro ranuras.*
IRAM - 5257	Axes and buckets slotted for machines tools. Six slots - *Ejes y cubos ranurados para máquinas heramientas. Seis ranuras*.
IRAM - 5258	Handles for machine tools. Steel - *Mangos para máquinas herramientas. De acero*.
IRAM - 5259	Rotating handles for machine tools. Steel - *Mangos giratorios para máquinas herramientas. De acero*.
IRAM - 5265	Levers with taper shank for machine tools - *Palancas con mango cónico para máquinas herramientas*.
IRAM - 5273	Teaching material. Centrifugal machine - *Material de enseñanza. Máquina centrífuga*.

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IRAM - 5277	School material. Pneumatic vacuum machine - *Material escolar. Máquina neumática de vacío*.
IRAM - 5294	Machine tool test code - *Código de ensayo de máquinas herramienta.*.
IRAM - 5322	Wood-working machines. Milling machine table single-spindle. Nomenclature and geometric verification - *Máquinas para trabajar madera. Fresadora de mesa monohusillo. Nomenclatura y verificación geométrica.*
IRAM - 5323	Wood-working machines. Myriad of table saw. Nomenclature and geometric verification - *Máquinas para trabajar madera. Sierra sinfín de mesa. Nomenclatura y verificación geométrica.*
IRAM - 5330	TACA fixture for mobile machines. Geometric verification and installation conditions - *Taca portapieza para máquinas de columna móvil. Verificación geométrica y condiciones de instalación*.
IRAM - 5335	Wood-working machines. Simple circular saw with mobile table or without it. Nomenclature and geometric verification - *Máquinas para trabajar madera. Sierra circular simple con mesa móvil o sin ella.Nomenclatura y verificación geométrica.*
IRAM - 5360	Roller chains. For agricultural and similar machines - *Cadenas de rodillos. Para máquinas agrícolas y similares*.
IRAM - 5371	Males for threading machine or by hand with ISO metric thread. Manufacturing in the threaded part tolerance - *Machos para roscar a máquina o a mano con rosca métrica ISO. Tolerancia de fabricación en la parte roscada.*.
IRAM - 5388	Wood-working machines. Parallel lathe. Nomenclature and geometric verification - *Máquinas para trabajar madera. Torno paralelo. Nomenclatura y verificación geométrica.*.
IRAM - 5389	Wood-working machines. A face with tool Rotary Planer. Nomenclature and geometric verification - *Máquinas para trabajar madera. Cepilladora de una cara con herramienta rotativa. Nomenclatura y verificación geométrica*.
IRAM - 5390	Wood-working machines. Jointer plane of a face with cylindrical blade Arbor. Nomenclature and geometric verification - *Máquinas para trabajar madera. Garlopa de una cara con portaherramienta cilíndrico de cuchilla. Nomenclatura y verificación geométrica.*
IRAM - 6629	Lubricants for refrigeration equipment - *Aceites lubricantes para máquinas frigoríficas.*.
IRAM - 6630	Lubricants for refrigeration equipment. Method for determination of insoluble matters in diclorodifluormetano - *Aceites lubricantes para máquinas frigoríficas. Método de determinación de materias insolubles en diclorodifluormetano.*.
IRAM-6665-1	Lubricants for refrigeration equipment. Method for the determination of the point of flocculation by the closed tube technique - *Aceites lubricantes para máquinas frigoríficas. Método de determinación del punto de floculación mediante la técnica del tubo cerrado.*.
IRAM-6665-2	Lubricants for refrigeration equipment. Method for the determination of the point of flocculation by the technique of the open tube - *Aceites lubricantes para máquinas frigoríficas. Método de determinación del punto de floculación mediante la técnica del tubo abierto*.
IRAM - 6670	Oils for refrigeration equipment. Comparative method for the determination of the chemical stability in the presence of dichlorodifluoromethane. The sealed tube technique - *Aceites para máquinas frigoríficas. Método comparativo de determinación de la estabilidad química en presencia de diclorodifluorometano. Técnica del tubo sellado*.
IRAM - 6731	Containers and packaging. Expedition packs complete and full or empty. Test method for compression and stacking using a compression machine - *Envases y embalajes. Embalajes de expedición completos y llenos o vacíos. Método de ensayo de compresión y apilamiento utilizando una máquina de compresión*.
IRAM-ATIPCA P 3044	Paper and cardboard. Determination of the direction of the machine - *Papel y cartón. Determinación de la dirección de máquina*.
IRAM-IAS U 500 108	Tensile testing machines. Methods of verification - *Máquinas de ensayo de tracción. Métodos de verificación*.
IRAM-IAS U 500 16-2	Steel. By Charpy impact bending test on specimen with notch in V. part 2: verification of testing machines - *Acero. Ensayo de flexión por impacto con péndulo Charpy sobre probeta con entalladura en V. Parte 2: Verificación de las máquinas de ensayo*.
IRAM-IAS U 500 18	Machines, pendulum type impact bending test. Methods of verification - *Máquinas tipo péndulo de ensayo a la flexión por impacto. Métodos de verificación*.
IRAM-IAS U 500 184-2	Forgings of steel, on horizontal forging machines. Dimensional tolerances - *Piezas de acero, forjadas en máquinas forjadoras horizontales. Tolerancias dimensionales*.
IRAM-IAS U 500 79	Vickers and Knoop microhardness testing machines. Verification method - *Máquinas de ensayo de microdureza Vickers y Knoop. Método de verificación*.
IRAM-IAS U 500 80	Vickers and Knoop microhardness testing machines. Method of calibration block pattern - *Máquinas de ensayo de microdureza Vickers y Knoop. Método de calibrado de bloques patrón.*
IRAM-IAS-NM-ISO 6506 - 2	Metallic materials - Brinell hardness test. Part 2: Verification and calibration of testing machines. (ISO 6506-2:2005, IDT) - *Materiales metálicos - Ensayo de dureza Brinell. Parte 2: Verificación y calibración de máquinas de ensayo. (ISO 6506-2:2005, IDT)*
IRAM-IAS-NM-ISO 6507 - 2	Metallic materials. Vickers hardness test. Part 2: Verification and calibration of testing machines. (ISO 6507-2:2005, IDT) - *Materiales metálicos. Ensayo de dureza Vickers. Parte 2: Verificación y calibración de las máquinas de ensayo. (ISO 6507-2:2005, IDT)*
IRAM-IAS-NM-ISO 6508 - 2	Metallic materials. Rockwell hardness test. Part 2: Verification and calibration of testing machines (scales A, B, C, D, E, F, G, H, K, N, T). (ISO 6508-2:2005, IDT) - *Materiales metálicos. Ensayo de dureza Rockwell. Parte 2: Verificación y calibración de máquinas de ensayo (escalas A, B, C, D, E, F, G, H, K, N, T). (ISO 6508-2:2005, IDT)*
IRAM-ISO 3308	Machine smoking routine analytics. Definitions and normal conditions - *Máquina de fumar analítica de rutina. Definiciones y condiciones normales*.
IRAM-ISO 3776 - 1	Tractors and machinery for agriculture. Safety belts. Part 1 - Location of the belt anchorages requirements - *Tractores y maquinaria para agricultura. Cinturones de seguridad. Parte 1 - Requisitos de ubicación de los anclajes*.
IRAM-ISO 3776 - 2	Tractors and machinery for agriculture. Safety belts. Part 2 - The anchorages strength requirements - *Tractores y maquinaria para agricultura. Cinturones de seguridad. Parte 2 - Requisitos de resistencia de los anclajes*.
IRAM-ISO 3776 - 3	Tractors and agricultural machinery. Safety belts. Part 3 - Requirements for the assembled sets - *Tractores y maquinaria agrícola. Cinturones de seguridad. Parte 3 - Requisitos para los conjuntos ensamblados*.

IRAM-ISO 4387	Cigarettes. Determination of total particulate material, and the particulate dry and free of nicotine, using a smoking machine analytical routine - *Cigarrillos. Determinación del material particulado total, y del material particulado seco y libre de nicotina, mediante una máquina de fumar analítica de rutina.*.
IRAM-NM-ISO 2860	Road machinery. Minimum dimensions of access - *Maquinaria vial. Dimensiones mínimas de acceso.*
IRAM-NM-ISO 3164	Road machinery. Evaluations of protective structures laboratory. Specifications for deflection limit volume - *Maquinaria vial. Evaluaciones de laboratorio de estructuras de protección. Especificaciones para el volumen limitador de deflexión.*
IRAM-NM-ISO 3449	Machinery for soil movement. The falling-object protection structures. Laboratory tests and performance requirements. (ISO 3449:2005, IDT) - *Maquinaria para movimiento de suelos. Estructuras de protección contra la caída de objetos. Ensayos de laboratorio y requisitos de desempeño. (ISO 3449:2005, IDT).*
IRAM-NM-ISO 3450	Road machinery. Machine equipped with pneumatic brake systems. Systems, performance and test methods and system requirements - *Maquinaria vial. Sistemas de frenos de máquinas equipadas con neumáticos. Sistemas, requisitos del sistema y de desempeño y métodos de ensayo.*
IRAM-NM-ISO 3457	Machinery for soil movement. Protections - definitions and requirements. (ISO 3457:2003, IDT) - *Maquinaria para movimiento de suelos. Protecciones - Definiciones y requisitos. (ISO 3457:2003, IDT).*
IRAM-NM-ISO 5005	Road machinery. Method of determining the center of gravity - *Maquinaria vial. Método para determinar el centro de gravedad.*
IRAM-NM-ISO 5006	Machinery for soil movement. Field of view of the operator - test method and performance criteria. (ISO 5006:2006, IDT) - *Maquinaria para movimiento de suelos. Campo de visión del operador - Método de ensayo y criterios de desempeño. (ISO 5006:2006, IDT).*
IRAM-NM-ISO 5010	Machinery for soil movement. Machines with pneumatic tires. Address requirements - *Maquinaria para movimiento de suelos. Máquinas con neumáticos. Requisitos de dirección*.
IRAM-NM-ISO 5353	Road machinery, tractors and machinery for agriculture and forestry. The seat index point - *Maquinaria vial, tractores y maquinaria agrícola y forestal. Punto índice del asiento*.
IRAM-NM-ISO 6014	Road machinery. Determination of the scroll speed - *Maquinaria vial. Determinación de la velocidad de desplazamiento.*
IRAM-NM-ISO 6015	Machinery for soil movement. Hydraulic excavators and backhoe loaders. Methods for the determination of the forces of the tool - *Maquinaria para movimiento de suelos. Excavadoras hidráulicas y retrocargadoras. Métodos para la determinación de las fuerzas de la herramienta*.
IRAM-NM-ISO 6165	Machinery for soil movement. Basic types. Identification, terms and definitions - *Maquinaria para movimiento de suelos. Tipos básicos. Identificación, términos y definiciones*.
IRAM-NM-ISO 6483	Road machinery. Dump boxes. Full nominal capacity - *Maquinaria vial. Cajas para volquetes. Capacidad nominal colmada*.
IRAM-NM-ISO 6484	Road machinery. Autocargadoras scrapers. Nominal capacities filled box - *Maquinaria vial. Traíllas autocargadoras. Capacidades nominales colmadas de la caja*.
IRAM-NM-ISO 6485	Road machinery. Nominal volumetric capacity of scrapers - *Maquinaria vial. Capacidad nominal volumétrica de mototraíllas*.
IRAM-NM-ISO 6683	Machinery for soil movement. Seat belts and seat belt anchorages - test and performance requirements - *Maquinaria para movimiento de suelos. Cinturones de seguridad y anclajes de cinturones de seguridad - Ensayos y requisitos de desempeño*.
IRAM-NM-ISO 6746 - 1	Machinery for soil movement. Definitions of measures and codes. Part 1: Basic machine - *Maquinaria para movimiento de suelos. Definiciones de las medidas y códigos. Parte 1: Máquina básica*.
IRAM-NM-ISO 6746 - 2	Machinery for soil movement. Definitions of measures and codes. Part 2: Equipment and accessories - *Maquinaria para movimiento de suelos. Definiciones de las medidas y códigos. Parte 2: Equipamientos y accesorios*.
IRAM-NM-ISO 6747	Road machinery. Bulldozer. Terminology and commercial specifications - *Maquinaria vial. Topadora. Terminología y especificaciones comerciales*.
IRAM-NM-ISO 7131	Road machinery. Wheel loaders. Terminology and commercial specifications - *Maquinaria vial. Cargadoras. Terminología y especificaciones comerciales*.
IRAM-NM-ISO 7132	Machinery for soil movement. Dump. Terminology and commercial specifications. (ISO 7132:2003, IDT) - *Maquinaria para movimiento de suelos. Volcadores. Terminología y especificaciones comerciales. (ISO 7132:2003, IDT)*
IRAM-NM-ISO 7133	Road machinery. Scrapers. Terminology and commercial specifications - *Maquinaria vial. Mototraíllas. Terminología y especficaciones comerciales*.

Source: IRAM. Elaborated by CCGI-EESP/FGV.

APPENDIX 5 - Medical Devices

Table 39 - Regulation on Medical Devices (Brazil)

NAME	THEME
DECREE 8077/13	Registry, control and monitoring of the products addressed by Law 6360/76, and the conditions for the operation of companies subject to sanitary licensing, within the scope of health
LAW 9933/99	Competences of Conmetro and Inmetro and establishes the metrological service tax
LAW 8078/90	Consumer protection and other arrangements
LAW 6437/77	Violations to federal sanitary legislation and their respective penalties
LAW 6360/76	Main legal norm controlling the sector
ANVISA RESOLUTION 102/16	Provisions on the procedures for the transfer of registration of products subject to health surveillance, global transfer of responsibility for clinical testing and update of registration data related to the operation and certification of companies as a result of corporate or commercial operations
ANVISA RESOLUTION 40/15	Aims at defining the registration requirements for the sanitary control of medical products exempt from *registro* registration, as per paragraph 1, of art. 25, of law no. 6.360/1976
ANVISA RESOLUTION 37/15	Standard sentences to be used on the labels of medical devices that contain natural rubber latex
ANVISA RESOLUTION 36/15	Classification of risks, *cadastro* and *registro* control systems, and labeling and instructions for use requirements, for *in vitro* diagnostic products, including their instruments
ANVISA RESOLUTION 15/14	Provisions on the requirements related to the proof of compliance with Good Manufacturing Practices for *registro* registration of healthcare products
ANVISA RESOLUTION 39/13	Provisions on the administrative procedures for granting Good Manufacturing Practice Certification and Good Distribution and/or Storage Practice Certification
ANVISA RESOLUTION 16/13	Provisions on the requirements of Good Manufacturing Practices, and medical products, and in vitro diagnosis products
ANVISA RESOLUTION 23/12	Provisions on the compulsory execution and notification of field actions by the registration holders for health products in Brazil
ANVISA RESOLUTION 27/11	Provisions on the procedures for the mandatory certification of equipment under the Health Surveillance Policy
ANVISA RESOLUTION 3/10	Chronological criteria for reviews of *registro* and *cadastro* applications of medical devices at ANVISA
ANVISA RESOLUTION 67/09	Provisions on technovigilance rules applicable to registration holders for health products in Brazil
ANVISA RESOLUTION 24/09	Scope and application form for the system of registration for the sanitary control of health products
ANVISA RESOLUTION – RE 2605/06	A list of medical products classified as of single use and prohibited to be reprocessed
ANVISA RESOLUTION 13/04	Health surveillance of import, consumption and export of products subject to health surveillance, not registered within the Brazilian Health Surveillance System, and intended for exhibition, demonstration or distribution in fairs or events
ANVISA RESOLUTION 185/01	Approves the technical regulations contained in the annex to this resolution, which deals with registration, alteration, revalidation and cancellation of the registration of medical devices through the National Health Surveillance Agency - ANVISA
ANVISA RESOLUTION 56/01	Minimal requirements with which manufacturers and importers must comply, seeking to unify the criteria for the information requested by the health surveillance authority pertaining to the safety and efficacy of healthcare products
ANVISA RESOLUTION 25/01	Provisions on the import, commercialization and donation of used and refurbished healthcare products
INMETRO ORDINANCE 54/16	Criteria and compliance evaluation procedures for Equipment under Health Surveillance Policy, with emphasis on safety through the mechanism of certification in order to prevent accidents. It approves improvement of the Requirements for the Compliance Evaluation of these devices considering Reference Term of the Brazilian Compliance Evaluation System (SBAC)
INMETRO ORDINANCE 248/15	Inmetro Vocabulary of Compliance Assessment with terms and definitions commonly used by the Compliance Assessment Inmetro Board
INMETRO ORDINANCE 118/15	Improves the General Requirements of Product Certification (RGCP)
INMETRO ORDINANCE 274/14	Regulations for the Use of Brands, Symbols, Marks and Labels of Inmetro
INMETRO ORDINANCE 332/12	Revision of conformity assessment requirements for surgical and non-surgical gloves made of natural rubber, synthetic rubber and a mixture of synthetic rubbers
INMETRO ORDINANCE 162/12	Conformity assessment requirements for breast implants
INMETRO ORDINANCE 503/11	Conformity assessment procedure for single use sterile hypodermic syringe
INMETRO ORDINANCE 502/11	Conformity assessment requirements for single use appliances for transfusion, gravitational infusion and infusion for use with infusion pump
INMETRO ORDINANCE 501/11	Conformity assessment requirements for single use sterile hypodermic needles and single use gum needles
INMETRO ORDINANCE 350/10	Period up to twelve (12) months, from the date this ordinance is published, for products certified according to Inmetro ordinance no. 86 (of April 3, 2006, published on the Federal Official Gazette of April 6, 2006, Section I, page 44) to comply with the requirements approved herein

INMETRO ORDINANCE 230/09	Conformity assessment procedure for Personal Protective Equipment (PPE) – to accessories for filtering facepiece respirators
INMETRO ORDINANCE 96/08	Metrological Technical Regulation of digital electronic sphygmomanometers
INMETRO ORDINANCE 89/06	Metrological Technical Regulation of digital clinical thermometers
ORDINANCE OF MINISTRY OF JUSTICE 487/12	Procedure of calling consumers or recall products and services that are considered harmful or dangerous after their introduction to the consumer market
ORDINANCE OF MINISTRY OF HEALTH AND SECRETARIAT OF SANITARY SURVEILLANCE 453/98	Radiological protection in medical and dental radiodiagnosis
INTERMINISTERIAL ORDINANCE MS/MDIC 206/13	Institutes the Technical Committee of Articulation with the Brazilian Health Surveillance Agency within the scope of Bigger Brazil Plan (CTVSPBM)
INTERMINISTERIAL ORDINANCE MS/MDIC 692/09	Operationalization of the actions Technical Cooperation and Quality Assurance of Medical Devices Safety subject to health surveillance control, as established by the Term of Technical Cooperation signed by the Ministry of Health (MS) and the Ministry of Development, Industry, and International Trade (MDIC)
ANVISA NORMATIVE INSTRUCTION 4/15	Updated list of Technical Standards which shall be adopted to the certification of compliance within the scope of Brazilian Compliance Evaluation System (SBAC), of equipment under health surveillance policy
ANVISA NORMATIVE INSTRUCTION 3/15	Regulates item I of Art. 20 of the RDC 36/15, that describes the classification of risk, the schemes for control of cadastro and registro registrations and the requirements for both labeling and instructions of use for in vitro diagnostic products, including its instruments, and gives other provisions
MS NORMATIVE INSTRUCTION 8/13	Scope of application of the provisions of GMP of medical devices and in-vitro diagnostic products to importers, distributors and storage companies, and makes other considerations
MERCOSUL GMC RESOLUTION 72/98	Essential requirements for safety and efficacy of medical devices

Source: ANVISA and MERCOSUL . Elaborated by CCGI/FGV-EESP.

Table 40 - Regulation on Medical (Argentina)

NAME	THEME
LAW 21908/78	Establishes the rights of importation of equipment of medical use
RESOLUTION 30/97	Updates norms that regulate the importation of products considered medical apparel and equipment subject to the intervention of ANMAT
DECREE LAW 2469/58	Establishes conditions for the use of every medical instrument or equipment with diagnosis or therapeutic goals
LAW 14583/13	Regulates medical equipment
ANMAT DISP 2318/02	Provides a definition of medical equipment
RESOLUTION 458/09	Creates the Coordinating Unity of Evaluation and Execution of Health Technologies

Source: ANMAT. Prepared by CCGI-EESP/FGV.

Table 41 - Standards on Medical Devices (Argentina)

NAME	TITLE
IRAM - 113060	Exams medical, sterile or non-latex gloves, use only once.
IRAM - 37008	Medical devices. Sterilization by ethylene oxide. Validation and routine control.
IRAM-37019-1	Biomedical devices. Good manufacturing practices. Directives for the design, construction specifications, operating conditions and the maintenance of the production area.
IRAM-37019-2	Biomedical devices. Good manufacturing practices. Directives relating to suitability, responsibility, hygiene and clothing of personnel in the area of development.
IRAM-37019-3	Biomedical devices. Good manufacturing practices. Directives for the design, maintenance and cleaning of the area of development teams.
IRAM-37019-4	Biomedical devices. Good manufacturing practices. Directives to make the documentation and records related to the area of development.
IRAM-37019-5	Biomedical devices. Good manufacturing practices. Guidelines for labeling and packaging.
IRAM-37019-6	Biomedical devices. Good manufacturing practices. Guidelines for quality assurance.
IRAM-37019-7	Biomedical devices. Good manufacturing practices. Guidelines for the laboratory of quality control.
IRAM-37021-1	Biological evaluation of biomedical devices. Part 1: Evaluation and testing.
IRAM-37021-2	Biological evaluation of biomedical devices. Requirements concerning the protection of animals.
IRAM-37021-3	Biological evaluation of biomedical devices. Tests for genotoxicity, carcinogenicity and toxicity on reproduction and development.
IRAM-37021-4	Biological evaluation of medical devices. Part 4 - Selection of interaction with blood tests.
IRAM-37030-1	Synthetic latex gloves to use only once. Part 1 - for sterile medical exams or not.
IRAM - 37105	Sterilization of health care products. Packaging for medical devices with terminal sterilization.
IRAM-4220-1	Electro-medical devices. Part 1: General requirements for safety.

Product 5: Final document consolidating the results, information and analysis obtained in previous steps; policy indications

IRAM-4220-1-1	Electro-medical devices. Part 1: General requirements for safety. 1 collateral standard: safety requirements for medical electrical systems.
IRAM-4220-1-2	Electro-medical devices. Part 1 - General requirements for safety. Section 2 - Collateral standard: electromagnetic compatibility. Requirements and tests.
IRAM-4220-1-3	Electro-medical devices. Part 1: General requirements for safety. 3. collateral standard: General requirements for radiation protection in diagnostic x-ray equipment.
IRAM-4220-1-4	Electro-medical devices. Part 1 - General requirements for safety. 4 collateral standard: systems programmable electrical.
IRAM-4220-2-12	Electro-medical devices. Part 2: Particular requirements for the safety of lung ventilators for medical use.
IRAM-4220-2-13	Electro-medical devices. Part 2-13 - Particular requirements for the safety and essential of anesthesia systems performance.
IRAM-4220-2-16	Electro-medical devices. Hemodialysis devices. Particular safety requirements.
IRAM-4220-2-19	Electro-medical devices. Baby incubators. Particular safety requirements.
IRAM-4220-2-2	Electro-medical devices. Part 2-2 - Particular safety requirements of high-frequency Electrosurgical apparatus.
IRAM-4220-2-20	Electro-medical devices. Infant transport incubators. Particular safety requirements.
IRAM-4220-2-24	Electro-medical devices. Part 2-24-Particular req for the safety of infusion pumps and controllers of infusion.
IRAM-4220-2-25	Electro-medical devices. Part 2-25: Particular safety requirements for electrocardiographs.
IRAM-4220-2-49	Electro-medical devices. Part 2-49 - Particular requirements for the safety of multifunction patient monitoring equipment.
IRAM-4220-2-7	Electro-medical devices. Part 2-7: Particular safety requirements for the high-voltage generators of diagnostic x-ray equipment.
IRAM - 60336	Electro-medical devices. Assembly of medical diagnostic x-ray tube. Characteristics of focal points.
IRAM - 62353	Electro-medical devices. Recurrent trials and trials after repairs from the electromedical device.
IRAM-IEC CISPR 11	Industrial, scientific and medical equipment. Characteristics of RF disturbances. Limits and methods of measurements.
IRAM-ISO 11137-1	Sterilization of health care products. Radiation. Part 1 - Requirements for development, validation and control of routine sterilization of medical devices.
IRAM-ISO 13485	Medical devices. The quality management system. Requirements for regulatory purposes.
IRAM-NM-ISO 15198	Clinical analysis laboratories. Medical products for in vitro diagnostic use. Validation by the manufacturer's quality control procedures for the user. (ISO 15198:2004, IDT)

Source: IRAM. Elaborated by CCGI/FGV-EESP.

APPENDIX 6 - Food

Table 42 - Regulation on Food (Brazil)

NAME	THEME
DECREE 9013/17	Establishes the set of regulations concerning the development of the industry and trade in products of animal origin
LAW 13305/16	Provisions regarding the labeling of foodstuffs containing lactose
DECREE 8772/16	Implements law 13123/15, which regulates access to components of the genetic heritage, protection of and access to associated traditional knowledge, and the sharing of benefits for the conservation and sustainable use of Brazilian biodiversity
DECREE 6871/09	Control, inspection, standardization, classification, establishment registration and product registration of beverages
DECREE 6759/09	Activities of the customs administration, control and taxation of foreign trade, including sanitary, phytosanitary or animal health controls
LAW 11346/06	Establishes the National System of Food and Nutrition Security (SISAN) with a view to ensuring the human right to adequate food
LAW 11265/06	Lays down provisions on food commercialization for breast-feeding babies and early childhood children, as well as pediatric products, forbidding advertising related to food supplements and pacifiers.
DECREE 5839/06	Provisions regarding the organization, attributions and electoral process of the National Health Council (CNS)
DECREE 5741/06	Organizes the Unified Animal and Plant Health Protection System and sets out further measures. The Unified System includes the control of activities related to health, inspection, education and surveillance on animals, plants and their products. This Presidential Decree establishes the rules wish must be complied with by the participants of the System and the procedures to carry out official controls to check compliance with Sanitary and Phytosanitary Legislation and quality of agricultural products.
LAW 11105/05	Safety regulations and inspection mechanisms for activities that involve Genetically Modified Organisms (GMOs) and their by-products
LAW 10674/03	Establishes that all labelling for foodstuffs must carry the inscription "contains gluten" or "does not contain gluten", as appropriate
DECREE 4680/03	Consumer protection rules (guaranteed by Law No. 8078/1990) as regards foods and food ingredients intended for human or animal consumption that contain or are produced from Genetically Modified Organisms (GMOs)
DECREE 4062/01	Provisions regarding the terms "cachaça" and "cachaça do Brasil" as geographical indications
LAW 9972/00	Establishes the classification of plant products, by-products and waste of economic value
LAW 9933/99	Establishes the competencies of National Council of Metrology, Standardization and Industrial Quality (Conmetro) and National Institute of Metrology, Quality and Technology (Inmetro), and makes other provisions
LAW 9782/99	Establishes the system of international agriculture and cattle surveillance
LAW 9677/98	Amends the Criminal Code to include in the classification of crimes considered heinous: falsification, corruption or adulteration of foodstuffs
DECREE 2314/97	Simple alcoholic distillate
DECREE 369/97	Supporting inclusion of technology/drafting technical regulation for identity and quality of milk powder
DECREE 352/97	Identity and quality of the Minas fresh cheese
LAW 9294/96	Restrictions on the use and advertising of tobacco products, alcoholic beverages, medicines and agricultural pesticides
DECREE 1812/96	Fluid milk quality in quantity for Industrial use
LAW 8918/94	Establishes provisions related to standardization, classification, registration, production and inspection of beverages and the Intersectoral Beverage Committee.
LAW 8171/91	Provisions on the agricultural policy
LAW 8080/90	Organic law of health
LAW 7967/89	Establishes the value of the fines for violations of health legislation, amends the Law No. 6437/1977, and provides other measures
LAW 7678/88	Registry of grape-based beverages, establishments, producers or bottlers of wine and beverages derived from grapes
LAW 6437/77	Provisions concerning the violations of the federal sanitary legislation, establishes their respective penalties, and makes other provisions
LAW 5966/73	Formulates and implements the national policy of metrology, industrial standardization and quality certification of industrial products
DECREE 72718/73	Lays down the general principles of food irradiation
DECREE-LAW 986/69	Basic food technical regulation
DECREE 63526/68	Creates technical requirements on additives approved by the National Commission on Food Standards
DECREE-LAW 212/67	Provisions concerning the sanitary safety measures in Brazil
DECREE 55871/65	Amends presidential decree no. 50040/1961 as regards the use of certain food additives
DECREE 50040/61	Lays down technical requirements on chemical additives and technology coadjuvants for use in food
DECREE 30691/52	Regulation of Industrial and Sanitary Inspection of Products of Animal Origin (RIISPOA of 1952), to be applied in interstate or international trade
LAW 1283/50	Prior inspection of all products of animal origin
ORDINANCE MS 710/99	Approves the National Food and Nutrition Policy
ORDINANCE SVS/MS 31/98	Approves the technical regulation concerning the addition of essential nutrients to foods

ORDINANCE SVS/MS 29/98	Approves the Technical Regulation on Foods for Special Purposes
ORDINANCE SVS/MS 27/98	Approves the Technical Regulation on Complementary Nutrition Information
ORDINANCE SVS/MS 579/97	Determines that the publication in the Federal Official Gazette of the registration of products related to the food area, is sufficient to prove the granting of registration in the Ministry of Health
ORDINANCE SVS/MS 326/97	Brazilian food good manufacturing practices (GMPs)
ORDINANCE MS 1428/93	General guidelines for the establishment of good manufacturing practices for food industry
ANVISA RESOLUTION 149/17	Authorizes the use of food additives and technology adjuvants in various food categories and gives other provisions
ANVISA RESOLUTION 138/17	Provisions concerning the maximum tolerated limits (LMT) for mycotoxin deoxynivalenol in wheat and wheat products ready for sale to the consumer
ANVISA RESOLUTION 136/17	Requirements for the mandatory declaration of the presence of lactose on food labels
ANVISA RESOLUTION 135/17	Amends Ordinance SVS / MS No. 29/1998, that approves the technical regulation referring to foods for special purposes, to lay down provisions concerning foods for diets with restriction of lactose
ANVISA RESOLUTION 91/16	Establishes criteria and procedures for sanitary control of water intended for human consumption from a water supply system or alternative solution for water supply in ports, airports and border crossings throughout the national territory
ANVISA RESOLUTION 43/15	Establishes rules on the provision of food services at mass events, including minimum requirements for prior assessment and operation of facilities and services related to trade and food handling and definition of responsibilities
ANVISA RESOLUTION 26/15	Provides for the requirements for the mandatory labeling of the main food causing food allergies. The food, ingredients, food additives and technology coadjuvants containing or derived from the food listed should contain the following statement: "Allergic: Contains (common names of food causing food allergies)"
ANVISA RESOLUTION 24/15	Provisions concerning the collection of food and its communication to ANVISA and to consumers
ANVISA RESOLUTION 54/14	Technical regulation on enzymes and enzymatic preparations for use in food production in general
ANVISA RESOLUTION 53/14	List of enzymes, food additives and authorized vehicles in enzyme preparations for use in food production in general
ANVISA RESOLUTION 52/14	Amends resolution RDC No. 216/2004 on the technical regulation of good practices for food services
ANVISA RESOLUTION 14/14	General provisions that contribute to the evaluation of macroscopic and microscopic foreign material as an indicative of risks to human health or failures in the application of Good Practices in the food and drinks supply chain and set their limits of tolerance
ANVISA RESOLUTION 42/13	Maximum residue levels of inorganic contaminants in foods
ANVISA RESOLUTION 8/13	Positive lists of food additives with their respective functions for manufacturing fruit and vegetable products and mocotó jelly
ANVISA RESOLUTION 7/13	Positive list of technology coadjuvants with their respective functions for the manufacture of fruit and vegetable products, including edible mushrooms
ANVISA RESOLUTION 5/13	Approves the use of food additives with their respective functions and maximum limits for alcoholic beverages, except fermented
ANVISA RESOLUTION 3/13	Provisions concerning the modifications in the composition of standardized foods for use of complementary nutritional information
ANVISA RESOLUTION 56/12	Approves the MERCOSUL technical regulation on the positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment in contact with food
ANVISA RESOLUTION 54/12	Technical regulation on complementary nutritional information
ANVISA RESOLUTION 53/12	Approves the MERCOSUL technical regulation on analytical methodologies, acceptable daily intake and maximum residue limits for veterinary drugs in foods of animal origin
ANVISA RESOLUTION 31/12	Nutritional labeling of non-alcoholic beverages traded in returnable packages
ANVISA RESOLUTION 5052/11	Prohibited the importation, manufacture, distribution and marketing, throughout the national territory, of foods and beverages based on Aloe Vera, because there is no proof of safety of using or registration
ANVISA RESOLUTION 40/11	Approves the use of tannic acid and tannins as processing aid in the function of clarifying/filtering agents for the manufacture of sugar and alcoholic beverages
ANVISA RESOLUTION 2468/10	Ban on the marketing of human milk in States parties
ANVISA RESOLUTION 52/10	Colorants on recipients and plastic equipment intended to be in contact with food
ANVISA RESOLUTION 51/10	Migration and equipments plastic packings aims of getting in contact con foods
ANVISA RESOLUTION 48/10	Conversion factor for calculating energy of erythritol
ANVISA RESOLUTION 46/10	Maximum residue limits for Additives excluded from the list of "Aditi you authorized for food use according las GMP"
ANVISA RESOLUTION 45/10	Additives authorized for food use according to Good Manufacturing Practices

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ANVISA RESOLUTION 27/10	Products with compulsory registration and products exempt from registration
ANVISA RESOLUTION 24/10	Rules concerning the supply, advertising, information and other related practices linked to the commercial promotion of foodstuffs with high amounts of sugar, saturated fat, trans fat, sodium, and low-nutritional beverages
ANVISA RESOLUTION 81/08	Technical regulation of imported goods for health surveillance purposes
ANVISA RESOLUTION 64/08	Additives and their maximum limits for foodstuffs and snacks
ANVISA RESOLUTION 20/08	Food grade recycled polyethylene terephthalate (PET) packaging intended to come into contact with foodstuffs
ANVISA RESOLUTION 17/08	Positive list of additives for plastic materials used in packaging and equipment in contact with food
ANVISA RESOLUTION 8/08	Prohibits the use of Propylparaben and Propylparaben Sodium in foods
ANVISA RESOLUTION 36/07	Nutrition labelling of packaged foods
ANVISA RESOLUTION 20/07	Technical regulation on packaging, coatings, utensils, lids and metallic equipment in contact with food
ANVISA RESOLUTION 5/07	Attribution of additives and their maximum levels for the food category 6.2: cereals and/or cereals
ANVISA RESOLUTION 4/07	Additive maximum limits for category 13 and food condiments for sauce
ANVISA RESOLUTION 3/07	Additive and its maximum limits for category 3 sweet foods eatables
ANVISA RESOLUTION 2/07	List of botanical species and update criteria
ANVISA RESOLUTION 163/06	Nutritional labeling of packaged foods (Complementation of Resolutions RDC No. 359 and RDC No. 360, of 2003)
ANVISA RESOLUTION 272/05	Technical regulation for products of vegetables, fruit products and edible mushrooms
ANVISA RESOLUTION 201/05	Use of certain additives
ANVISA RESOLUTION 216/04	Good practices procedures for food services in order to ensure the hygienic sanitary conditions of the prepared food
ANVISA RESOLUTION 123/04	Labelling of packaged foods
ANVISA RESOLUTION 360/03	Technical regulation on nutritional labeling of packaged foods, making nutrition labeling compulsory
ANVISA RESOLUTION 359/03	Technical regulation of portions of packaged foods for the purposes of nutrition labeling
ANVISA RESOLUTION 253/03	Program for Analysis of Residues of Veterinary Medicines in Foods of Animal Origin (PAMVet)
ANVISA RESOLUTION 340/02	Food manufacturers using tartrazine dye must state on the labeling in the list of ingredients the name of the tartrazine dye in full
ANVISA RESOLUTION 275/02	Standard operational procedures that contribute to the guarantee of hygienic sanitary conditions necessary for the industrialization of food, complementing the good manufacturing practices
ANVISA RESOLUTION 274/02	Quantitative indication of the net content of pre-measured products
ANVISA RESOLUTION 259/02	Technical regulation on packaged food labeling
ANVISA RESOLUTION 218/02	Synthetic casings of regenerated cellulose film in contact with foodstuffs
ANVISA RESOLUTION 217/02	Regenerated cellulose films aimed at getting in contact with food
ANVISA RESOLUTION 130/02	Packaging and cellulosic equipment in contact with food
ANVISA RESOLUTION 129/02	Technical regulation on recycled cellulosic material for food packaging
ANVISA RESOLUTION 40/02	Technical regulation for the labeling of packaged foods and beverages containing gluten
ANVISA RESOLUTION 124/01	Prepared film makers based on polymers and/or resins for the coating of food
ANVISA RESOLUTION 123/01	Analytical methodologies for the control of packaging and equipment intended to come into contact with food
ANVISA RESOLUTION 122/01	Paraffins in contact with food
ANVISA RESOLUTION 91/01	Adhesives used in the manufacture of packaging and equipment intended to come into contact with food
ANVISA RESOLUTION 34/01	Technical regulation on the use of food additives, establishing their functions and their maximum limits for industrial culinary preparations
ANVISA RESOLUTION 33/01	Technical regulation on the use of food additives, establishing their functions and their maximum limits for soups and broths
ANVISA RESOLUTION 12/01	Technical regulation on microbiological standards for food and identity and quality of the Parmesan cheese, Reggianito and Sbrinz

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ANVISA RESOLUTION 5/01	Technical regulation on sampling methods for the control of veterinary drug residues in food of animal origin
ANVISA RESOLUTION 1/01	Technical regulation on the use of additives with a function of flavor enhancers, establishing their maximum limits for foods
ANVISA RESOLUTION 23/00	Basic procedures for the registration and exemption of registration
ANVISA RESOLUTION 22/00	Product's exemption from registration
ANVISA RESOLUTION 383/99	Technical regulation on the use of food additives, establishing their functions and their maximum limits for bakery products and cookies
NATIONAL COUNCIL OF HEALTH RESOLUTION 408/08	Guidelines for the promotion of human nutrition with impact on the reversal of the obesity epidemic and prevention of chronic non-communicable diseases
RE-ANVISA RESOLUTION 386/99	Updating the general harmonized list of additives Mercosul : gelatine
RE-ANVISA RESOLUTION 382/99	Insertion of additives and their limits for category 13: food sauces and condiments; and the subcategory 13.10: Vinegar
MS/ANVS RESOLUTION 105/99	Packaging and polyethylene Fluor equipment in contact with food
CNNPA RESOLUTION 15/93	Potassium bromate
CISA RESOLUTION 10/84	Provisions concerning the Instructions for preservation in the transportation, commercialization and consumption phases of perishable, industrialized or processed foods, packaged
CNNPA RESOLUTION 35/77	Identity and quality standards for fast frozen foods
CNNPA RESOLUTION 17/77	Criteria for authorization of using of additives and technology coadjuvants in foods, and setting the respective limits of addition
INMETRO/MDIC ORDINANCE 391/14	Facilities and equipment in the production of food baskets
INMETRO/MDIC ORDINANCE 298/12	Provisions on foodstuffs that are packaged in unit-dose in blister pack, on the safety of using and precaution of handling accidents
INMETRO/MDIC ORDINANCE 157/02	Approves the Technical Metrological Regulation establishing how to express the liquid content to be used in the pre-measured products
INMETRO ORDINANCE 75/99	Contents of aerosols
CONMETRO RESOLUTION 5	Establishes INMETRO activities to implement WTO TBT practices and rules
ORDINANCE SDA/MAPA 126/16	Aims to modernize the procedures for equivalence recognition of foreign sanitary inspection systems with regard to export animal products to Brazil
INTERMINISTERIAL ORDINANCE 701/15	Updates the values of Sanitary Surveillance Inspection Fees (TFVS)
ORDINANCE OF MINISTRY OF JUSTICE 2658/03	Creates provisions concerning the use of the transgenic symbol.
ORDINANCE OF MINISTRY OF MINES AND ENERGY 470/99	Establishes that the label to be used in the bottling of mineral and table water must be approved by the National Department of Mineral Production (DNPM), at the request of the interested party, after publication in the Official Gazette of the respective mining concessionaire
ORDINANCE SSC 451/97	Identity and quality of the food casseinatos
ORDINANCE MAA 370/97	Inclusion of the additive Sodium Citrate as a stabilizer in the RTM of identity and quality of U.H.T. Milk (U.A.)
ORDINANCE MAA 185/97	Identity and quality of fresh fish
ORDINANCE MAA 183/96	Maximum levels for pesticide residues
ORDINANCE MAA 146/96	Fluid milk quality in quantity for Industrial use
ORDINANCE 540/97	Almidones modified
ORDINANCE 366/97	Identity and quality of the dough to make Mozarella cheese
ORDINANCE 365/97	Identity and quality of the cheese Tandil
ORDINANCE 364/97	Identity and quality of the mozzarella
ORDINANCE 363/97	Identity and quality of the Pategras cheese sandwich
ORDINANCE 362/97	Identity and quality of the cheese Tybo
ORDINANCE 361/97	Identity and quality of the cheese Tilsit
ORDINANCE 360/97	Identity and quality of the Dambo cheese
ORDINANCE 359/97	Identity and quality of cheese curd
ORDINANCE 358/97	Identity and quality of the cheese plate
ORDINANCE 357/97	Identity and quality of grated cheese
ORDINANCE 146/96	Tolerance limits for inorganic contaminants
ORDINANCE MAARA 183/96	Tolerance limits for inorganic contaminants
ORDINANCE MAARA 146/96	Identity and quality of milk CTU

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ORDINANCE MAARA 646/95	Identity and quality of tomato
ORDINANCE MAARA 553/95	Identity and quality of tomato
ORDINANCE MAARA 529/95	Identity and quality of onion
ORDINANCE SVS/MS 987/98	Disposable packaging of polyethylene terephthalate-pet-for multilayer packaging of carbonated non-alcoholic drinks
ORDINANCE SVS/MS 685/98	General principles for the establishment of maximum levels of chemical contaminants in foods
ORDINANCE SVS/MS 540/97	Transfers of food additives
ORDINANCE SVS/MS 451/97	Identity and quality of the Minas fresh cheese
ORDINANCE SVS/MS 326/97	Sanitary hygienic conditions and good manufacturing practices for policy makers/industrializers food establishments
ORDINANCE SVS/MS 71/96	List of coloring agents allowed
ORDINANCE SVS/MS 26/96	Determination of residual styrene monomer
ORDINANCE SVS/MS 10/95	Pesticide residues in agricultural products *in natura*
NORMATIVE INSTRUCTION MAPA 17/17	Production, sale and use of seeds and seedlings of forest species or environmental or medicinal interest, native and exotic, in order to guarantee their origin, identity and quality
NORMATIVE INSTRUCTION MAPA 5/17	Establishes the requirements for the equivalence evaluation of the Unified Animal and Plant Health Protection System relating to the physical structure, dependencies and equipment of small agroindustrial establishment of products of animal origin
NORMATIVE INSTRUCTION SDA/MAPA 1/17	Procedures for registration, renewal, modification, audit and cancellation of registration regarding animal products produced by establishments registered on the Federal Inspection Service (Serviço de Inspeção Federal, SIF), and foreign establishments authorized to export to Brazil
NORMATIVE INSTRUCTION SDA/MAPA 57/13	Establishes the criteria and requirements for the accreditation and monitoring of laboratories by the Ministry of Agriculture, Livestock and Supply
NORMATIVE INSTRUCTION SDA/MAPA 66/03	Establishes, within the scope of the Ministry of Agriculture, Livestock and Supply, the System of Registration of Agents of the Productive Chain of Vegetables, its Products, Byproducts and Derivatives for Safety and Quality Certification (SICASQ)
NORMATIVE INSTRUCTION ANVISA 15/17	Procedures for the evaluation of flavoring additives from regional plant species, according to the Resolution RDC No. 2/2007, approving the technical regulation on flavoring additives
INTERMINISTERIAL NORMATIVE INSTRUCTION 1/04	Technical regulation on labeling of foods and food ingredients that contain or are produced from Genetically Modified Organisms (GMOs)
JOINT NORMATIVE INSTRUCTION 9/02	Provisions concerning the packagings intended for the packaging of vegetables “in natura”
NORMATIVE RULING SDA 54/01	Brewery products
NORMATIVE RULING SDA/MAA 15/01	Principles, guidelines, criteria and parameters for the recognition of equivalence of Food control systems between the States parties of Mercosul
NORMATIVE INSTRUCTION MA/SDA 12/01	Analytical methodologies acceptable for daily intake, maximum residue limits for residues and veterinary medicinal products in foodstuffs of animal origin
NORMATIVE INSTRUCTION SDA/MAPA 5/00	Technical regulation for the manufacture of beverages and vinegars, including wines and grape derivatives
NORMATIVE STATEMENT 46/07	Identity and quality of fermented milk
NORMATIVE STATEMENT 45/07	Identity and quality of the blue cheese
MERCOSUL CMC RESOLUTION 20/02	Structure and Criteria for the elaboration of identity and quality of vegetable products "in natura"
MERCOSUL GMC RESOLUTION 50/01	Positive list of additives for plastic materials intended for the production of packaging and equipment in Contact with food

Table 43 - Technical Regulation on PAPs (Argentina)

NAME	THEME
LAW 18284/69	Creates the Argentine Food Code
DECREE 2126/71	Regulates the Argentine Food Code
DECREE 2092/91	Regulates all imported food and beverage products both manufactured domestically and imported, except wine
DECREE 1490/92	Creates the National Administration of Drugs, Foods and Medical Devices

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DECREE 815/99	Sets the basis for the creation of the National Food Inspection System (SNCA) and creates the National Food Commission (CONAL)
SENASA RESOLUTION 256/03	Establishes the Maximum Residue Levels (MRLs) for products that are traded in the country
RESOLUTION 5/15	Establishes the System for Import Control
DECREE 133/15	Revised export taxes and eliminated or reduced export tariffs on agricultural and industrial products
DECREE 160/15	Revised export taxes and eliminated or reduced export tariffs on agricultural and industrial products
RESOLUTION 3823/15	Establishes the System for Import Control
OFFICIAL RESOLUTION 6/16	Revokes the Label Supervision System

Source: SENASA. Elaborated by CGTI-EESP/FGV.

Table 44 - Technical Standards on PAPs (Argentina)

NAME	TITLE
IRAM-1109-B13	Paintings. General test methods. Method for detecting alterations of the smell and taste of food by the painting effect.
IRAM-12901-1	Articles of glass and ceramic glazed in contact with food. Release of lead and cadmium. Method of determination.
IRAM-12901-2	Articles of glass and ceramic glazed in contact with food. Release of lead and cadmium. Permissible limits.
IRAM-12909-1	Ceramic articles for cooking food. Release of lead and cadmium. Part 1: Methods of determination.
IRAM-12909-2	Ceramic articles for cooking food. Release of lead and cadmium. Part 2: Permissible limits.
IRAM - 14100	Food. Best practices in the conservation of the cold chain. Storage, transport and distribution.
IRAM - 14103	Food industry. Guide for the implementation and application of good manufacturing practices.
IRAM - 14107	Food. Guide for the evaluation of suppliers.
IRAM - 14108	Food for animal feed. Good manufacturing practices. Requirements.
IRAM - 14201	Food services. Good manufacturing practices.
IRAM - 14202	Food services. Vocabulary.
IRAM - 14203	Food. (POES) sanitation standard operating procedures. Application guide.
IRAM-14808-2	Natural toxins in foods. Patulin. Rapid determination in juice of apples and cider.
IRAM-14809-2	Natural toxins in foods. Determination of ochratoxins A and B in coffee. In thin layer chromatographic method.
IRAM-14821-1	Natural toxins in foods. Qualitative determination of sulphur in rapeseed oil. Silver benzoate method.
IRAM-14821-2	Natural toxins in foods. Qualitative determination of sulphur in rapeseed oil. ' Currency' or the silver object method.
IRAM - 14824	Natural toxins in foods. Determination of the total content of glucosinolate in rapeseed. Routine method.
IRAM - 14825	Natural toxins in foods. Determination of total Glucosinolates in rapeseed. Reference method by liquid chromatography (HPLC) high resolution.
IRAM - 14903	Microbiology of food and animal feed products. Horizontal method for the detection of Salmonella spp.
IRAM-14915-1	Microbiology of food and animal feed products. Horizontal method for detection and enumeration of Listeria monocytogenes. Part 1 - Method of detection.
IRAM-14915-2	Microbiology of food and animal feed products. Horizontal method for detection and enumeration of Listeria monocytogenes. Part 2 - Counting method.
IRAM-186-1	Sanitary polished. Part 1 - Metallic elements used in the food industry and beverage.
IRAM - 20022	Sensory analysis. General guidelines and methodology for the evaluation of the color of the food.
IRAM - 20301	Food irradiation. Good practices for the process of irradiation of foodstuffs intended for human consumption.
IRAM - 20304	Food irradiation. Guide for selection and use of containers and materials in contact with foods to be irradiated as a whole.
IRAM - 20305	Food irradiation. Requirements for the control of micro-organisms and insects in spices, herbs and vegetable seasonings dried, through the application of ionizing radiation.
IRAM - 20306	Food irradiation. Requirements for the control of sprouting bulbs and tubers through the application of ionizing radiation.
IRAM-2120-4	Apparatus for cooling. Household. Apparatus for storing frozen food and freezer of food (freezers). Characteristics and test methods.
IRAM-2120-5	Domestico-refrigeradores frost-free use refrigeration products, refrigerador-congeladores - storage compartments for frozen food and freezer food cooled by internal forced air circulation. ANCI

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IRAM - 23010	Pesticide residues. Classification of food and feed according to their approximate content of fat and water.
IRAM-23026-1	Pesticide residues. Process diagram for the systematic analysis of pesticide residues in non-fatty foods.
IRAM-23026-2	Pesticide residues. Process diagram for the systematic analysis of pesticide residues in fatty foods.
IRAM-23029-1	Organ-phosphorus pesticide residues. Method of determination in non-fatty foods with more than 70% water content.
IRAM-29012-5	Quality of the environment. Quality of water. Sampling. Part 5: Guide on sampling of drinking water and water used for food processing and beverages.
IRAM-AMN ISO TS 22003	The food safety management systems. Requirements for bodies carrying out the audit and certification of food safety management systems. (ISO/TS 22003:2007, IDT)
IRAM-AMN ISO TS 22004	The food safety management systems. Guidance for the implementation of NM ISO 22000:2008 standard. (ISO/TS 22004:2005, IDT)
IRAM-ISO 14470	Food irradiation. Requirements for development, validation and control of routine of the process of irradiation using ionising radiation for the treatment of food.
IRAM-ISO 16654	Microbiology of food for human and animal consumption. Horizontal method for the detection of Escherichia coli O157.
IRAM-ISO TS 22002-1	Prerequisites of food safety programs. Part 1 - Food processing.
IRAM-ISO TS 22002-2	Prerequisites of food safety programs. Part 2 - Catering.
IRAM-ISO TS 22002-4	Prerequisites of food safety programs. Part 4 - Manufacture of food containers.
IRAM-NM 324	The food industry. Good manufacturing practices. Requirements.
IRAM-NM-ISO 22000	The food safety management systems. Requirements for any organization in the food chain. (ISO 22000:2005, IDT)

Source: IRAM. Elaborated by CGTI-EESP/FGV.

APPENDIX 7 - Pharmaceuticals

Table 45 - Regulation on Pharmacutical Products (Brazil)

NAME	THEME
LAW 13411/16	Modifies the registration process
LAW 10742/03	Creates the Regulatory Chamber of Medicines Market
LAW 9782/99	Creates ANVISA
LAW 8080/90	Creates the Unified Health System (SUS)
LAW 6360/76	Products subject to the health surveillance
LAW 5991/73	Sanitary control of drugs, medicines, pharmaceutical and correlated inputs
ANVISA RESOLUTION 208/18	Labeling in Brazilian Portuguese within the Brazilian territory
ANVISA RESOLUTION 108/16	Minimum requirements for inspection in establishments which work with controlled products. Incorporates into the national legal order the GMC Resolution Mercosul n. 46/15
ANVISA RESOLUTION 74/16	Importing process of medicines
ANVISA RESOLUTION 67/16	Provides on the requests for authorization of habilitation, renewal of habilitation, modifications after habilitation, outsourcing of tests, suspensions and cancellations of Pharmaceutical Equivalence Centers and other measures.
ANVISA RESOLUTION 65/14	Provides for prior notification of export of ephedrine, pseudoephedrine and special containing them. This Resolution incorporates the GMC Resolution Mercosul nº 30/12 into the national legal system.
ANVISA RESOLUTION 60/14	Criteria for grant renewal of registration of drugs with active principles, synthetic and semi-synthetic, classified as new, generic and similar
ANVISA RESOLUTION 56/14	Certificate of good practices
ANVISA RESOLUTION 16/14	Technical and administrative requirements for the authorization of operation of the company
ANVISA RESOLUTION 15/14	Certificate of good practices
ANVISA RESOLUTION 39/13	Inspection of goods and products under sanitary surveillance and certificate of good practices
ANVISA RESOLUTION 61/12	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 60/12	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 13/11	Provides for the common criteria of the Mercosul for conversion factors for substances controlled nationally by the States Parties that are not objects of international control. This Resolution incorporates the Mercosul Resolution n°. 21/10 into the national legal system.
ANVISA RESOLUTION 12/11	Provides on the Mercosul mechanism of periodicity of the updating of lists and exchange of information on narcotic, psychotropic, precursory and other substances under special control. This Resolution incorporates the MERCOSUL Resolution n° 20/10 into the national legal system.
ANVISA RESOLUTION 23/10	It extends validity of Resolution of the Collegiate Board for purposes of adequacy of the productive sector to the requirements of the norm.
ANVISA RESOLUTION 21/10	Provides the updating of Annex I, Lists of Narcotic Substances, Psychotropic, Precursors and Other under Control Special Issue of Ordinance SVS/MS nº 344 from May 12th, 1998 and makes other provisions.
ANVISA RESOLUTION 71/09	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 47/09	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 12/09	Revoke Art. 1° of RDC nº. 239 from August 28th , 2002
ANVISA RESOLUTION 81/08	Technical regulation on imported goods and products for sanitary surveillance
ANVISA RESOLUTION 63/08	Revoke the provisions applicable to List "C4", to antiretroviral substances and medicinal enacted by RDC N° 103 from August 31st, 2016. New text to art. 34 of the Ordinance SVS/MS N° 344 of May 12th, 1998 providing that the purchase and sale on the internal and external market of the list in this Technical Regulation and its updates. It considers GMC Resolution n° 46/99, which provides for the use of a reimbursement system for the purchase / sale of narcotic drugs and psychotropic substances
ANVISA RESOLUTION 58/08	Provides for the improvement of the control and monitoring of substances psychotropic and other measures.
ANVISA RESOLUTION 25/07	Provides the outsourcing of production steps, analysis of quality control and storage of medicines.
ANVISA RESOLUTION 233/05	Approves the technical regulation of production and quality control for registration, post-registration alteration and revalidation of allergenic extracts and allergenic products.
ANVISA RESOLUTION 217/05	To approve the Extension of Use of the Additive Sulfur Dioxide and its Salts of Calcium, Sodium and Potassium.
ANVISA RESOLUTION 323/03	Approve the technical regulation of registration, modification and revalidation of registration of probiotic medicines, according to the Technical Regulation attached.
ANVISA RESOLUTION 332/02	It is based on the technical criteria established and applicable to the inspections of drug-producing establishments located in countries outside MERCOSUL, according to Resolution - RDC nº 25, of December 9, 1999. Prohibits the importation and sale through the national territory, of the drug

	registered as a similar drug based on CICLOSPORINA of *Laboratório Químico Farmacêutico Bêrgamo* Ltda., under the name Pharmosporin.
ANVISA RESOLUTION 298/02	Requirements concerning raw material importation, ganglioside-based drugs manufacturing, distribution, trading and prescription as well as drug usage will be subject to the control of the Brazilian Sanitary Surveillance Agency
ANVISA RESOLUTION 214/02	The importer must present the information listed in resolution's annexes and fill in the forms contained in it.
ANVISA RESOLUTION 172/02	It is based on the technical criteria established and applicable to the inspections of drug-producing establishments located in countries outside MERCOSUL, according to Resolution - RDC nº 25, of December 9, 1999. Prohibits the importation and sale, throughout the national territory, of medicines registered as medicines Similar products based on MICOFENOLATO MOFETIL.
ANVISA RESOLUTION 168/02	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 137/03	Labeling of medicines and content of the package inserts
ANVISA RESOLUTION 33/01	It is established, considering the importance of making national legislation compatible, harmonized instruments in the Mercosul related to food additives (GMC Resolution 16/00). It creates the "Technical Regulation that approves the use of Food Additives, establishing their functions and their maximum limits for Food Category 12: Soups and Broths.
ANVISA RESOLUTION 92/00	Labeling of medicines and content of the package inserts
ANVISA ORDINANCE 4/08	Certificate of good practices
ANVISA ORDINANCE 344/98	ANVISA's prior consent and authorization to ship to Brazil
NORMATIVE INSTRUCTION 26/09	Manufacturing, quality control, trading and the usage of antimicrobial drugs in animals
MAPA NORMATIVE INSTRUCTION 7/06	Production, evaluation, control and use of poultry vaccines and diluents
MAPA NORMATIVE INSTRUCTION 4/06	Animal Health
MAPA ORDINANCE 23/16	Guidelines on performance of the Ministry of Agriculture, Livestock and Supply (MAPA)
INTER-MINISTERIAL ORDINANCE 701/15	Monetary update on registration and GMP certification fees related to health products in Brazil
ORDINANCE 230/04 OF THE MINISTRY OF HEALTH	Labeling of medicines and content of the package inserts
ORDINANCE 572/02 OF THE MINISTRY OF HEALTH	Labeling of medicines and content of the package inserts
ORDINANCE 510/99 OF THE MINISTRY OF HEALTH	Labeling of medicines and content of the package inserts
RESOLUTION 433/05 OF THE NATIONAL COUNCIL OF PHARMACY	Responsibility to monitor the compliance with sanitary regulations

Source: ANVISA Elaborated by CGTI-EESP/FGV.

Table 46 - Pharmaceutical Products Standard (Brazil)

STANDARD	CONTENT
ABNT NBR 16090: 2012	Aluminum tube for pharmaceuticals - Requirements and test methods
ABNT NBR 11819: 2004 ERRATA 1: 2005	Glass bottles for pharmaceutical products - Requirements and test methods
ABNT NBR 11819: 2004 VERSION FIXED: 2005	Glass bottles for pharmaceutical products - Requirements and test methods
ABNT NBR 11280: 2008	Glass ampoules - Requirements and test methods

Table 47 - Regulation on Pharmaceutical Products (Argentina)

NAME	THEME
DISPOSITION 828/17	Establishes that the laboratories authorized by the national administration as importers and/or processors of medicinal specialties may request authorization of programs of expanded access (PAE) drugs for groups of patients that required treatments with drugs not yet marketed in the country, as specified in article 2 of this provision
DISPOSITION 6301/15	From 6 months of the entry into force of this provision, medicinal disciplines reached by the ANMAT N provision 3683/11 should be released to the market by its respective register without identification of die holders
DISPOSITION 5039/13	Stating that the information contained in the official list of marketed drugs (LOMAC) and in the drug formulary will be available in the "VADEMECUM national drug" (VNM), which will be published in the institutional Web page: www.anmat.gov.ar

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DISPOSITION 2574/13	Gluten-free medications
DISPOSITION 4990/12	Adopted the common name Argentina (DCA) for ingredients pharmaceutical assets (IFA's), used in human medicine contained in annex I of this provision, which is part of the same
LAW 26688/11	Declared of national interest research and public production of medicines, raw materials for the production of medicines, vaccines and healthcare products, understanding them as social goods
DISPOSITION 3686/11	" Minimum requirements to apply for the status of OTC of a medical specialty"
DISPOSITION 2124/11	Crease in the scope of the national administration of medicines, foods and medical technology (A.N.M.A.T.) National Control of drugs and medical products-market program
DISPOSITION 1719/11	Be created within the scope of this national administration of drugs, foods and medical technology, the program for the support to the innovation in medicines and products for health, whose main objective will be the availability of a specific platform for assistance in research and development projects related to processes and products that are innovative character and of interest to public health
DISPOSITION 5576/09	Become the Technical Advisory Committee of chemical substances and medicines, which will act as a pro bono, which shall consist of the scope of this national administration by: the Director of the National Institute of medicine, who will exercise ((the Presidency, a professional representative of each of the following areas: a) direction of Legal Affairs, b) Department of psychotropic and narcotic drugs; (c) Department of Pharmacology; (d) Department of studies and projects; e) Department of registration; (f) Department of pharmaceutical technology); (g) Department of pharmacovigilance; and two professionals by the Directorate of evaluation of drugs
LAW 26492/09	Medicines regulation of medicinal cold chain
DECREE 248/09	Medicines observed and enacted the law No. 26.492
RESOLUTION 1644/08	Created the national registry of drug stores enabled. Conditions of registration
DISPOSITION 4932/08	Approve is the procedure operating for the processing of the requests of authorization of distribution with transit interprovincial and/or between provinces and the city autonomous of Buenos Aires, of lots of products immunobiological, made in laboratories of Public production of medicines, not enrolled in the register of specialities Medicinales
RESOLUTION 609/08	Ministry of health – the national administration of medicines, food and technology medical (ANMAT) through the National Drug Institute supervise and control the medicinal and pharmaceutical specialties whose importation authorized for carry out the Ezeiza delegation of the Directorate GENERAL of customs of income of Administration FEDERAL public
RESOLUTION 582/08	Ministry of health-administration national of medication, food and medical technology through the National Drug Institute supervise and control the medicinal and pharmaceutical specialties whose importation is carried out by the Income Federal Administration public, Dirección General de Ingresos Publicos, Directorate-General for customs, delegation Bahía Blanca
RESOLUTION 627/07 (WITH AMENDMENTS TO THE RESOLUTION 1061/07)	Health publishes approving the "good practices of promotion of drugs for sale low recipe"
RESOLUTION 17/06 MSA	DRUGSTORES. Establishment legal and technical conditions that must comply with the signatures requesting the habilitation as drugstore.
DECREE 987/03	Regulation of the law of promotion the use of medicines by its generic name, law Nº 25649
RESOLUTION 145/03	Adopted the Mercosul technical regulation for transport of infectious substances and samples for diagnosis, incorporating the legal regulations national vigente
LAW 25649	Law of generic drugs
DISPOSITION 3554/02	Requirements for registration of pharmaceutical products registered and processed in a State part of Mercosul (State part producer) similar to products registered in the country (part receiving State). Deadline for completion of the process. Time to start the marketing of products
DISPOSITION 2321/02	Apruebase document "mandatory communication between States part of MERCOSUL on the removal of drug from the market" (resolution GMC No. 78/99)
LAW 24766	Privacy Act information and products
DECREE 150/92 (WITH MODIFICATIONS OF THE DECREES 968/92, 1890/92, 177/93, 1528/04 AND RES. CONJ. 452/14 AND 1227/14)	Rules for registration, preparation, fractionation, prescription, dispensing medications
RESOLUTION 147/92 AND JOINT RESOLUTION 342/92	Regulate the development of activities in pharmacies and marketing of medicines, products of hygiene and toiletries, cosmetics, Perfumes, equipment and devices for medical use, and dental, diagnostic reagents and products for household use with impact on the health of people
JOINT RESOLUTION 268/92	Regulating Decree No. 150/92 (medical specialties)
RESOLUTION 129/87 (WITH AMENDMENTS TO THE RES. 50/07 OF THE SPRRS)	Modify the conditions of sale of the specifics that contain dextromethorphan, antihistamines, aspirin in Pediatrics and Zipeprol
REGULATORY DECREE 9763/64	Regulates Act No. 16463
LAW 16463	Drugs
DISPOSITION 10564/16	The system of traceability of medicines that need to implement the natural or legal persons involved in the chain of marketing, distribution and dispensing of pharmaceutical products included in the registration of pharmaceutical products (REM) of the national administration in the terms established in the resolution of the Ministry of health no. 435/11, will apply to all those specialties, already

	registered or which in the future register containing in their composition the ingredients pharmaceutical assets (IFA's) included in annex I, alone or in partnership (unless otherwise stated) and pharmaceutical forms that therein
DISPOSITION 963/15	The system of traceability established, must be implemented for all of the previously listed medicinal specialties, to the first business day of March 2015, for all links in the chain of distribution
DISPOSITION 247/13	Incorporanse to the national system of traceability of medicines, starting on June 15, 2013, all those medical specialties containing in their composition the active pharmaceutical ingredients (IFA's) included in annex I that is an integral part of it, either as monodroga or in association with any one or more other IFA's, in all of its pharmaceutical forms
DISPOSITION 1831/12	System of traceability of medicines that need to implement the natural or legal persons involved in the chain of marketing, distribution and dispensing of pharmaceutical products included in the register of specialities Medicinal
RESOLUTION 435/11	Established that natural or legal persons involved in the chain of marketing, distribution and dispensing of medicinal specialties included in the registration of pharmaceutical products, need to implement a system of traceability that allows ensuring control and follow-up
DISPOSITION 3683/11	Technical requirements and stages of implementation of the system of traceability of medications
RESOLUTION 549/11	Traceability - the insurance agents (resolution No. 594/11 of the Superintendence of health services)
CIRCULAR 4/16	Update data in the VNM
CIRCULAR 7/16	Update of data in the national formulary of drugs
DISPOSITION 7304/14	Set that on the medicinal specialities containing as IFA Amphotericin B Iiposomal must be the acute toxicity test on the finished product at least in a different batch every six months, according to the test described in annex I forming an integral part of this provision
DISPOSITION 7240/14	Approve the inspection Guide to implement market monitoring of medicines distributed, as annexes I and II form an integral part of this provision
DISPOSITION 7066/13	Establish that companies enabled by the ANMAT to develop and/or air conditioning, own plant or of third parties, and/or importing and/or exporting drugs or active pharmaceutical ingredients, must annually submit the master site file (AMS)), according to the specifications provided for in this provision
DISPOSITION 5569/13	Approval of the "Guide for inspectors on good practices of manufacturing of ingredients pharmaceutical assets", which, as annex I, form an integral part of this provision, as complementary to the annex VI of the ANMAT NO2819/04 available
DISPOSITION 7667/10	Companies that produce and/or import not necessarily sterile products must comply with the microbiological Control in accordance with the limits of acceptability set out by article 20 of the present provision
DISPOSITION 5469/10	Incorporated into the national legal order the resolution Nº 15/09 GMC Mercosul "good practices of manufacture of pharmaceuticals and mechanisms of implementation in the scope of the MERCOSUL (repeal of the RES.)" (No 14/96 GMC and 61/00)
DISPOSITION 5363/10	Incorporated into the national legal order the GMCN Mercosul resolution nº 16/09 "common procedures for inspections in establishments pharmacists in States parties (repeal of the RES.)" (Nº 23/96 GMC and 34/99) ".
DISPOSITION 5743/09	The evaluation of information relating to the methods of control, development, trials pharmacotechnical, stability, operational capacity to develop and/or control included in requests for registration in the register of specialities medicinal, will be made by technical verification of such information, having completed the requirements laid down in the provision no. 2819 A.N.M.A.T. / 2004 or in the future replace it and stated quality specifications in the Argentina Pharmacopeia, Pharmacopoeia Brazilian and/or other internationally recognized pharmacopoeia
DISPOSITION 5260/08	Establishment requirements that must be completed settlements which develop and/or divide drugs and medications
DISPOSITION 2372/08	Approving the "Guide for inspectors on good practices of manufacture of drugs" and the "classification of deficiencies of compliance of them good practices of manufacture- " "
DISPOSITION 1402/08	Pharmaceuticals, PERSONAL hygiene, cosmetics and PERFUMES approving procedures for the removal of Personal hygiene products and pharmaceutical products, cosmetics and Perfumes
DISPOSITION 3477/05	Ministry of Foreign Affairs, international trade and worship Mercosul /GMC/Res. No 50/95 contracting outsourcing services for pharmaceutical products in the scope of the Mercosul
DISPOSITION 3476/05	Modifications of the authorization of functioning of the companies applicants registration products pharmaceutical of the Member State receiver
DISPOSITION 2123/05	Good practices of production and Control of medicinal/Prod specialties. Pharmacists
DISPOSITION 2819/04 (WITH AMENDMENTS OF THE DISP. 4844/05)	General guidelines of good manufacturing practice for processors, importers / exporters of drugs
DISPOSITION 6826/02	Practices and procedures of manufacturing, control and marketing that is must apply for ensure that them facilities, methods and controls used in the development and sale of products allergens for use in live are appropriate to ensure it efficiency , quality, stability and safety of them
DISPOSITION 3555/02	Requirements to be fulfilled by companies seeking to be recognized as representatives in the country's signature holders of registrations of pharmaceutical products manufactured in another State part of the Mercosul
DISPOSITION 2386/02	Adopted the document "Self-inspection mandatory on good practices of manufacturing and Control" (resolution GMC No. 79/99)
DISPOSITION 2338/02	Approve the document "Contractual relationship between the holder of the registration in the State part producer and its representative at the State party recipient of Mercosul , in the framework of the resolution GMC 23/95" (resolution GMC No 39/97)
DISPOSITION 2313/02	Adopted the document "Re-inspections joint in the scope of Mercosul " (resolution GMC N ° 34/99)
DISPOSITION 2309/02	Approves the document "Good practice for manufacture and Control of medicines who 92", (resolution No. 61/00 GMC)

DISPOSITION 6897/00 (WITH AMENDMENTS OF THE DISP. 3595/04)	Pharmaceutical products - sanitary risk
DISPOSITION 5221/97	Public health adopted the document entitled "Strategy of adaptation on surveillance health"
DISPOSITION 5220/97	Establishes that the training of human resources to inspections to pharmaceutical processing facilities will take place pursuant to the so-called technical paper: "training for inspectors in good manufacturing practices"that, as annex I, form an integral part of the present provision
DISPOSITION 5219/97	Specialties medicinal regime of inspections
DISPOSITION 5218/97	Establishes that pharmacochemistry industry inspections will be carried out in accordance with the so-called technical paper: "System of evaluation of procedures for the inspection of industries APIs" which, as annex I, part Member of the present provision
DECREE 1299/97 (WITH THE ELUCIDATION OF THE RES. EX MSYAS 832/98)	Presidency of the nation – Ministry of health and Social Action-Regulanse critical stages of marketing of medicines. Laboratories. Distribution companies. Pharmacies. Sale to the public. Create database only establishments
DISPOSITION 1930/95	Compliance with BPFyC
DISPOSITION 7038/15	The drugstores must comply with the requirements and conditions established in this provision, for the purposes of commercial transactions of drugs and pharmaceutical products outside the jurisdiction that are enabled) inter-jurisdictional transit)
DISPOSITION 5316/09	Incorporated into the national legal system resolution Mercosul GMC No. 48/08 "Regulation technical MERCOSUL on good practices health of transport of supplies and pharmaceutical products"
DISPOSITION 5307/09	Approving the "Guide for inspectors on good practices for storage, distribution and transportation of drugs" and the "classification of compliance deficiencies of the good practices of storage, distribution and transportation of" Drugs"
DISPOSITION 3475/05	Annex Mercosul /GMC/Res. Nº 49/02: regulation technical Mercosul on good practices of distribution of pharmaceutical products
DISPOSITION 105/02	Distributors of drugs - system of registration and Control
DISPOSITION 7439/99	Medicinal enabling specialties of distributors of drugs
RESOLUTION 538/98	Creation of the national register of establishments distributors of pharmaceutical-products
DECREE 1299/97 (WITH THE ELUCIDATION OF THE RES. EX MSYAS 832/98)	Presidency of the nation – Ministry of health and Social Action-Regulanse critical stages of marketing of medicines. Laboratories. Distribution companies. Pharmacies. Sale to the public. Create database only establishments
RESOLUTION 223/96	SPECIALTY medical Actualizanse rules governing the same productive sector, for the purpose of placing in a symmetry plane competitive industries on the international arena and in harmony with the activities carried out in the MERCOSUL
DISPOSITION 4010/17	Approving new forms for application for authorisation and the presentation of results of bioavailability/bioequivalence studies
DISPOSITION 4009/17	Approving the requirements and conditions to be fulfilled the assistance centers to be permitted to carry out studies of phase I pharmacology clinical and/or bioequivalence, appearing as annex I to this provision and which forms an integral part of the same
DISPOSITION 4008/17	Replaced item 2 ° of the ANMAT provision N ° 6677/10 which will be drafted in the following way "article 2 °.establish that once submitted and accepted the documentation which is referenced in the scheme approved by the article 1 of the present Available, the technical areas involved must be dispatched in the term of 60 (sixty) business days. This period may be suspended whenever objections are made and until the person concerned delivery of all documentation and/or complete all observations or clarifications chosen. Once issued the report, within (the 10 ten) business days will be extended the corresponding administrative act."
DISPOSITION 12792/16	Established by this provision the procedure for the application for import of the medication/treatment and materials for access post-research by participants in a clinical pharmacology study authorized by this National Administration
CIRCULAR 3/11	EFC sponsors must submit filed version of informed consent
CIRCULAR 1/11	Sets a field intended for the presentation of clinical research projects
RESOLUTION 1480/11	Approval of the guidelines for research involving humans, which, as annex I, form an integral part of the present resolution, and which aims to guide researchers, sponsors and members of committees of ethics in research and regulatory authorities and health of different jurisdictions in the development and evaluation of research involving humans
CIRCULAR 4/10	Clinical trials in the country. Phase I and/or II.
DISPOSITION 6677/10	" Adopted the regime of good clinical practice clinical pharmacology studies"
DISPOSITION 2247/09	Medical specialties - Approved guide for clinical studies of type 2 Diabetes. Criteria of evaluation of protocols
DISPOSITION 1310/09	Public health incorporated the best practices guide of clinical research in humans, approved by resolution of the Ministry of health no. 1490/07, as part of specific regimes in force in this national administration
RESOLUTION 102/09	Create the registration of clinical trials in human beings
DISPOSITION 6/08 AND ANNEXES – PUBLIC HEALTH	Development of procedures relating to clinical pharmacology trials subject to approval of the national administration of drugs, foods and medical technology (ANMAT)
RESOLUTION 1490/07	Approval of the guide of the good practices of research clinic in humans, which form an integral part of the present resolution as annex I
DISPOSITION 9222-E/17	Labs holders of certificates of pharmaceutical products registered in the register of medicinal specialties (REM) and sold, containing, as monodroga, one of the ingredients pharmaceutical assets

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	(IFA) referred to then must submit protocols to the studies of equivalence vivo within one hundred twenty (120) calendar days as from the entry into force of this provision
DISPOSITION 8870/17	The pharmaceutical products containing the pharmaceutical active ingredients (IFAs), monodroga, as indicated in annex I to the present, and for all its authorized concentrations, will not require bioequivalence studies
DISPOSITION 8262/17	Establish product called LEVOTHYROXINE GLAXOSMITHKLINE / LEVOTHYROXINE sodium, tablets, as reference product for bioequivalence studies of the ingredient pharmaceutically active levothyroxine sodium
DISPOSITION 8259/17	Establish product called T4 MONTPELLIER / LEVOTHYROXINE sodium, tablets SLOTTED, as reference product for bioequivalence studies of the ingredient pharmaceutically active levothyroxine sodium
DISPOSITION 4010/17	Dejanse annexes II, III and IV of the ANMAT provision void No. 5040/06. Approval of the new form for the request for authorization to carry out studies of bioavailability/bioequivalence guidelines and requirements of information and documentation which appears as annex I to this provision and is an integral part of the same
DISPOSITION 12704/16	Adopt the criteria of the average bioequivalence with escalation to the reference product to the IFAs or formulations of high variability intra-subject, for pharmacokinetic parameter maximum concentration (Cmax), provided that such escalation does not have any impact on the safety and efficacy of the product
CIRCULAR 11/16	Compliance with requirement of bioequivalence studies applicable to new applications for registration and applications for registration of pharmaceutical products pending
DISPOSITION 11247/16	Establishment products of reference medicinal specialties that contain active pharmaceutical ingredients subject to bioequivalence studies contained as an annex to this provision
DISPOSITION 6766/16	Requests for Bioexenciones of pharmaceutical active ingredients with bioequivalence requirements shall be carried out according to the "Guide for the application of active pharmaceutical ingredients with bioequivalence requirement Bioexenciones" that annexed it forms an integral part of this provision
CIRCULAR 5/2013	First phase of the timetable for pharmaceutical products containing the following psychoactive drugs such as IFA: CLOZAPINE, HALOPERIDOL, OLANZAPINE, QUETIAPINE and RISPERIDONE
DISPOSITION 4394/13	Approve the rules of good laboratory practice applicable to the Bioanalytical centers for bioavailability/bioequivalence studies, which appears as annex I to this provision and an integral part of it
DISPOSITION 2434/13	Established that the holders of laboratories of pharmaceutical products containing IFAs, for which this national administration requires the completion of bioequivalence studies, requesting the approval of results of studies carried out abroad, they shall comply with the requirements listed in annex I to this provision
DISPOSITION 1918/13	Establishment criteria for the selection of a medical specialty as reference product for Bioequivalence and equivalence In-Vitro studies referred to in annex I to this provision, which forms an integral part of it
CIRCULAR 1/13	Authorization of clinical studies of bioavailability and bioequivalence
DISPOSITION 4788/12	Incorporanse the requirements of preparation of bioequivalence/bioavailability studies, established by provision (ANMAT) No. 3185/99, active pharmaceutical ingredients contained in annex I of this provision, which is part a member of the same
DISPOSITION 4326/12	Adoptanse as criteria of risk health, for the inclusion of ingredients pharmaceutical active in the schedule of requirement of studies of bioequivalence vivo, to them hearing in the annex I of the present provision
DISPOSITION 4133/12	Established that, from the entry into force of this provision, shall only present results of bioequivalence studies that are included within the confidence interval 90% of 0, 80-1, 25, both for concentration Maxima as for the Area under the curve
DISPOSITION 4132/12	Merge, the requirement for demonstration of bioequivalence established in the provision (ANMAT) N ° 3185/99, all concentrations marketed and/or placed on the market of a medical specialty, oral solid dosage form, containing any Ingredients pharmaceutical assets included in the national rules referred to in the seen, and subsequent supplementary provisions of bioequivalence requirement
DISPOSITION 1263/12	Establishment new requirements for the realization of the equivalence or bioequivalence study "in vitro"
DISPOSITION 4351/10	Designanse members of the Commission adviser ad honorem at themes of Bioequivalence and bioavailability
DISPOSITION 3113/10	Incorporanse the requirement of bioequivalence studies / bioavailability, established by the provision (ANMAT) No. 3185/99, topiramate and lamotrigine active pharmaceutical ingredients
DISPOSITION 758/09	Products medicinal criteria of Bioexencion of bioequivalence studies for immediate-release oral solid medications
DISPOSITION 556/09	Medicinal SPECIALTIES available 556/2009 approval of the Guide to apply on changes of scale and subsequent changes to the registry drugs subject to demonstration of bioequivalence
DISPOSITION 7188/07	Aceptanse the results of the "study of bioequivalence in healthy volunteers single dose of two different formulations of Saquinavir Mesilato: PROTEOVIR Saquinavir mesylate Richmond and FORTOVASE (products Roche S.A.Q. e I.)."
DISPOSITION 5643/07	Aceptanse the results of the "study of comparative bioavailability of Indinavir after a single administration of 400 mg"
DISPOSITION 2446/07	Incorporanse medicinal SPECIALTIES certain active principles (Serolimus, Everolimus, Tacrolimus and mycophenolate) the requirement of bioequivalence studies / bioavailability, established by the provision no. 3185/99
DISPOSITION 5040/06 (WITH AMENDMENTS TO THE DISP. 1746/07 AND 4010/17)	Adopted the regime of good practices for the realization of studies of bioavailability / bioequivalence

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DISPOSITION 2749/05	Pharmaceutical products - product reference for beginning active DIDANOSINE
DISPOSITION 4218/04	Settles as a product of reference for equivalence studies in vitro to the medical specialty called 3tc / LAMIVUDINE tablets coated 150 and 300 mg, oral solution 10 mg/ml, owned by the firm Glaxosmithkline Argentina S.A.
RESOLUTION 60/03	Repeal of resolution Ministerial No. 189/00
RESOLUTION 46/03	Approving the Plan and timetable for the realization of bioavailability/bioequivalence studies of all the pharmaceutical products containing active ingredients. Antiretroviral drugs
SPRRS RESOLUTION 19/03 (WITH AMENDMENTS TO THE RES. 46/03 OF THE SPRRS)	Suspension of the former resolution SPyRS No. 40/01
DISPOSITION 4290/02	Establishment of products for: phenytoin, warfarin, Ethosuximide, quinidine, Levodopa/Carbidopa and Levodopa/Benserazida
DISPOSITION 5318/02	Establishment of product for simple-release phenytoin
DISPOSITION 3598/02	Declaration sworn of the researcher
DISPOSITION 2814/02	Pharmaceutical forms that do not require studies of Equivalencia
DISPOSITION 7062/02	Establishment of products to theophylline
DISPOSITION 2807/02	Incorporation of the drug isotretinoin to bioequivalence schedule. Selection of products comparators for bioequivalence studies, the drug carbamazepine, Oxcarbazepine, valproate, Cyclosporine, theophylline, digoxin, Verapamil and isotretinoin
DISPOSITION 3311/01	Establishment of conditions for bioequivalence studies of antiretrovirals and schedule of presentation of results
SECRETARIAL RESOLUTION 40/01	Inclusion in the schedule of bioequivalence of drugs antiretroviral
SECRETARIAL RESOLUTION 229/00	Inclusion in the schedule of bioequivalence of Pyridostigmine
DISPOSITION 3185/99	Requirement study of bioequivalence
DISPOSITION 13054/17	Approving the requirements called "Guide of good practices of manufacture of products of Pharmacopoeia" for establishments authorized to do so
DISPOSITION 8417/16	Official medicines, encoded in the current of the pharmacopoeia Argentina Edition and listed in the list as annex I form an integral part of this provision, and the drug may only be bottled, made and marketed, bound to the inter-jurisdictional trade, laboratories enabled to do so before the ANMAT
DISPOSITION 6501/13	Approving the texts of volumes II, III and IV of the seventh edition of the PHARMACOPOEIA of ARGENTINA, made by the Permanent Commission of the Argentina Pharmacopoeia, based in this national administration, which, as annex I, is part of the present Provision
DISPOSITION 4675/08	Pharmacopoeia Argentina joining the Commission permanent of the pharmacopoeia Argentina
DISPOSITION 3409/99	Enabling building and functional for the manufacture of products of Pharmacopoeia and registration of products
DISPOSITION 12665/17	Incorporated into Schedule II of the law No. 19.303 of psychotropic substances, the substance DRONABINOL delta-9-tetrahydrocannabinol and its stereochemical variants [(6aR,10aR)-6a, 7, 8, 10a - tetrahidro-6,6,9-trimetil-3-pentil-6H-dibenzo[b,d]pirano-1-ol]
DISPOSITION 13831/16	All physical and/or legal person performing import, export, production, manufacture, fractionation, marketing and/or deposit, within national jurisdiction or destined for interprovincial trade, of substances listed in the annex of the This provision, as well as also for medicinal or pharmaceutical specialities containing them, must register with the DVSSCE of the INAME to obtain a special certification for the management of these substances
DISPOSITION 10692/16	Holders laboratories registration of pharmaceutical products which use or contain in their precursor chemicals, they must inform the national administration, with 45 days in advance, the date and time that will be carried out the weighing and mixing of substances concerned activities
DISPOSITION 3263/13	Incorporated into the national legal order the GMC Mercosul resolution N ° 30/12: "prior notification of export of EPHEDRINE, PSEUDOEPHEDRINE and medical SPECIALTIES to the contain", which is attached as an annex and an integral part of the present provision
DISPOSITION 8700/11	Incorporated into Schedule II of the 17.818 law of narcotic drugs to the active pharmaceutical ingredient (I.F.A.) HYDROCODONE, their salts and derivatives active, and those products pharmaceutical's use human that it contain
DISPOSITION 7927/11	Incorporated into Schedule I, of the 17.818 Act on narcotic drugs, the substance ORIPAVINE, main alkaloid of the opium poppy (papaver somniferum) straw
DISPOSITION 5319/10	Incorporated into the national legal order the resolution GMC Nº 20/10 Mercosul "periodicity of the updating of lists in MERCOSUL and exchange of information on narcotic drugs, psychotropic substances, PRECURSORS and subject to CONTROL" Special (COMPLEMENTATION of the RES.) (No. 38/99 GMC) "
DISPOSITION 5317/10	Incorporated into the national legal order the resolution GMC Nº 21/10 Mercosul "Common criteria of the MERCOSUL for factors of CONVERSION for substances controlled NATIONALLY by the States part which not are object of CONTROL international"
DISPOSITION 885/10	Adoptanse new definitions of potential, psychotropic and narcotic for the purposes deemed to correspond
DECREE 299/10	Narcotic update of the list of narcotic drugs and other chemical substances which must be included in the scope of the law No. = BA 23.737
RESOLUTION 1645/08	Ministry of health SPECIALTIES medical prohibited the manufacture, marketing and use of ephedrine as monodroga. Exception
RESOLUTION 932 JOINT, 2529 AND 851/08	Set the import ban, either as raw material or semi-finished products of ephedrine, its salts, optical isomers and salts of its optical isomers and pseudoephedrine; at drugstores and/or physical and/or juridical persons that are not holders of registration of pharmaceutical products in accordance with the regulations in force

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DISPOSITION 7165/08	Established that the condition of the sale of all pharmaceutical products containing as active ingredient TRAMADOL as monodroga or the partner, shall be filed under RECIPE for the reasons given in recital of this provision. Holders of the pharmaceutical products containing as active ingredient TRAMADOL as monodroga or partner, must be the presentations related to modify its condition of sale, the Autorizantes certificates and labels and prospects, within a period of 30 days from the date of entry into force of this provision. Prohibited the manufacture and distribution of medical samples of pharmaceutical products containing TRAMADOL as monodroga or partner. The owners of the pharmaceutical products containing TRAMADOL as monodroga or associate active comoprincipio, must remove medical samples of such pharmaceutical products, within a period of 60 days from the date of entry into force of this provision, according to the procedures established by the ANMAT 1402108 available. Repeal is it available ANMAT 1863 / 2002
DECREE 2094/08	Create the inter-jurisdictional Committee of the register of chemical precursors
DISPOSITION 4712/08	Requirements for authorizing the import of the active ingredient ephedrine and Pseudo ephedrine
LAW 26052/05	Narcotic drugs. Modify the 23.737 law
DISPOSITION 3474/05	Apruebase the "technical regulation MERCOSUL on the common documents required for import and export of narcotic drugs and psychotropic substances", resolution GMC No. 29/2002-MERCOSUL
DISPOSITION 3682/03	Incorporated into Schedule II of the Act 19.303 of psychotropic substances, the substance ketamine (2-(2-chlorophenyl 1) - (methylamino) - cyclohexanone), being its status as 'Low official recipe' for sale
DISPOSITION 2621/02	Approve the document "Control input and output of psychotropic and narcotic drugs for use in special cases / compassionate use of drugs in patients" (resolution No. 66/00 GMC)
DISPOSITION 2385/02	Approve the document "Glossary of common terms for narcotic drugs, psychotropic substances and precursors", (resolutions GMC Nros. 70/00 and 10/02)
DISPOSITION 2340/02	Adopted the document "Use of systems of reimbursement for the purchase/sale of narcotic drugs and psychotropic substances" (resolution GMC N ° 46/99)
DISPOSITION 2339/02	Approve the document "distribution of samples for professionals and advertising of medicines containing narcotic drugs or substances psychotropic" (resolution GMC No 57/99)
DISPOSITION 2336/02	Pass is the document "Control and control of the origin of the narcotic" (resolution GMC N ° 24 / 00)
DISPOSITION 2334/02	Approve the document "authorization for the entrance and exit of drugs containing narcotic drugs and substances psychotropic for patients in transit" (resolution GMC N ° 74/00)
DISPOSITION 2322/02	Approve the document "technical regulation on Narcotic Drugs lists and subject to Control psychotropic substances" (resolution GMC N ° 38/99)
DISPOSITION 2316/02	Approve the document "technical regulation on associations of drugs containing anorectics in drugs and compounding"(Resolución GMC N° 39/99)
DISPOSITION 2315/02	Adopted the document "Technical regulation on controls and control of narcotic drugs and psychotropic to perform in areas zones and Areas Customs Special" (resolution GMC No 37/99)
DISPOSITION 2311/02	Apruebase document "technical regulation MERCOSUL on associations of drugs in medications and magistral preparations containing anxiolytics"(Resolucion GMC Nro. 57/00)
DISPOSITION 2310/02	Approve the document "the concentrations of Narcotics Control, master forms and pharmaceutical psychotropic substances" (resolution GMC N ° 22/00)
DISPOSITION 2308/02	Adopted the document "Control and control of poppy seeds (Papaver Somniferum)" (resolution GMC N ° 23/00)
DISPOSITION 5492/98	Pharmaceutical products - establish that the specialties and prepared medicinal containing as active ingredient drugs included in the list of law 17.818 have prescription on file status
DECREE 341/92	Unificanse the fines to be applied to offences committed against health rules identified in the annex l
RESOLUTION 3329/91	Adopted as a complementary list of drugs subject to the checks provided for in the provision no. 38/90 of the Subsetaria of administration of health programs and services which add corro annex 1 to the present
DECREE 722/91	Actualizanse lists of narcotic drugs, psychotropic substances and other substances that can produce dependence physical or mental, for the purpose set forth in the last paragraph of article 77 of the code criminal
DISPOSITION 38/90	Psychotropic and narcotic drugs - billing, recipes
RESOLUTION 56/89	The establishments engaged in "Veterinary use" products that require any drug controlled by laws 17.818 and 19.303 preparedness specialties, must register previously in the national drug Directorate, Drugs and foods (national register)
RESOLUTION 1031/86	Psychotropic drugs. Maximum dose for Jack and day
LAW 19303/71 (WITH THE SUBSEQUENT REGULATORY AMENDMENTS IN THE RESPECTIVE LISTS)	Psychotropic
DECREE 4589/71	Adopted the body of provisions which constitute the regulation of the Law 19.303, and which as Annex forms an integral part of this Decree
LAW 17818/68 (WITH AMENDMENTS OF THE DISP. 4861/97 AND 7487/97)	Narcotic drugs
RESOLUTION 10874/17	Approve the exception regime of access to unregistered medicines (MSAR - NR), through which establishes the procedure for the approval of import of unregistered in the country medicines intended for the treatment of an individual patient for which there is no available a record of a product that is identical, similar or adequate therapeutic alternative
RESOLUTION 1537/17	The national program for the study and investigation of the use plant Medicinal Cannabis and its derivatives and non-conventional treatments, hereinafter "The programme", is located in the orbit of the Secretariat for policy, regulation and institutions

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DECREE 738/17	Approval of the regulations of the law No. 27,350 "Research medical and scientific use MEDICINAL of the plant of CANNABIS and its derivatives", than as annex I (IF-2017-21401340-APN-DD #MS) is part of the present
LAW 27350/17	The ANMAT will allow the importation of oil of cannabis and its derivatives, when required by the patients who have the diseases referred to in the program and have appropriate medical indication. The provision will be free for those who are incorporated into the program. Enforcement authority must regulate this law within one period not exceeding sixty (60) days from its publication in the Official Gazette
JOINT RESOLUTION 942/01 AND 426/01	Exempt from payment of the right of import and port services rates, statistics and verification, imports for consumption of drugs for compassionate use which is not marketed in the country and that are necessary for the personal use of patients with diseases that compromise their life, that evolve towards the disability, renders or damage their quality of life
DISPOSITION 5482/15	This provision applies to those establishments that request the habilitation as fractionator, producer or importer of drugs plant, preparations of vegetable drugs or herbal medicines or herbal medicines for traditional
DISPOSITION 5418/15	Fall under the terms of this provision the authorisation of marketing and sale, import, export, production, fractionation and distribution, within national jurisdiction, or bound for trade inter-jurisdictional, of vegetable drugs, preparations of vegetable drugs, herbal medicines and natural and legal persons involved in such activities
RESOLUTION 1817/13	They fall under the terms of this resolution import, export, manufacture, fractionation, distribution - whether for payment or free - national jurisdiction, or with destination to the inter-jurisdictional drug trade vegetables, vegetable drug preparations, herbal medicines and natural and legal persons involved in such activities
DISPOSITION 1788/00	List of drugs plant to be excluded as constituents of medicines phytotherapy, on the grounds that have effects toxic to humans
DISPOSITION 9571-E/17	Established as substance of reference PHARMACOPOEIA Argentine - Brazilian PHARMACOPEIA for physical and chemical tests, to ingredient pharmaceutical active nitrate of ECONAZOLE (113013 batch number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 99.9%, expressed over the dried substance
DISPOSITION 8640/17	Established as substance of reference PHARMACOPOEIA ARGENTINA - MERCOSUL PHARMACOPOEIA for physical and chemical tests, to ingredient pharmaceutical active LEVODOPA (113016 batch number), which has been packaged in vials ampoules containing approximately of 300 mg each and a title of 99.9%, expressed over the dried substance
DISPOSITION 8254/17	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active HYDROCORTISONE (control 115023 number), which has been packaged in vials ampoules containing approximately 300 mg each one and a title of 99.8%, expressed over the dried substance
DISPOSITION 13145/16	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active LORATADINE (control 115021 number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed over the dried substance
DISPOSITION 13144/16	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active ATORVASTATIN calcium (114019 control number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 99.5% on the anhydrous basis
DISPOSITION 5411/15	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active hydrochloride of PSEUDOEPHEDRINE (111007 control number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.4%, expressed over the dried substance
DISPOSITION 1857/15	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to ingredient pharmaceutical active IBUPROFEN (114018 control number) which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed on the anhydrous basis
DISPOSITION 1743/15	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the ingredient pharmaceutical active AMOXICILLIN (114017 control number), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 99.8%, expressed on the anhydrous basis
DISPOSITION 6928/14	Established as substance of reference PHARMACOPOEIA ARGENTINA to the 6-AMINOPENICILLANIC acid IMPURITY, (control number 111006/6-APA) for physical and chemical tests, corresponding to the pharmaceutical ingredient active SULBACTAM sodium, which has been packaged in vials ampoules containing approximately 30 mg each and 97.2%, expressed on the substance of such title which
DISPOSITION 6217/14	Set as reference substance PHARMACOPOEIA ARGENTINA for physical and chemical tests, to ingredient pharmaceutical active FLUCONAZOLE (number of control 112010), which has been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed over the dried substance
DISPOSITION 7926/11	Set as reference substance PHARMACOPOEIA ARGENTINA to SULBACTAM sodium (111006 control number) for physical and chemical tests, having been packaged in vials ampoules containing approximately 300 mg each and a title of 100.0%, expressed on the anhydrous basis
DISPOSITION 5510/11	Set as reference substances PHARMACOPOEIA ARGENTINA to the DICETOPIPERAZINA IMPURITIES, ENALAPRILAT and IMIDAZOLE of ENALAPRIL MALEATE (control numbers 110004/DICETOP., 110004/ENALAP. and 110004/IMIDAZ., respectively) for testing physicochemical, having been packed every one of them in bottles vials containing approximately 40 mg

DISPOSITION 3937/11	Reconocense as reference substances PHARMACOPOEIA ARGENTINA for physical and chemical tests, developed by the Brazilian PHARMACOPEIA substances listed in annex I, which forms an integral part of the present
DISPOSITION 2728/11	Established as substance of reference PHARMACOPOEIA ARGENTINA to ENALAPRIL MALEATE (110004 control number) for physical and chemical tests, as a in vials ampoules containing approximately 300 mg each and a 99.8% degree, expressed above the dried substance
DISPOSITION 7591/10	Established as reference substances PHARMACOPOEIA ARGENTINA to the IMPURITIES A, B, C and D of TIOCONAZOLE (lot numbers 109003/A, B, / c and/d respectively) for testing chemical, having been packed each one of them in bottles containing blisters approximate 50 mg
DISPOSITION 3110/10	Established as substance of reference certified PHARMACOPOEIA ARGENTINA - PHARMACOPOEIA Brazilian to TIOCONAZOLE (batch No. 109003) for testing chemical, packaged in jars blisters with an approximate content of 300 mg. of TIOCONAZOLE each and a 99.8% degree expressed on the anhydrous basis
DISPOSITION 2604/10	Reconocense as reference substances PHARMACOPOEIA ARGENTINA for physical and chemical tests, to the PHARMACOPOEIA Brazilian reference substances listed in annex I, which forms an integral part of the present
DISPOSITION 194/10	Set as reference substances PHARMACOPOEIA ARGENTINA impurities D, E and H of AMIODARONE hydrochloride (control numbers 107001/D, /E and/h respectively) for testing physical - chemical, having been packed every one of them in bottles, ampoules with content approximately of 25 mg
DISPOSITION 6829/08	Set as substance of reference PHARMACOPOEIA ARGENTINA hydrochloride of AMIODARONE (control 107001 number) for physical-chemical tests, packaged in vials ampoules containing approximately 250 mg of AMIODARONE hydrochloride each and a title of 100.6% expressed on the dried substance. Aware that the vials ampoules of AMIODARONE hydrochloride will be kept at the National Institute of medicine, which will be distributed to applicants, under the payment of the relevant fee and will be accompanied by a technical report summarized
DISPOSITION 7356/07	Established as reference substance to LOPERAMIDE hydrochloride (107053 control number) for physical and chemical tests, as a in vials ampoules containing approximately 300 mg LOPERAMIDE hydrochloride each and a title of 99.2% expressed on the anhydrous basis
DISPOSITION 5003/07	Established as reference substance to OMEPRAZOLE (106052 control number) for physical and chemical tests, as a in vials ampoules containing approximately 200 mg of OMEPRAZOLE each and a title of 100.5% on the anhydrous basis
DISPOSITION 615/07	Established as first reference substance to tobramycin for microbiological assessments
DISPOSITION 6975/06	MEDICINAL products set as first reference substance to Gramicidin, for microbiological assessments
DISPOSITION 1336/06	Set as reference to Diazepam for physical and chemical tests, as a substance to vials ampoules containing approximately 250 mg of Diazepam each and a title of 99.7% on the anhydrous basis
DISPOSITION 8285/05	Becoming a certified reference substance to Mebendazole for physical-chemical tests
DISPOSITION 6938/05	Public health - settle like reference substance certified to Amiodarone hydrochloride for testing physical chemists, packaged in bottles containing approximately 60 mg each-Amiodarone hydrochloride
DISPOSITION 3208/05	Public health-set as reference to Enalapril maleate for testing physical substance chemical
DISPOSITION 1927/05	Established as reference substance of furosemide to trials physicochemical
DISPOSITION 5535/04	Settles the second reference substance of NEOMYCIN for microbiological evaluations, packaged in vials ampoules containing approximately 300 mg each of NEOMYCIN sulfate
DISPOSITION 4198/04	Settles as first reference substance to VANCOMYCIN, for microbiological assessment
DISPOSITION 1489/04	Settles as a drug reference to the substance of CIPROFLOXACIN hydrochloride for testing physical-chemical, packaged in vials ampoules
DISPOSITION 998/04	Medicinal products set as first reference substance to streptomycin for microbiological assessments
DISPOSITION 5249/03	Set as first substance of reference to gentamicin for microbiological assessment, which has been packaged in vials ampoules containing approximately 300 mg each, to which has been assigned a power of 669 µg/mg gentamicin, expressed as on the dried substance
DISPOSITION 1507/02	Established as drug official reference to the substance metronidazole, to physico - chemical testing, as a in vials ampoules containing approximately 300 mg each and a title of 100.1%
DISPOSITION 5358/12	Approving the good practices of pharmacovigilance that annex I of this provision, which will be mandatory for holders of authorization for registration and marketing of pharmaceutical products
DISPOSITION 6083/09	ESPECIALIDADES MEDICINALES adopted the "program of intensive pharmacovigilance of prevention of pregnancy in women in fertile age who are prescribed isotretinoin systemic"
DISPOSITION 7720/06	Pharmaceutical products. Established medical specialties containing as active principle Thalidomide accession intensive pharmacovigilance program when it is indicated for any other illness other than the Erythema Nodosum lepromatous, in terms the provision no. 2552/95
DISPOSITION 4087/03	Joining the Nimesulide drug surveillance, controlled by the national pharmacovigilance system
DISPOSITION 2438/00	Accepted annex I of this provision as a guide of the pharmaceutical industry for participation in the national system of pharmacovigilance
DISPOSITION 935/00	Approval of the updated programme of monitoring for outpatient and treated with clozapine
RESOLUTION 498/08	Resolution 498/2008 standards national immunization adopted V update national standards of vaccination; regulations that will be incorporated into the national programme of Control warranty
DISPOSITION 705/05	Requirements for the registration of vaccines. Presentation of the technical documentation. Processing establishments. Forms
DISPOSITION 3962/17	Set is a procedure optional of pending unified for the request of registration in the registration and its authorization of marketing (first batch) of specialties medicinal elaborate and marketed in the country, as facturas, and whose active pharmaceutical ingredients (IFAs), are of proven efficacy and safety and condition of free sale
DISPOSITION 2038/17	Established that the holders of certificates enrolled in the registry of medicinal specialties (REM) which are marketed character shall notify this national administration the circumstances or facts under his knowledge that could put at risk the supply of products and cause your temporary or permanent discontinuity in the market

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CIRCULAR 06/16	Procedures for change of ownership of pharmaceutical products
CIRCULAR 13/16	Attestation of certificates (available ANMAT No. 3366/12)
CIRCULAR 10/16	Records under special conditions
DISPOSITION 7030/15	This provision shall apply to submissions vending, in terms of its content expressed in units, ml, grams, etc., of those pharmaceutical products registered or entered in the register of medicinal specialties (REM), which active pharmaceutical ingredient (IFA) have antimicrobial activity
DISPOSITION 4622/12	Create the Committee assignment and evaluation of medicinal products that must be registered "Under special conditions"
DISPOSITION 2066/09	Pharmaceutical products limit the validity of the provision A.N.M.A.T. No. 818/98 which established requirements for information and documentation for a new registration in the register of pharmaceutical products
DISPOSITION 3022/06	ANMAT - medicinal specialities approve the operational procedure for the management of the procedures for dealing with requests for extension to testimonies of inscription in the registry of medicinal specialties of ANMAT (REM), for the export of products
DISPOSITION 1907/06	Approve the procedure operational for the management of the procedures for dealing with applications for unification of certificates of authorization of pharmaceutical products registered in the register of the ANMAT (REM), appearing as annex I to this provision and that is part of the same
DISPOSITION 163/03	Establishment requirements documentation to provide for the processing of requests for extension to testimonies of registration in the register of medicinal specialties (REM), for the export of products and information to overturn
DISPOSITION 818/98	Specialty medical establishment of information and documentation requirements for a new registration of medicinal specialties of specialty whose registration was cancelled
DISPOSITION 5755/96 (WITH AMENDMENTS TO THE DISP. ANMAT 1646/97)	Standard application to the management of the procedures for dealing with applications for registration of pharmaceutical products framed in articles 3, 4 and 5 of the Decree 150/92
DISPOSITION 858/89	MEDICINAL specialities registration transfer presentation that must be made to apply for the registration of transfer of a certificate authorizing
DISPOSITION 857/89	SPECIALTIES medicinal name change presentation that must be made to request the change of name of a medical-specialty
DISPOSITION 856/89	SPECIALTIES Medical Director technical presentation that must be carried out for the approval of the change of Technical Director of a lab producer of pharmaceutical-products
DISPOSITION 855/89	SPECIALTIES medicinal presentation of sale.-presentation which must be made to seek approval of a new presentation of sale regarding the content in units, ml, grams, etc
DISPOSITION 854/89	SPECIALTIES medicinal laboratory producer presentation to change it will be for the approval of change of laboratory producer of a medical specialty
DISPOSITION 853/89	ESPECIALIDADES MEDICINALES - excipient change or container-presentation that must be performed to request approval of a change of excipient or container
DISPOSITION 617/11	Suspend the marketing and the use, throughout the national territory, of all pharmaceutical products containing lindane as active pharmaceutical ingredient (IFA), in all of its pharmaceutical forms, concentrations and presentations
DISPOSITION 6533/10	Suspended the importation of active pharmaceutical ingredient SIBUTRAMINE (IFA) and the production, import, marketing, distribution and use, throughout the national territory, of all pharmaceutical products containing it as monofármaco or in association and in all of its pharmaceutical forms"
DISPOSITION 4430/09	Pharmaceutical products suspended the marketing and use in the whole country of all pharmaceutical products containing Nimesulide as ingredient pharmaceutical active (IFA) only or in partnership, in all its forms pharmaceutical
DISPOSITION 1743/09	Suspend the marketing and sale of RAPTIVA, medical specialty whose active drug ingredient is Efalizumab
RESOLUTION 1645/08	Prohibit the manufacture, marketing and use of ephedrine as monodroga. Exception
DISPOSITION 6238/08	Prohibited use and commercialization, and ordered the removal of market of the medicinal product labeled as Rimonabant
DISPOSITION 7398/07	Preventively suspended marketing, in any form, in concentrations of 100 mg and 400 mg of the pharmaceutical products containing as active ingredient Lumiracoxib
DISPOSITION 6628/07	Pharmaceutical products preventively suspended the production, marketing, distribution and dispensing of medicinal specialties containing aprotinin as monodroga or in association
DISPOSITION 5136/07	Preventive suspension of Clobutinol
DISPOSITION 5034/07	Pharmaceutical products suspended trade, marketing in any form of the concentration of 200 mg of the pharmaceutical products containing as a principle active Lumiracoxib
DISPOSITION 3110/07	Suspend the processing, marketing, distribution and dispensing of medicinal specialties containing as a principle active TEGASEROD
DISPOSITION 1955/07	Preventively suspended the production, marketing, distribution and dispensing of medicinal specialties containing as active ingredient pergolida
DISPOSITION 3435/06	Suspendese preventive registration, processing, marketing, distribution and dispensing of medicinal specialties containing CISAPRIDE, such as monodroga or other principles associated assets
DISPOSITION 2060/05	Prohibition principle active VALDECOXIB
DISPOSITION 5997/04	Prohibition principle active ROFECOXIB
DISPOSITION 4327/03	Prohibition principle active ASTEMIZOLE
DISPOSITION 6809/01	Prohibition of use and commercialization of the drug PHENYLPROPANOLAMINE
DISPOSITION 2227/98	Adopted a new list of dyes synthetic and its aluminium lacquers for use in pharmaceutical products for oral administration
DISPOSITION 2009/07	Establishment guidelines, documentation, and requirements to file for the authorization of drugs intended to be administered to human beings with diagnostic or monitoring products for diagnostic use so-called "in vivo"

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RESOLUTION 102/98	Pharmaceutical products establish a regulation which specifically regulates the registration, preparation, fractionation, marketing or importation of products of diagnostic use "in vivo"
DISPOSITION 8277/11	Established that the primary packaging - blister - solid oral dosage forms that are intended for the use and hospital distribution, shall be punched in order to allow the division of the primary container in each dosage unit, preserving the unique identification, traceability and shelf life of the product
DISPOSITION 11857/17	Must be used closed infusion system in replacement of the open system. Approve the document "Solutions parenteral large volume in system closed"
DISPOSITION 1149/97	Approve the document 1/91 solutions for high-volume application is mandatory for all companies for manufacture, import and/or distribution of this product enabled
DISPOSITION 1682/12	Approving the requirements and guidelines contained as an annex to this provision which forms an integral part of it, on quality assurance and good manufacturing practice applicable to blood banks in its character of establishments Suppliers of human Plasma as a starting Material for the production of blood products
DISPOSITION 1582/12	Establishment scientific and technical requirements and specific requirements for the approval of operating blood banks
DISPOSITION 8278/08	Establishment conditions and colours that must carry the labels of the primary packaging of parenteral solutions of electrolytes of small volume, in accordance with Annex I to this provision
DISPOSITION 7266/08	Available 7266/08 adopted orphans, elaborate the operating procedure for the processing of applications for authorization of distribution with interprovincial transit and/or between provinces and the autonomous city of Buenos Aires, of lots of drugs in Laboratories of public production of medicines, not enrolled in the register of specialities medicinal (REM) of the A.N.M.A.T submitted by national or provincial government agencies or from the city of Buenos Aires, which, as annex I, is part integral of This provision, to cover emergency health risk or lack of productos
RESOLUTION 505/06	PUBLIC health - SADS-s - Adoptanse measures in connection with the sending of data and information by the companies producing drugs with inhalers, relative to the treatment of asthma and chronic Neuropathies obstructivas
DISPOSITION 2592/03	Preparation, control, distribution and marketing in national jurisdiction or destined for interprovincial trade in medicaments classified as mixtures of extemporaneous Parenteral Nutrition. Establishments enabled
DISPOSITION 2476/03	Establishments-physiologic solutions to Nebulize-processors enabling
DISPOSITION 4373/02	Technical standards for the development of medical oxygen through air separation by adsorption PSA. General requirements. Quality control of the finished product. Requirements of control of quality
DISPOSITION 3429/00	Set the mandatory declaration of the content of alcohol ethyl to the leaflets/information of medications that contain it. (Note: repealed by art.6 available ANMAT nro.1206-2002 b.o.12-04-2002)
RESOLUTION 1130/00	Regulation for medicinal Gases
DISPOSITION 617/99	The pharmaceutical products containing active ingredients phenolphthalein and/or dantrona, alone or in partnership, will have condition of sale "Low recipe", without exception
DISPOSITION 3779/98	General for the production of blood plasma-origin products SPECIALTIES medical establishment rules
DISPOSITION 2227/98	Pharmaceutical products adopted a new list of synthetic dyes and its aluminium lacquers for use in pharmaceutical products for oral administration
DISPOSITION 2795/97	It determined a standard on the manufacturing, marketing and distribution of concentrated solutions and mixtures salinas, to be used in the hemodialysis
RESOLUTION 508/94	They are subject to the present Res. fractionation, container and tank for the marketing and the sale to ethyl alcohol (ethanol) which is intended for use in cosmetics and human medicine and visible or legal persons involved in such activities
DISPOSITION 753/12	Establishment definitions and guidelines general information which shall include leaflets/tags/labels of condition of over-the-counter pharmaceutical products
DISPOSITION 6907/10	Laboratories holders of certificates of pharmaceutical products containing PSEUDOEPHEDRINE active ingredients, allowed or pending authorization, shall include the information contained in annex I, which forms in prospectuses an integral part of this provision"
DISPOSITION 751/09	Establish the condition of sale under prescription filed for all medical specialties containing pharmaceutical active Carisoprodol ingredient as facturas or in association
DISPOSITION 555/09	Pharmaceutical products established information that shall contain leaflets of medicinal specialties containing Zolpidem active principle
DISPOSITION 7726/07	Laboratories holders of certificates of pharmaceutical products containing STRONTIUM RANELATE as an active ingredient, they should add in the prospectus and the date authorized in highlighted form, as stated in annex I of this provision, forming an integral part of it
DISPOSITION 6290/07	Pharmaceutical products - Establish that laboratories holders of certificates of pharmaceutical products containing oral fluoroquinolones, ciprofloxacin, levofloxacin, Moxifloxacin and Ofloxacin should add in the prospect in highlighted form, information related to warnings and precauciones
DISPOSITION 5555/07	Pharmaceutical products established laboratories holders of certificates of pharmaceutical products containing gadolinium derivatives in any form shall add the package leaflet / Manual authorized use to date, in the form highlighted the warnings, precautions, and contraindications
DISPOSITION 5554/07	SPECIALTIES medicinal establish is that them laboratories holders of certificates of specialties medicinal that contain as principle active Escitalopram, indicated in the treatment of the disorder depressive greater and of maintenance for the relapse prevention, treatment of disorders of anxiety with or without agoraphobia, social phobia, generalized anxiety treatment must adapt their prospects and add in the text of the safety information concerning indications, contraindications, warnings and adverse effects
DISPOSITION 5553/07	Pharmaceutical products establish that laboratories holders of certificates of pharmaceutical products containing as active ingredient Citalopram, indicated for the treatment of major depressive disorder, also indicated in the treatment of the disorder of anxiety (panic disorder) with or without agoraphobia, and in the treatment of obsessive-compulsive disorder, must modify their prospects and add in the text of the safety information concerning indications, contraindications, warnings and adverse effects

DISPOSITION 5363/07	Pharmaceutical products established laboratories holders of certificates of pharmaceutical products containing as active ingredient Cabergoline, indicated in the treatment of Parkinson's disease, should change their prospects and add in the text of the safety information concerning indications, contraindications, warnings and adverse effects
DISPOSITION 4719/07	Laboratories holders of certificates of pharmaceutical products containing OLIGO or as facturas or in associations, must add in the prospect to the date authorized, in highlighted form, warning that accompanies as annex I of this provision, and which forms an integral part of it
DISPOSITION 4372/07	Laboratories holders of certificates of pharmaceutical products containing active substance RIMONABANT should add in prospectus and the date authorized in highlighted form, as stated in annex I of this provision, shaping an integral part of the same
DISPOSITION 2123/07	Especialidades Medicinales.-modification of prospects beginning active methylphenidate and ATOMOXETINE indicated in the treatment of attention Deficit with hyperactivity-disorder
DISPOSITION 4562/06	Establish that laboratories holders of certificates of pharmaceutical products containing active substance in raloxifene, they must add in the prospect, in highlighted form, a warning of use
DISPOSITION 4525/06	Establish that laboratories holders of certificates of pharmaceutical products containing as active inhibitors type 5 Phosphodiesterase (PDE5), which are known to Sildenafil, Tadalafil or Vardenafil, must add in the prospectus, in highlighted form, a warning of use
DISPOSITION 3059/06	ESPECIALIDADES MEDICINALES - ANMAT - requirements that must be met laboratories holders of certificates of pharmaceutical products containing as a principle active only or associated with ibuprofen for intramuscular administration and endovenosa
DISPOSITION 7908/04	Modification of certain antidepressants such as paroxetine-prospects
DISPOSITION 1863/02	Established that the pharmaceutical products containing TRAMADOL as an active ingredient, should include the legend: "shows medical restricted."
DISPOSITION 1206/02	ESPECIALIDADES MEDICINALES established that the condition of over-the-counter specialties signs/labels or prescription, whose pharmaceutical form is liquid for parenteral or oral administration with ethyl alcohol in its formulation, must be declare the content thereof specified in % weight/volume
DISPOSITION 1970/01	Information that shall include the prospects of pharmaceutical products containing active substance hypericum perforatum-St. John's wort
DISPOSITION 1879/99	Information to be included, laboratories holders of certificates of pharmaceutical products containing as a principle active chlorzoxazone
DISPOSITION 1210/99	Information to be included in their leaflets, laboratories holders of certificates of pharmaceutical products containing as a principle active sildenafil
DISPOSITION 5214/98	Information to be included in prospectuses, laboratories holders of certificates of pharmaceutical products containing, alone or associated, as a principle active ginseng
DISPOSITION 3855/98	Mechanism to include information in prospectuses
DISPOSITION 593/98	Requirements that must comply with the labeling and packaging bags plastic used for the collection, storage, processing, and administration of blood
DISPOSITION 7096/97	Information that must be included in your prospects, laboratories holders of certificates of pharmaceutical products containing as active ingredient loperamide
DISPOSITION 4538/97	Modification provision 5904/96-limited art 2
DISPOSITION 2574/97	Information that must be included in your prospects, the laboratories holders of certificates of those specialties that contain as principle active Doxazosin
DISPOSITION 5904/96	Definition and guidelines about how information in leaflets include
DISPOSITION 5510/96	Information that must complete laboratories holders of those specialities containing active ingredients melatonin
DISPOSITION 5104/96	Information that should be disseminated through the prospects in the pharmaceutical products containing their actives to lindane
DISPOSITION 4856/96	Approve the model prospectus for those containing pyrethrins
DISPOSITION 3918/96	Information that should fill them laboratories holders of certificates of those specialties that contain between their principles active the drug Oxybutynin
DISPOSITION 3288/96	Information that laboratories holders of certificates of related specialties, containing Tretinoin for topical use in all their concentrations among its active principles must be completed
DISPOSITION 388/93	Laboratories holding certificates of pharmaceutical products containing as, or in its active principles to drug ketorolac, the only prospect that transcript appears in annex 1 of this provision should be adopted
DISPOSITION 573/88	Package inserts that accompany blood products, derived from placenta, glands, and other raw materials of human origin, should include a warning about the possible risks to the recitals of the present allude

Source: ANMAT. Prepared by CCGI-EESP/FGV.

Table 48 - Standards on Pharmaceuticals (Argentina)

STANDARDS	DESCRIPTION
IRAM- 37001-1	Medicaments. Good manufacturing practices. Aseptic processing of small volume solutions. Directives relating to the design, building specifications, operation conditions and the maintenance of manufacturing area.
IRAM- 37001-2	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37001-3	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives relating to the design and maintenance of equipment in the processing area.
IRAM- 37001-4	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives to prepare documentation and records related to the pharmaceutical plant.
IRAM- 37001-5	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives for labeling and packaging.

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IRAM- 37001-6	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives for quality assurance.
IRAM- 37001-7	Medicines. Good manufacturing practices in the aseptic processing of small volume injectable solutions. Directives for the quality control laboratory.
IRAM- 37002	Medicines. Water for the preparation of injectables of small volume.
IRAM- 37003-1	Medicines. Small volume injectable solutions Production with terminal sterilization. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37003-2	Small volume medications Production with terminal sterilization. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37003-3	Small volume medications Production with terminal sterilization. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37003-4	Small volume medications Production with terminal sterilization. Directives to prepare documentation and records related to the preparation area.
IRAM- 37003-5	Small volume medications Production with terminal sterilization. Guidelines for labeling and packaging.
IRAM- 37003-6	Small volume medications Production with terminal sterilization. Directives for quality assurance.
IRAM- 37003-7	Small volume medications Production with terminal sterilization. Directives for the quality control laboratory.
IRAM- 37004	Medicines. Good manufacturing practices. Liquid injectables of small volume. Process validation
IRAM- 37006-1	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37006-2	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37006-3	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37006-4	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37006-5	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Guidelines for labeling and packaging.
IRAM- 37006-6	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for quality assurance.
IRAM- 37006-7	Medicines. Good manufacturing practices in the processing of solid penicillin antibiotics for oral use. Directives for the quality control laboratory.
IRAM- 37009-1	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37009-2	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives relating to the suitability, responsibility, hygiene, safety and clothing of the staff of the processing area.
IRAM- 37009-3	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37009-4	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37009-5	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Guidelines for labeling and packaging.
IRAM- 37009-6	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for quality assurance.
IRAM- 37009-7	Medicines. Good manufacturing practices in the processing of oral estrogenic products. Directives for the quality control laboratory.
IRAM- 37010	Medicines. Criteria for selection, approval and qualification of suppliers. Conditioning materials for the pharmaceutical industry.
IRAM- 37011-1	Medicines. Good manufacturing practices. Process control Oral solid pharmaceutical forms. Directives for the control of the process.
IRAM- 37011-2	Medicines. Good manufacturing practices. Process control Oral solid pharmaceutical forms. Parameters to be controlled.
IRAM- 37012	Medicines. Good manufacturing practices. Oral solid pharmaceutical forms. Validation of processes.
IRAM- 37013-1	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for the design, construction specifications, operating conditions and maintenance of the processing area
IRAM- 37013-2	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37013-3	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37013-4	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37013-5	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Guidelines for labeling and packaging.
IRAM- 37013-6	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for quality assurance.
IRAM- 37013-7	Medicines. Good manufacturing practices in the processing of oral cephalosporin solid antibiotics. Directives for quality control.
IRAM- 37014-1	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for design, construction specifications, conditions. of operation and maintenance of the area.
IRAM- 37014-2	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37014-3	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for the design, maintenance and cleaning of the processing area.
IRAM- 37014-4	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives to prepare the documentation and requirements related to the preparation area.
IRAM- 37014-5	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Guidelines for labeling and packaging.

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IRAM- 37014-6	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for quality assurance.
IRAM- 37014-7	Medicines. Good manufacturing practices in the processing of cephalosporin solid antibiotics for parenteral use. Directives for the quality control laboratory.
IRAM- 37015-1	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for the design, specifications for the construction, operating conditions and maintenance of the area
IRAM- 37015-2	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37015-3	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37015-4	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives to prepare documentation and records related to the preparation area.
IRAM- 37015-5	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for labeling and packaging.
IRAM- 37015-6	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for quality assurance.
IRAM- 37015-7	Medicines. Good manufacturing practices in the processing of antiseptics and disinfectants for surgical use. Directives for the quality control laboratory.
IRAM- 37016-1	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use.
IRAM- 37016-2	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use directed regarding the suitability, responsiveness, hygiene and dress of the personnel affected to the area of the elaboration.
IRAM- 37016-3	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for the design, maintenance and cleaning of the equipment in the processing area.
IRAM- 37016-4	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use.
IRAM- 37016-5	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for labeling and packaging.
IRAM- 37016-6	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for quality assurance.
IRAM- 37016-7	Medicines. Good manufacturing practices in the processing of semi-solid products: ointments, creams, gels, ointments and emulsions for external use. Directives for the quality control laboratory.
IRAM- 37017-1	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for the design, construction specifications, operating conditions and maintenance of the pharmaceutical plant.
IRAM- 37017-2	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives regarding the suitability, responsibility, hygiene and clothing of the staff of the pharmaceutical plant.
IRAM- 37017-3	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for the design, maintenance and cleaning of the equipment of the pharmaceutical plant.
IRAM- 37017-4	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives to prepare documentation and records related to the pharmaceutical plant.
IRAM- 37017-5	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for labeling and packaging.
IRAM- 37017-6	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for quality assurance.
IRAM- 37017-7	Medicines. Good manufacturing practices in the processing of antineoplastic drugs. Directives for the quality control laboratory.
IRAM- 37018-1	Medicines. Conservation of the cold chain in its distribution. Storage.
IRAM- 37018-2	Medicines. Conservation of the cold chain. Transport and distribution.
IRAM- 37023	Medicines. Criterion of selection, approval and qualification of suppliers. Storage, distribution and transport for the pharmaceutical industry.
IRAM- 37024-1	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37024-2	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37024-3	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives relating to the design and maintenance of equipment in the processing area.
IRAM- 37024-4	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives to prepare documentation and records related to the pharmaceutical plant.
IRAM- 37024-5	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for labeling and packaging.
IRAM- 37024-6	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for quality assurance.
IRAM- 37024-7	Medicines. Good manufacturing practices in the aseptic processing of lyophilized parenteral products. Directives for the quality control laboratory.
IRAM- 37025-1	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives for design, construction specifications, operating conditions and maintenance of the processing area.
IRAM- 37025-2	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives regarding suitability, responsibility, hygiene and clothing of the staff of the processing area.
IRAM- 37025-3	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives relating to the design, maintenance and cleaning of the processing area.
IRAM- 37025-4	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives to prepare documentation and records related to the preparation area.
IRAM- 37025-5	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Guidelines for labeling and packaging.

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IRAM- 37025-6	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives for quality assurance.
IRAM- 37025-7	Medicines. Good manufacturing practices in the manufacture of solid oral medications. Directives for quality control.
IRAM- 37026	Medicines. Good manufacturing practices in the preparation of medicines. Validation of cleaning procedures for equipment and accessories.
IRAM- 37031	Medicines. Traceability management system in the pharmaceutical chain.
IRAM- 37400	Administration of intravenous medications to patients with HIV + and AIDS. Security criteria
IRAM- 37401	Antineoplastic drugs. Preparation, storage, transportation and administration. Security and biosafety criteria.
IRAM- 9800-3	Good pharmaceutical practices Part 3 - Drugs in the pharmacy.

Source: IRAM. Prepared by CCGI-EESP/FGV.

APPENDIX 8 - Plastic

Table 49 - Standards on Plastic (Brazil)

STANDARD	CONTENT
ABNT NBR 14474:2018	Plastic films-determination of resistance to static puncture
ABNT NBR 15107:2017	Shredders for plastics machines — safety requirements for granulators and shredders
ABNT NBR 11992:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes by water blast — determination of the coefficient of friction
ABNT NBR 11993:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes by water blast — determination of the resistive force on passing through PVC TILDE
ABNT NBR 11996:2017 N	Plastic hoses for clearing and cleaning of rigid PVC pipes, water blast — determination of bursting pressure after 1 000 cycles of flexion
ABNT NBR 14952:2017	Injected plastic pails for industrial use-requirements and test methods
ABNT NBR ISO 7206-2:2012 AMENDMENT 1:2017	Implants for surgery--partial and total Prosthesis of hip joint Part 2: joint surfaces made of metallic material, ceramic and plastic
ABNT NBR ISO 7206-2:2017	Implants for surgery--partial and total Prosthesis of hip joint Part 2: joint surfaces made of metallic materials, ceramic and plastic
ABNT NBR 11995:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes for water-determination of resistance to hydrostatic pressure internally
ABNT NBR 16578:2017	Plastic glazing applied to road vehicles — requirements and test methods
ABNT NBR 11991:2017	Sanitary appliances plastic material-verification of mechanical characteristics
ABNT NBR 12450:2017	Monolithic sink plastic -material Dimensions
ABNT NBR 12451:2017	Material plastic tub to sink-dimensions
ABNT NBR 11994:2017	Plastic hoses for clearing and cleaning of rigid PVC pipes for water-verification of resistance to abrasion
ABNT NBR 7394:2017	Traffic safety-Ballasts in plastic holder
ABNT NBR ISO 7207-2:2013 AMENDMENT 1:2016	Implants for surgery--partial and total prosthesis components of knee joint Part 2: joint surfaces made of metal, ceramic and plastic materials
ABNT NBR ISO 7207-2:2016	Implants for surgery-partial prosthesis components and total knee joint Part 2: joint surfaces made of metal, ceramic and plastic materials
ABNT NBR 16544:2016	Copper and copper alloys-connections with compression terminals for use with plastic and multilayer tubes-Requirements
ABNT NBR ISO 3126:2016	Plastics piping systems--plastics Components-determination of dimensions
ABNT NBR 11479:2016	Motor road vehicles-fuel tank plastic -determination of resistance to fire
ABNT NBR 16491:2016	Implants for surgery-polymeric materials-Radiopacity of plastics
ABNT NBR 11473:2016	Fuel tank plastic for motor road vehicles-determination of resistance to impact
ABNT NBR 15870:2016	Horizontal road signs-cold Plastic resin based reactive metacrílicas-supply and application
ABNT NBR 13536:2016	Safety of machinery — plastic and rubber injection molding machine
ABNT NBR 15057:2016	Plastic containers for transport and/or storage of liquefied petroleum gas (LPG)-design, manufacturing and inspection
ABNT NBR 16242:2016	Plastic pallets-requirements and test methods
ABNT NBR NM 337:2014 1:2015 ERRATA	Non-destructive testing-acoustic emission Testing (EA) in pots and plastic tanks reinforced with fiberglass (FRP)-Procedure
ABNT NBR NM 337:2014 CORRECTED VERSION: 2015	Non-destructive testing-acoustic emission Testing (EA) in pots and plastic tanks reinforced with fiberglass (FRP)-Procedure
ABNT NBR 15174:2014	Metallic and plastic components for footwear and artifacts-Buckles, ornaments and trailers/fenders-determination of tensile strength and compression
ABNT NBR 15804-2:2013	Polymeric materials for medical applications Part 2: specification for polyethylene plastics for short-term Implantable devices

Table 50 - Plastic Standards (Argentina)

NAME	DESCRIPTION
IRAM-NM 337	Non-destructive tests. Test of acoustic emission (EA) in containers and tanks of reinforced plastic with fiber of glass (PRFV). Procedure.
IRAM-ISO 1133-1	Plastics. Determination of the index of mass flow (IFM) and of the index of volume flow (IFV) of thermoplastics. Part 1 – normalized method.
IRAM-ISO 1167-1	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 1 – General method.
IRAM-ISO 1167-2	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 2 – Preparation of the test tubes of tubes.
IRAM ISO 1167-3	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 3 – Preparation of components.
IRAM-ISO 1167-4	Tubes, accessories and unions on thermoplastic materials for the conduction of fluids. Determination of the resistance to internal pressure. Part 4 – Preparation of the mounting.
IRAM-1211	Thermoplastic coverings to pavement demarcation.

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IRAM-1212	Reflecting thermoplastic coverings to pavement demarcation.
IRAM-1737	Thermal insulating materials. Cell plastics. Determination of apparent density.
IRAM-1745	Thermal insulating materials. Cell plastics. Determination of compression for rigid materials.
IRAM-1746	Thermal insulating materials. Cell plastics. Tests of dimensional stability.
IRAM-1747	Thermal insulating materials. Cell plastics. Determination of the temperature that produces permanent deformation on rigid materials submitted to compression.
IRAM-1749	Thermal insulating materials. Cell plastics. Determination of the apparent density by the displacement of the water.
IRAM-1861	Thermal insulating materials. Determination of absorption of water on cell plastics for use in thermal insulators.
IRAM-1863	Thermal insulating materials. Determination of the content of closed cells on cell plastics.
IRAM-2179	Cables of energy insulated with excluded solid dielectric. Test methods for insulators and wrappers (elastomeric and thermoplastic compounds).
IRAM-2217	Thermoplastic materials and synthetic rubber for coverage of electric cables with metal sheath.
IRAM-2350	Light naval cable with conductors of copper insulated with thermoplastic material based on polyvinyl chloride.
IRAM-ISO 3126	Systems of plastic tubes. Plastic components. Determination of measures.
IRAM-3548	Sleeves for fire extinguishing of synthetic fibers (polyesters, polyamide and its mixtures), covered internally with a flexible plastic material or with an elastomer.
IRAM-3574	Safety protections on machines. Molding machines for the insertion of plastic material and rubber.
IRAM-3633	Simple portable ladders of reinforced plastic with characteristics of safety, mainly electrical.
IRAM-3634	Simple portable ladders, of extension, of reinforced plastic with characteristics of safety, mainly electrical.
IRAM-6017	Screw cap of rigid plastic for glass recipients. Dimensions.
IRAM-FA L 7678	Cloth coated with vinyl plastic for seat upholstery.
IRAM-9021	Plastic sterile equipment for the extraction of blood applied on transfusions, applied with vacuum glass jar and to be used only once.
IRAM-9022	Plastic sterile equipment for transfusion of blood or of derivatives of blood to be used only once.
IRAM-9023	Plastic sterile equipment for the management of parenteral solutions to be used only once.
IRAM-9025-1	Plastic material for medicinal use. Biologic test methods: toxicological tests.
IRAM-9025-2	Plastic material for medicinal use. Biologic test methods: tests of pyrogens and bacterial endotoxins.
IRAM-9025-3	Plastic material for medicinal use. Methods of biological test. Tests of sterility.
IRAM-9037	Discardable sterile syringe, of plastic material, for insulin. Characteristics and test methods.
IRAM-9406-1	Surgical implants. Metallic materials. Alloys based on cobalt. Part 1: alloy of cobalt, chrome, nickel, molybdenum and iron to forge and form plastic at low temperatures.
IRAM-ISO-9854-1	Thermoplastic tubes for the transport of fluids. Determination of resistance to impact of the pendulum through the Charpy method. Part 1 – Method of general test.
IRAM-ISO-9854-2	Thermoplastic tubes for the transport of fluids. Determination of resistance to impact of the pendulum through the Charpy method. Part 2 – Test conditions for tubes of different materials.
IRAM-10501	Geotechnics. Method of determination of the liquid limit and of the plastic limit of a sample of the soil. Index of fluidity and index of plasticity.
IRAM-12523	Refractory materials. Refractory silica-aluminous and of high alumina plastic.
IRAM-12524	Refractory materials. Method of determination of the index of workability of refractory plastic and refractory tampers.
IRAM-12553	Refractory materials. Plastic and tampers materials that are refractory, silica-aluminous and of high alumina. Method of determination of permanent linear variation for drying and cooking.
IRAM-12563	Refractory concrete and refractory plastic. Method of determination of thermal conductivity.
IRAM-12609	Refractory materials. Refractory plastics and tampers. Method for determination of disintegration through thermal shock.
IRAM-13015	Plastics in general. Profiles of non-plasticized polyvinyl chloride for rolled up curtains. Requisites.
IRAM-13100	Plastic bags for family residues.
IRAM-13130	Sleeves of polyvinyl chloride or other thermoplastics with textile reinforcement. Internal diameters and discrepancies on longitudes.
IRAM-13131	Sleeves of polyvinyl chloride or other thermoplastics with textile reinforcement for air, water and non-corrosive liquids in general.
IRAM-13240	Plastics in general. Determination of the final degradation of flexible plastics of polyethylene (PE) and polypropylene (PP) under conditions of exposition to ultraviolet light (UV). Method through elongation at break.
IRAM-13251	Rigid cell plastics. Method of determination of the apparent density.
IRAM-13272	Bottles of plastic material. Method of determination of the seal tightness.
IRAM-13273	Bottles of plastic material. Method of compression test.
IRAM-13274	Bottles of plastic material. Method of impact test through accumulated falls.
IRAM-13276	Bottles of plastic material. Method of determination of fatigue resistance produced by the transport.
IRAM-13303	Plastics. Normal atmospheres to conditioning and tests of plastic materials.
IRAM-13304	Plastics. Recommended method to molding through compression of test tubes of thermoplastic materials.
IRAM-13305	Plastics. General principles to molding through injection of test tubes of thermoplastic materials.
IRAM-13306	Plastics. General principles to molding through compression of test tubes of thermo-rigid materials.
IRAM-13307	Plastics. Method of determination of the content of soluble materials in methanol of unmodified polystyrene.
IRAM-13308	Plastics. Method of determination of the content of free phenols on pieces molded of phenolic plastics.
IRAM-13309	Plastics. Method of determination of the content of free ammonia and ammonia components on pieces molded of phenolic plastics.
IRAM-13310	Plastics. Method of determination with Wijs solution of the content of styrene on unmodified polystyrene.
IRAM-13311	Plastics. Method of determination of soluble material on acetone on materials of phenolic molding.

IRAM-13312	Plastics. Qualitative method to determine free ammonia or other volatile basis on components molded of phenolic plastics.
IRAM-13313	Plastics. Method of red congo to the determination of the thermal stability of related copolymers of polyvinylchloride and its components.
IRAM-13314	Plastics. Method of change of color to the determination of the thermal stability of related copolymers of polyvinylchloride and its components.
IRAM-13315	Plastics. Polyethylene and components of polyethylene. Method of determination of the index of hot fluidity.
IRAM-13316	Plastics. Traction tests.
IRAM-13317	Tubes and accessories of thermoplastic material. Determination of the temperature softening Vicat.
IRAM-13318	Plastics. Method of determination of soluble materials in water and water absorption.
IRAM-13319	Plastics. Method of determination of the black of the smoke and its degree of dispersion on components of polyethylene.
IRAM-13320	Plastics. Methods of determination of antioxidants on components of polyethylene.
IRAM-13321	Plastics. Method of granulometric analysis of homopolymer resins or copolymers of polyvinylchloride.
IRAM-13322	Pieces of connection of rigid plastic material of plug for rigid plastic tubes applied on the conduction of fluids under pressure. Basic dimensions.
IRAM-13327	Plastics. Method of determination of absorption of boiling water.
IRAM-13328	Plastics. Method of determination of apparent density of molding materials capable of drain through a specific funnel.
IRAM-13329	Plastics. Method of determination of the index of viscosity of polyamide resins on diluted solutions.
IRAM-13332	Plastics. Method of determination of the temperature of deformation under load.
IRAM-13334	Plastics. Method of determination of the index of viscosity of homopolymer or copolymer resins of polyvinylchloride on solution.
IRAM-13335	Plastics. Test methods of resistance to chemical agents.
IRAM-13336	Plastics. Method of active carbon to determine the loss of plasticizers.
IRAM-13338	Plastics. Test method of flexion.
IRAM-13339	Plastics. Method of determination of extractable materials by water or ethyl alcohol on polyamide resins.
IRAM-13340	Plastics. Method of determination of resistance to Izod impact of rigid plastics.
IRAM-13341	Plastics. Method of determination of resistance to incandescence of self-extinguishing thermal-rigid plastics.
IRAM-13344	Plastics. Method to determine the changes on linear dimensions of blades or films of non-rigid thermoplastic materials.
IRAM-13347	Tubes and accessories of thermoplastic material. Determination of ashes.
IRAM-13348	Plastics. Method of determination of volatile materials on homopolymer or copolymer resins of polyvinylchloride.
IRAM-13349	Tubes of thermoplastic materials. Measures and nominal pressures.
IRAM-13352	Tubes of plastic material to conduction of drinking water. Bromatological requirements.
IRAM-13354	Plastics. Method of determination of strange materials on homopolymer or copolymer resins of polyvinylchloride.
IRAM-13355	Plastics. Method of determination of pH of watery extract of homopolymer or copolymer resins of polyvinylchloride.
IRAM-13356	Plastics. System of designation of resins of polyvinylchloride.
IRAM-13359	Pieces of connection of plastic material for tubes applied on conduction of drinking water. Bromatological requirements.
IRAM-13361	Thermal stable blade plastic, decorative. Method of determination of visible failures at a glance.
IRAM-13362	Thermal stable blade plastic, decorative. Method of determination of thickness.
IRAM-13363	Thermal stable blade plastic, decorative. Method of determination of superficial thermal resistance at 180ºC.
IRAM-13364	Thermal stable blade plastics, decorative. Method of determination of dimensional stability.
IRAM-13365	Thermal stable blade plastics, decorative. Method of determination of moldability.
IRAM-13367	Thermal stable blade plastics, decorative. Method of determination of resistance to immersion in boiling water.
IRAM-13368	Thermal stable blade plastics, decorative. Method of determination of resistance to stained.
IRAM-13369	Thermal stable blade plastics, decorative. Test method of abrasion.
IRAM-13370	Thermal stable blade plastics, decorative. Test method of impact.

Source: IRAM. Prepared by CCGI-EESP/FGV.