



**Multiple Framework Contract FWC FPI PSF 2015**

**Lot 4 "Market Access and Trade & Investment Agreement Negotiation & Implementation"**

**Mapping of applicable technical regulations, conformity assessment procedures and supporting standards in support of EU-Brazil business development**

**DELIVERABLE 2  
BRAZIL - OVERVIEW  
BRAZIL AND ITS STANDARDIZATION**



**A project implemented by  
Eurosupport Consortium - AESA**

# **Delegation of the European Union to Brazil**

## **Multiple Framework Contract FWC FPI PSF 2015**

### **Lot 4: "Market Access and Trade & Investment Agreement Negotiation & Implementation"**



#### **Request for Service 2016/379494 Version 1**

### **Mapping of applicable technical regulations, conformity assessment procedures and supporting standards in support of EU-Brazil business development**

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#### **BRAZIL - OVERVIEW**

#### **BRAZIL AND ITS STANDARDIZATION POLICIES**

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*This is a working document, and hence it represents research in progress. The opinions expressed in this paper are those of the research team and coordinator. They are not intended to represent the positions or opinions of the European Union or its members and are without prejudice to members' rights and obligations under the European Union. Any errors are attributable to the research team and coordinator.*

## LIST OF ABBREVIATIONS

<b>ABNT</b> Brazilian Association of Technical Standards
<b>AMN</b> Mercosur Standardization Association
<b>ANCINE</b> Brazilian National Cinema Agency
<b>ANEEL</b> Brazilian National Electric Energy Agency
<b>ANP</b> Brazilian National Agency of Petroleum, Natural Gas and Biofuels
<b>ANVISA</b> Brazilian Health Regulatory Agency
<b>ANTT</b> Brazilian Land Transport Agency
<b>CAMEX</b> Brazil Foreign Trade Chamber
<b>CNI</b> Brazil National Confederation of Industry
<b>CONAMA</b> Brazilian Environment Council
<b>COPANT</b> Pan American Standards Commission
<b>DECEX</b> Department of Foreign Trade Operations, Ministry of Defense
<b>DFPC</b> Controlled Products Oversight Board
<b>DNPM</b> Brazilian National Department of Mineral Production
<b>DPF</b> Brazil Federal Police Department
<b>FIESP</b> Federation of Industries of the State of São Paulo
<b>FNDCT</b> Brazilian Fund of Scientific and Technological Development
<b>GMC</b> Common Market Group, Mercosul
<b>IAF</b> International Accreditation Forum
<b>IEC</b> International Electrotechnical Commission
<b>IBAMA</b> Brazilian Institute of the Environment and Renewable Natural Resources
<b>ILAC</b> International Laboratory Accreditation Cooperation
<b>ILO</b> International Labor Organization
<b>INMETRO</b> Brazilian National Institute of Metrology, Quality and Technology
<b>ISO</b> International Standardization Organization
<b>MCT</b> Brazil Ministry of Science and Technology
<b>MDIC</b> Brazil Ministry of Industry, Foreign Trade and Services
<b>MERCOSUL</b> Common Market of the South
<b>MMA</b> Brazil Ministry of Environment
<b>MRA</b> Mutual Recognition Agreement
<b>MTE</b> Brazil Ministry of Labor and Employment
<b>NM</b> Mercosul Standard
<b>NR</b> Regulatory Standard
<b>PROFARMA</b> Brazilian Program for Supporting the Development of the Pharmaceutical Productive Chain
<b>RDC</b> Resolution of the Board of Directors, ANVISA
<b>SDCI</b> Secretariat of Industrial Development and Competitiveness, MDIC
<b>SGT</b> Working Subgroup, GMC, Mercosul
<b>SIEMA</b> Brazilian National Environmental Emergency System
<b>SINMETRO</b> Brazilian National System of Metrology, Standardization and Industrial Quality
<b>SISNAMA</b> Brazilian National System of Environment
<b>SUASA</b> Unified Agricultural Health Care System
<b>SUS</b> Unified Health System
<b>TBT</b> Technical Barriers to Trade
<b>WTO</b> World Trade Organization

**Project Brazil – EU:****Mapping of applicable technical regulations, conformity assessment procedures and supporting standards in support of EU-Brazil business development****Deliverable 2****BRAZIL - OVERVIEW****BRAZIL AND ITS STANDARDIZATION POLICIES****1. INTRODUCTION**

Regulatory, standardization, accreditation and certification policies usually affect direct or indirectly Brazil's international trade performance. There are some public and private bodies responsible for applying the measures and requirements set forth by the government to each of these areas. In general, regulatory policies aim at the protection of public health, the environment, the consumer, as well as to guarantee the credibility of conformity assessment procedures.

This brief describes the main public and private bodies involved in the elaboration and application of such regulatory policies, which will be of interest to grasp policies developed for each of the sectors analyzed in the following studies.

**2. REGULATION<sup>1</sup>**

The Brazilian regulatory framework is composed of four main systems: (i) the National System of Metrology, Standardization and Industrial Quality (SINMETRO); (ii) the National Health Surveillance System (SNVS); (iii) Unified Agricultural Health Care System (SUASA); and (iv) National Environment System (SISNAMA) (see Figure 1 below).

These systems contain many overlapping competences amongst themselves and across different levels of government (federal, state and local). Although they are created by the federal government, it reflects on the competences attributed to subnational governments. In fact, there are different public bodies under those systems, which represents a very decentralized manner to issue technical regulations. Finally, state and local governments hold competences in strategic regulatory areas affecting the sectors analyzed in this project, for which the examination of the regulation issued by each of these four systems is not exhaustive, albeit very representative of the most important technical regulations in force in Brazil.

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<sup>1</sup> In Brazil, many public bodies and agencies issue technical regulations for different economic sectors. Therefore, the research goes 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 Deliverable 2 are exhaustive lists.

Figure 1 : Brazilian Systems according to the respective areas



Elaborated by: CCGI – EESP/FGV.

## 2.1. SINMETRO

Only the federal government can create rules for the measurement system, in accordance with the Brazilian Federal Constitution in force. In this sense, the 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)<sup>2</sup>. INMETRO is a federal authority, linked to MDIC, and it also performs 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<sup>3</sup> for the management of its registry of items and its non-automatic import licensing activities. As at the end 2016, INMETRO's registry 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).

## 2.2. SNVS

In relation to health surveillance actions, the National Health Surveillance System of Brazil (SNVS), coordinated and supervised by the Ministry of Health, is responsible for dealing with issues related to preventive action in general, health surveillance and control of borders. The Ministry of Agriculture, Livestock and Food Supply (MAPA) deals with the themes of defense of plant and animal health and the monitoring of inputs used in farming activities and the provision of services to the sector.

In this system, ANVISA<sup>4</sup> plays a fundamental role in the regulatory structure of the country. The agency was created by Law No. 9.782/99, and is competent to establish regulation on public health. Other authorities have similar competence in the state and municipal levels, however, in practice, the regulation from ANVISA prevails in the most important aspects of

<sup>2</sup> **INMETRO** issues technical regulations for all aforementioned sectors. It is possible to search by keywords, date and number of the technical regulation [here](#).

<sup>3</sup> More details on Orquestra System can be found in [http://www.inmetro.gov.br/credenciamento/manual\\_orquestra.asp](http://www.inmetro.gov.br/credenciamento/manual_orquestra.asp)

<sup>4</sup> ANVISA issues regulations for medical devices sector and there is a search tool on its website in which regulations can be searched by their status, subject, type of act, date of publication in the Official Gazette, number, or keywords in the summary. It is available [here](#).

public health. The Sanitary Surveillance and its public agents are holders of the so-called "Police Power", which allows them to carry out certain administrative acts, such as irregular inspection, assessment and prohibition of establishment, in order to guarantee adequate security for the population, based on a set of legal norms established by the legislation.

### **2.3. SUASA**

In the Unified Agricultural Health Care System (SUASA), the main authority is the Ministry of Agriculture, Livestock and Food Supply (MAPA). The Ministry through diverse normative acts regulates directly different aspects of the agriculture. It plays a key role in pest control and the dissemination of good animal health practices, especially with regard to the frequent use of vaccines, antibiotics and prophylactic practices. Therefore, MAPA has ministerial status but plays a role of a technical agency for some dimensions of the agriculture sector. The important role of MAPA in regulating techniques and taking sanitary and phytosanitary measures can be evidenced in the various notifications made by the body to the TBT and SPS Committees of the WTO.

### **2.4. SISNAMA**

The National System of Environment (SISNAMA) is also a complex system. The environment is an issue characterized by shared legislative competence: it was constitutionally the competence of all the Federation's entities to protect the environment. The federal Ministry of Environment has the function to formulate, implement and monitor the national policy of environment, as well as propose strategies, economic and social mechanisms and instruments for the improvement of environmental quality and sustainable use of natural resources. The regulation of more specific dimensions, however, can be object of regulation issued by state and municipal bodies. The local environment, for example, is usually regulated by the municipal authority and by local bodies specifically designed to take into account local necessities.

In the federal level, it must be stressed the role of the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA), created by Law 7,735 of February 22, 1989. IBAMA is a federal body linked to the Ministry of the Environment (MMA). It is the executive body responsible for implementing the National Environmental Policy (PNMA), established by Law No. 6.938, of August 31, 1981. IBAMA carries out various activities for the preservation and conservation of natural heritage, exercising control and oversight over the use of natural resources (water, flora, fauna, soil, etc.). It is also responsible for granting environmental licenses to undertakings within its competence.

### **2.5. Regulation and Foreign Trade**

Specifically, in foreign trade, the first regulatory aspect to be considered is the existence of a group of products that cannot be traded without authorization of a specific public body. In the case of imports, these bodies, known as authorizing bodies (*órgãos anuentes*), authorize the entry of products into Brazilian territory. The following bodies have the function of permitting or, on the basis of the law, of prohibiting the importation of goods to Brazil: ANCINE - National Cinema Agency; ANEEL - National Electric Energy Agency; ANP - National Petroleum Agency; ANVISA - National Health Surveillance Agency; CNEN - National Commission of Nuclear Energy; DECEX - Department of Foreign Trade Operations; DFPC - Brazilian Army / Controlled Product Inspection Board; DNPM - National Department of Mineral Production; DPF - Federal Police Department; ECT - Brazilian Post and Telegraph Company; IBAMA - Brazilian Institute of Environment and Renewable Natural Resources; INMETRO - National Institute of Metrology, Standardization and Industrial Quality; MAPA - Ministry of Agriculture, Livestock and Food Supply; MCT - Ministry of Science and Technology; and SUFRAMA - Superintendence of the Manaus Free Trade Zone.

Some of the authorizing bodies have a broader competence than others or deal with a variety of issues related to one or more of the sectors hereby analyzed (more details in Annex). ANVISA, for example, has a very broad competence, acting as an independent body to examine several products, located in the most different chapters of the harmonized system. INMETRO is another very important body, mainly in the importing of mechanical and electrical apparatus and equipment<sup>5</sup>. Both agencies also perform accreditation of conformity assessment bodies, and they usually represent Brazil in regulatory cooperation initiatives.

Often, it is necessary the simultaneous consent of two bodies in order to meet the aspects required by Brazilian regulation for imports. There are also cases of authorizing bodies with a very restricted jurisdiction, such as the Federal Police (which is an authority in the importation of products that can be used in the production of psychotropic substances) and the Army Command (which controls chemical substances of dual use - civil/military), both acting mainly in the sector of basic chemical products of industrial use.

In terms of trade policy formulation, the Union and its administrative bodies play a central role. In particular, the Board of Foreign Trade (CAMEX, according to the initials in Portuguese), an integral part of the Presidency of the Republic, in the context of the Civil House, defines the guidelines and procedures for the implementation of foreign trade policy, aiming at Brazil competitive insertion in the international economy. It also defines, in the field of export and import activities, the guidelines on policies and procedures to streamline and simplify procedures, requirements and administrative controls on imports and exports.

The international trade is frequently affected by the regulation produced in the four major regulatory systems presented. Each one of the systems involved several actors which are linked to others with specific competence to implement regulatory policies internally. Such actors also influence international bodies and international initiatives to discuss standards and regulations policies in the same basis. For example, ANVISA, which is the main axis of SNVS, participates in important international initiatives, such as the International Medical Device Regulators Forum (IMDRF) and the International Council for Harmonization (ICH).

More than 170 bodies have been identified with regulatory functions. Such bodies occupy different levels in the hierarchy in the four systems: 34 of SINMETRO, 97 of SUASA and SNVS, 25 of whose activities may cause impacts in SISNAMA.

The activities of such bodies that cause domestic and international impacts can be partially measured by the notifications made by some of these bodies to the WTO, especially to the TBT and SPS Committees.

### **3. NOTIFICATIONS TO THE WTO**

The issues analyzed in this report are all objects of the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT), established in the framework of the World Trade Organization (WTO).

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<sup>5</sup> In such sectors, it must be stressed the role of two other agencies: Ministry of Labor and Employment or Superior Labor Court (it has a lists with NRs (labor regulations) for machinery and electric-electronic sectors available [here](#)) and Ministry of Science, Technology, Innovation, and Communications (MCTI) (it provides a search tool in which one can search regulations by subject or type of act. It is available [here](#)).

In Brazil, the focal point responsible for providing information concerning such adjustments is the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) in the case of technical measures and the Brazilian Health Regulatory Agency (ANVISA) and the Ministry of Agriculture, Livestock and Food Supply (MAPA), in the case of sanitary and phytosanitary measures. However, several other agencies issue regulations and standards and shall notify the WTO on a regular basis.

In the period between the years 2012 and September 2016, for example, Brazil sent 241 notifications to the TBT Committee and 363 to the SPS Committee.

Figure 2 - Notifications sent between 2012 and 09/2016 to the TBT agreement (total: 214)

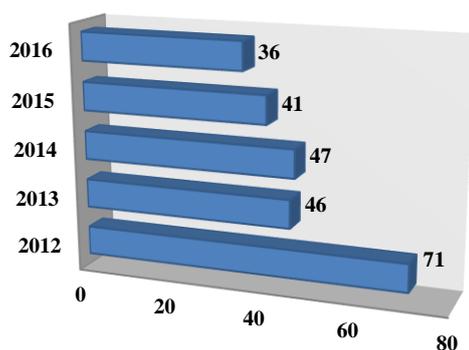
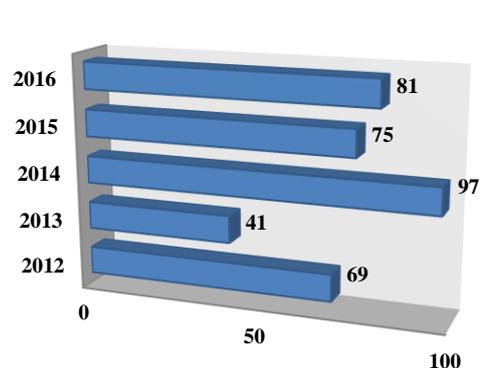


Figure 3 - Notifications sent between 2012 and 09/2016 to the SPS agreement (total: 363)



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

With regard to the agencies responsible for the drafting of acts that are notified, the following agencies have notified to the TBT agreement between 2012 and September 2016.

Figure 4 - Agencies that have notified to the TBT Committee between 2012 and 09/2016 (total: 214)

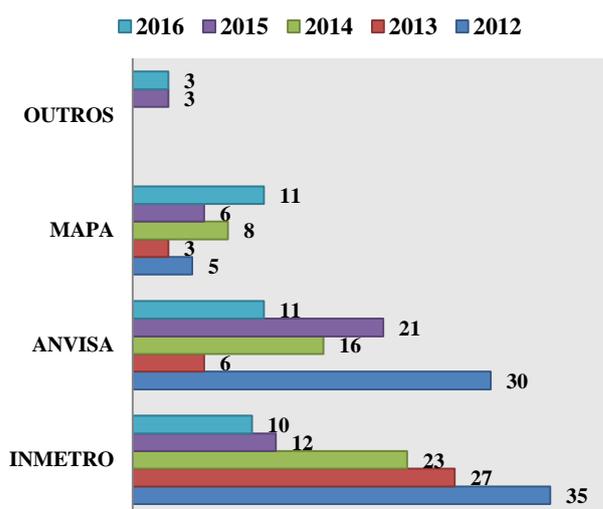
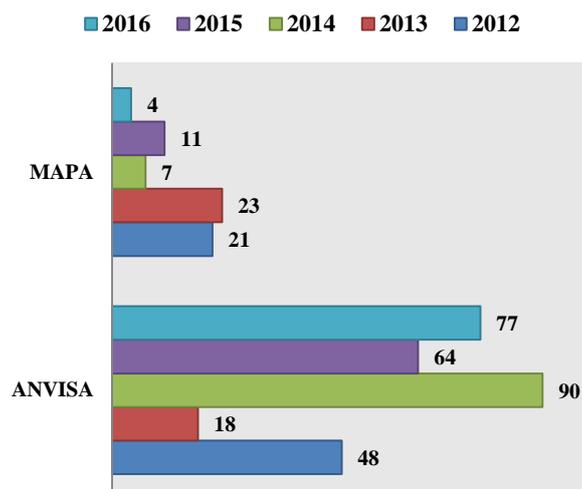


Figure 5 - Agencies that have notified to the SPS Committee between 2012 and 09/2016 (total: 363)



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

In addition to the focal points that are part of the systems reviewed, other organs appear in the notifications sent to the WTO, such as: Ministry of Mines and Energy (MME), Brazilian

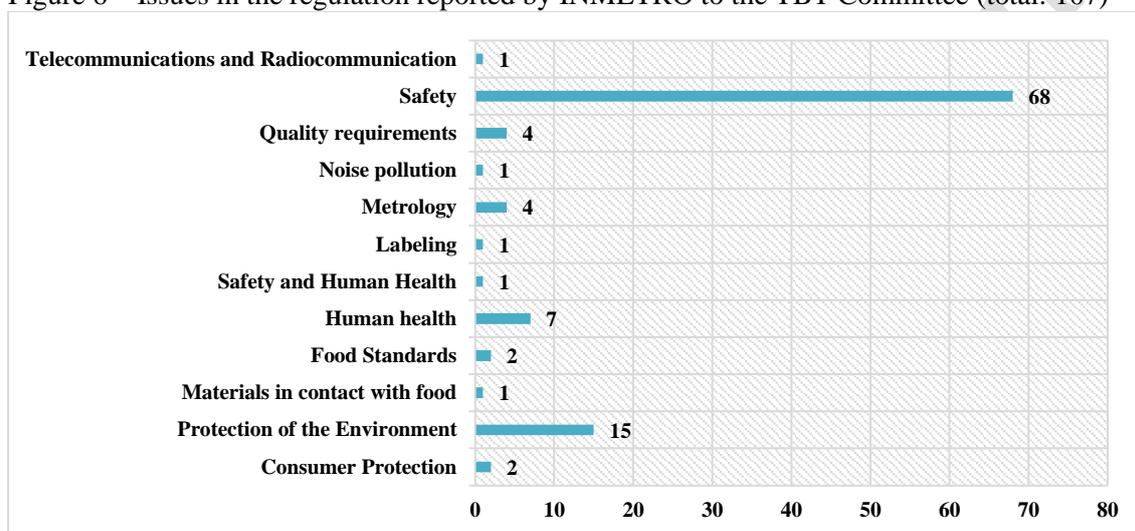
Institute of Environment and Renewable Natural Resources (IBAMA), Ministry of the Environment (MMA), Subcommittee for Legal Affairs of the Civil House of the Presidency of the Republic and the Department of Control and Monitoring of Fisheries and Aquaculture (SEMOC-MAPA).

Here is an overview of the notifications sent by focal points to participate in the systems studied in this report.

### 3.1. Notifications from INMETRO

In the period between the years 2012 and August 2016, the INMETRO sent 107 notifications to the TBT agreement. Most of them focus on safety, but there are several other issues that deserved attention of this organ:

Figure 6 – Issues in the regulation reported by INMETRO to the TBT Committee (total: 107)



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

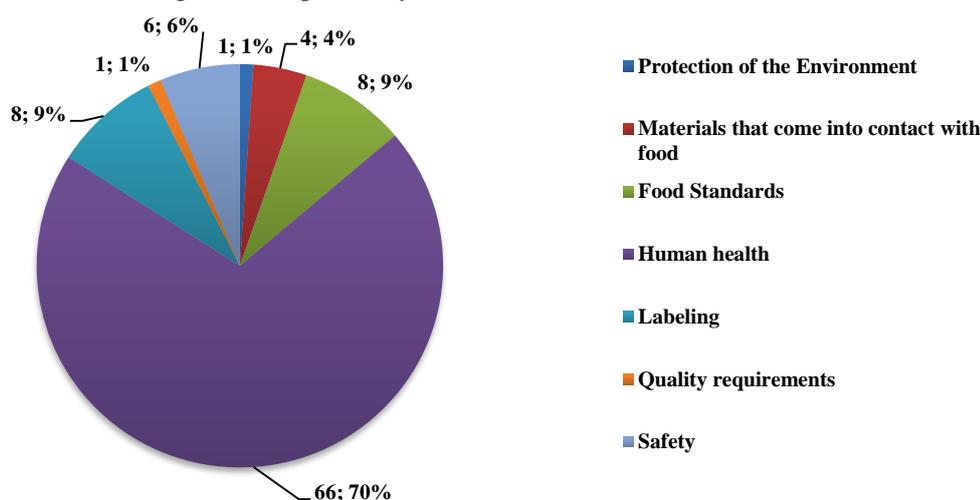
The notifications sent by INMETRO intend to communicate public consultations or final publication of metrological and technical regulations, and conformity assessment (RTCA). The INMETRO regulation set out the characteristics of a product or process and related production methods, including administrative 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.

Before being approved, the RTCAs prepared 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 on the website of INMETRO.

### 3.2. Notifications from ANVISA

The regulations issued by different organs of ANVISA are communicated to the TBT or SPS Committee in the WTO. In the period between the years 2012 and 2016, the notifications to the TBT Agreement totaled 93. Most of them focus in the area of human health.

Figure 7 – Issues of the regulation reported by ANVISA (total: 93)



Source: WTO. Elaborated by: IGCC PROCESS-EESP/FGV.

The notifications sent by ANVISA to the TBT Committee intend to communicate both public consultations and final publication of Collegiate Board Resolutions (RDCs). The RDCs consists on the legal provision that expresses the collective decision to issue technical regulations. ANVISA also notifies Normative Instructions (IN, according to the initials in Portuguese), a provision that is a normative species inferior to the RDC, and it is issued by the Collegiate Board with details for the rules and procedures of the technical regulation.

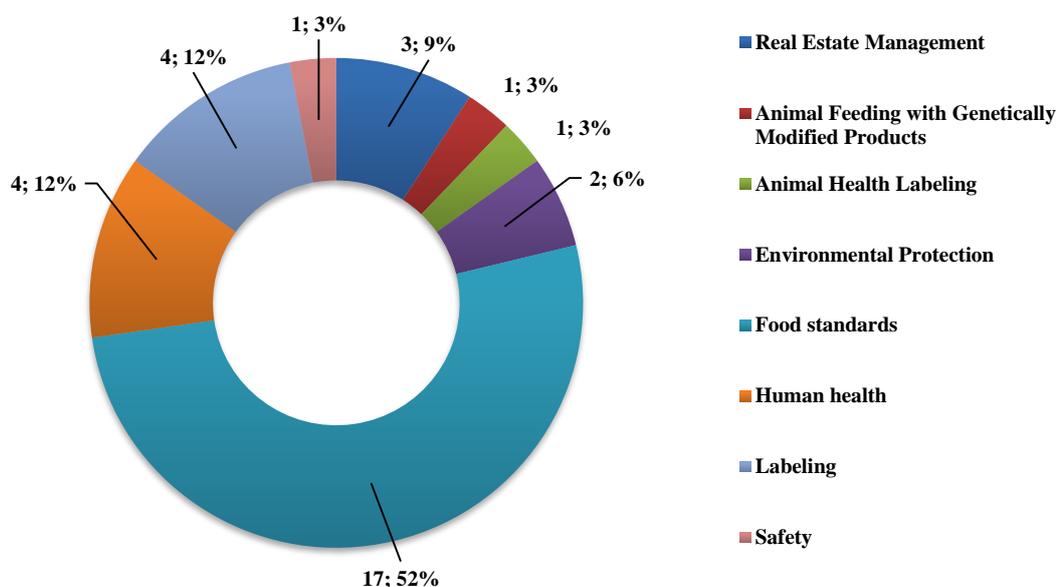
Resolutions usually determine the publication of monograph of the active ingredients of pesticides, household cleaners and preservatives from wood, whose employment is authorized as outlined in the monograph accompanying the resolution. Each inclusion of an ingredient needs to complete the entire process for formulating a new technical regulation.

It is important to note at this point that, according to explanations presented in electronic newsletters from ANVISA, pesticides are products with high risk to health and the environment and, therefore, suffer strict control of three government agencies: ANVISA, IBAMA and MAPA. Any change in the formula of these products significantly increases the chances of developing various harms to health as cancer, reproductive toxicity and endocrine disruption in rural workers and consumers from contaminated products.

### 3.3. Notifications from MAPA

MAPA, in the period between the years 2012 and 2016, notified different regulations to the TBT and SPS Committees. The main themes of the notifications are the following:

Figure 8 - Issues notified by MAPA to TBT Committee (total: 33)

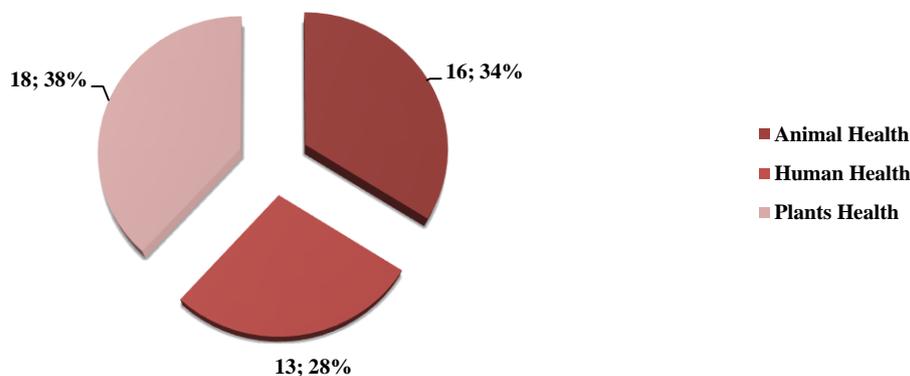


Source: WTO. Elaborated by: CCGI – EESP/FGV.

In the notifications made by MAPA, there is a clear predominance of issues related to food standards, which represents more than a half of the notifications to TBT Committee.

With regard to notifications to the SPS Committee, there are many different issues notified, stressing aspects related to plants health.

Figure 9 – Issues of regulation reported by MAPA to the SPS Committee (total 47)



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

In both cases, ordinances and normative instructions are notified to the Committee. The ordinances are generally used by Ministers to drive the procedures governing the administrative body and its operational services. The normative instructions establish details of the content of the ordinances and other normative provisions.

It is worth noting, therefore, that the notifications identified have a double objective: to make transparent the regulatory practices in Brazil, contributing to the efforts of international convergence, and indicate potential overlaps of the regulation in specific areas, in order to keep internal coherence of the regulatory system.

#### 4. STANDARDIZATION

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 SINMETRO and according to strategic guidelines of CONMETRO.

ABNT is recognized by international standardization bodies such as the International Organization for Standardization (ISO), International Electrotechnical 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 Accreditation 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).

It is responsible for:

- a. Encouraging the use of technical standards in the scientific, technical, industrial, commercial and agricultural fields and related, keeping them updated;
- b. Encouraging and promoting the participation of the technical communities in research, development and dissemination of technical standardization in the country;
- c. Representing Brazil in international technical standardization bodies and participate;
- d. Collaborating with similar foreign organizations, exchanging information and technical standards;
- e. Collaborating with the State in the study and solution of the problems related to the technical standardization in general;
- f. Granting, directly or through third parties, marks of conformity and other certificates relating to the adoption and application current sector;
- g. Providing services in the field of technical standardization;
- h. Mediating with the Government the interests of civil society concerning technical standardization issues.

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. Such a process addresses the conditions necessary for the product, project, process, system, person, good or service to meet determined purposes. Therefore, the standardization process envisages dealing with the technology innovation as an objective and neutral step towards the commercialization of products, projects, processes, systems, persons, goods or services.

The objectives of standardization are the following:

- a. Communication: provides the means necessary for the proper exchange of information between customers and suppliers;
- b. Reduces the varieties of products and procedures, in order to simplify the relationship between producer and consumer;

- c. Consumer protection: defines the requirements that allow to evaluate the quality of products and services;
- d. Security: technical requirements designed to ensure the protection of human life, health and the environment;
- e. Decreases the cost of products and services through the systematization, rationalization and ordering processes and production activities;
- f. Elimination of barriers: prevents the existence of conflicting regulations on products and services in different countries in order to facilitate trade.

The process of elaboration of technical standards is based on the following principles:

- a. Willingness – participation in the standardization process is not obligatory and depends on a voluntary decision of the parties concerned.
- b. Representation – there must be participation of experts from all sectors: producers, consumer organizations and neutrals (other stakeholders such as universities, laboratories, research institutes, and governmental bodies), so that all the views are considered.
- c. Update – updating the standards development process, with the adoption of new management methods and new tools of information technology, contributes to the standardization process that follow the technological evolution.
- d. Transparency – to all interested parties should be made available, at any time, information on the control activities and decisions on the technical standards development process.
- e. Simplification - the standardization process must have rules and procedures that are simple and accessible, to ensure consistency, speed and quality in the development and implementation of standards.
- f. Consensus - a standard has its content as close as possible to the reality of implementation. Consensus among the participants of its preparation is necessary.

Bearing in mind that the standardization process is executed by bodies that rely on the participation of diverse stakeholders (producers, consumers, universities, laboratories, research centers and government), it must be governed by transparency principles. Standardization bodies are responsible for the preparation, adoption and dissemination of publicly available standards. ABNT is the main Brazilian standardization body recognized to perform the standardization process at national level. In this condition, it is a member of the corresponding regional and international organization for standardization.

In technical sense, the standard is a document established by consensus and approved by a recognized body. It provides, for common and repetitive use, rules, guidelines or necessary characteristics for products or related processes and production methods. The compliance with de provisions of a standard is not mandatory.

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 n° 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 n° 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 the public<sup>6</sup>.

It is important to clarify that the area of standardization in the SINMETRO is under the responsibility of the ABNT, which has authority over the sectorial standardization bodies (ONS) for the performance of these tasks. Similarly, the ABNT represents Brazil in ISO/IEC and in regional standardization fora and is supported by government and private entities.

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 3. 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), AMN (Mercosul Standardization Association) 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, in the MERCOSUL technical committees.

A perspective 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<sup>7</sup>. 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 n° 3 (CB 03) to find relevant supporting standards for electric-electronic and machinery sectors.

As at 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.

## 5. ACCREDITATION AND CERTIFICATION

Accreditation is a process that provides 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 a metrological verification procedure. 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 can focus on products, processes, services, management systems and personnel. By definition, it is performed by a

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<sup>6</sup> 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.

<sup>7</sup> ABNT Catalog with all searching tools is available [here](#).

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.

INMETRO General Coordination of Accreditation (CGCRE) is Brazil's national accreditation body in the field of conformity assessment<sup>8</sup>. It accredits entities engaging in certification, inspection, calibration, and testing. The accreditation process is managed online through *Orquestra*<sup>9</sup> and comprises the submission of a formal request, a review of supporting documentation, and an *in situ* assessment. Accredited entities are periodically evaluated by INMETRO.

As at 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.

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<sup>8</sup> On conformity assessment procedures, INMETRO provides a list with all regulations setting compulsory procedures, by type of product, available here. In addition to compulsory procedures, there is also a list with voluntary conformity assessment procedures (especially for information technology goods such as desktops, laptop computers, printers, monitors, servers, and plotters) available here.

<sup>9</sup> Electronic System available in <https://orquestra.inmetro.gov.br/workbase/wlogin.aspx>.

## ANNEX

The table below indicates the bodies responsible for the consent in non-automatic licensing, the pertinent legislation and the indication of the measure to be applied by the authorizing body, in the form of art. 5 of the Agreement on Procedures for the Licensing of Imports.

Table 1 Authorizing Bodies (*órgãos anuentes de importação*)

AUTHORIZING BODIES	LEGAL BASIS	TYPE OF PRODUCT (HS)
National Electric Energy Agency ( <a href="#">Agência Nacional de Energia Elétrica - ANEEL</a> )	Art. 3, XX, of Law 9427/96: Aneel is responsible to define additional tariffs of specific use of the international interconnection facilities for exportation and importation of electricity. Art. 26 of law 9427/96: the grantor power must, directly or through delegation to Aneel, authorize the importation and exportation of electricity, as well the implantation of the respective associated transmission facilities.	27
Brazilian Health Regulatory Agency ( <a href="#">Agência Nacional de Vigilância Sanitária - ANVISA</a> )	Art. 7, VII of Law 9872/99: the agency must authorize the functioning of import companies of goods and products submitted to the control and oversight by the agency. Art. 7, VIII of Law 9872/99: the agency must agree with the importation of goods and products submitted to the sanitary control and oversight by the agency.	Ex: 02, 03, 04, 05, 07, 09, 11, 12, 13, 15, 16, 17, 18, 19, 20, 21, 22, 25, 27, 28, 29, 30, 32, 33, 34, 35, 37, 38, 39, 40, 48, 54
Brazilian Cinema Agency ( <a href="#">Agência Nacional do Cinema - ANCINE</a> )	CONDECINE is a tax that focuses on the amounts paid, credited, applied, sent or delivered to producers, distributors or intermediates abroad for its importation on fixed price. The non-advertising, cinematographic and audiovisuals works fixed in the movie support are the only that need the consent of ANCINE to enter the country through customs. The requirement of consent is made through the importation license (LI) or simplified importation license (LSI), which are documents that gather information about the product and the operation. The importer or its legal representative must elaborate the LI or the LSI in the Integrated System of International Trade (SISCOMEX-Importação) and transmit it to the Central Base of the Network SERPRO, where these licenses receive specific numbering and are available to ANCINE, which analyses and issues an opinion about importation. The collection of the corresponding taxes is due to IRS and not to ANCINE and is calculated on the basis of the physical support and not on the content of the imported material.	37
Army Command ( <a href="#">Comando do Exército - COMEXE</a> )	In order to import any product controlled by the Army, the individual or legal entity must obtain the previous importation license, the international certificate of importation (CII). The referred license can be conceded by the Controlled Products Inspection Board (DFPC), after its filling and the referral of the application. When all the documents are received, the Controlled Products Inspection Service performs the customs clearance, inspects the package, confirms that all the items were legally imported through CII, verifies the payment of the traffic route, fills the papers about consent and releases the good to allow the IRS to collect taxes, do the customs clearance and redraw through post offices. Art. 9, III of decree 3665/2000: for importation, there must be a register in the army through the emission of title of register or certificate of register and the previous importation license through the international certificate of importation.	28, 29, 32, 36, 65, 87, 90, 93
Department of Foreign Trade Operations ( <a href="#">Departamento de Operações de Comércio Exterior - DECEX</a> )	Art. 17, IV of decree 8917/2016: SECEX must propose aliquots to the importation tax, its alterations and its regimes of preferential and non-preferential regimes. Art. 17, XXIII of decree 8917/2016: SECEX must administer and control tariff and non-tariff quotas of importation. Art. 18, IV, “a” and “d” of decree 8917/2016: DECEX must analyze and deliberate importation licenses and importation agreements with the participation of national companies.	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25,

	<p>Art. 18, V of decree 8917/2016: DECEX must inspect prices, weights, measures, classification, qualities and types, declared in importation exports.</p> <p>Art. 22, VI of decree 8917/2016: DECEX must articulate with willing bodies in international trade, respecting each one's competences, aiming the harmonization and the operation of license procedures and of other administrative requirements to the concretization of importations.</p> <p>Art. 22, XVII of decree 8917/2016: DECEX must keep and update the register of exporters and importers.</p>	<p>26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 89, 90, 91, 92, 93, 94, 95, 96</p>
<p>Federal Police Department <a href="#">(Departamento de Polícia Federal - DPF)</a></p>	<p>Art. 7 of law 10357/2001: In order to import chemical products subject to control and inspection, a previous authorization of DPF will be necessary, in the cases foreseen in ordinance.</p> <p>Art. 10, § 3 of ordinance 1274/2003: In a request of special authorization to import, the interested physical person or legal person must require to DPF the emission of a corresponding previous authorization, in the cases foreseen in the ordinance, through a proper requirement instructed with specific documents.</p> <p>Art. 12 of ordinance 1274/2003: DPF will issue a multilateral notification of information of chemical substances to the competent authorities of exporting countries.</p> <p>Art. 13 of ordinance 1274/2003: Importation proceedings of chemical controlled products are subject to the compulsory administrative treatment of SISCOMEX.</p> <p>Art. 14 of ordinance 1274/03: In the importation of any chemical product foreseen in list I of annex I of the ordinance, the customs clearance will occur in the entry port authorized in the national territory.</p> <p>Art. 17, § 2° of ordinance 1274/03: a previous authorization of DPF is necessary to import chemical products mentioned in lists I, II and III of annex I, when the amount involved in the operation overcomes the exemption limits specified in the addendum of lists I and II for any nature of the operation to be performed and for any chemical controlled product involved.</p> <p>Art. 17, § 3° of ordinance 1274/03: as an additional measure of control, DPF can establish for a physical person or for a legal person a fixation of an annual quota for any chemical products foreseen in list I, to the exercise of the activity in the following year of the concession of the quota and also, upon technical justification, a supplemental quota of importation for the period of effective exercise.</p> <p>Art. 17, § 4° of ordinance 1274/03: if the situation foreseen in § 3° occurs, DPF can adopt the same technical criteria used by other official organs of control, which includes the homologation of importation quotas conceded by these organs due to a covenant.</p> <p>Art. 28, IV of ordinance 1274/03: a previous authorization of importation is a document of control.</p>	<p>27, 28, 29, 33, 38, 81</p>
<p>National Department of Mineral Production <a href="#">(Departamento Nacional de Produção Mineral - DNPM)</a></p>	<p>Art. 1, II of ordinance 397/2003: the importation of rough diamonds can only be made after the previous consent of DNPM, through favorable manifestation in the Siscomex, previously to the register of the corresponding importation declaration. Art. 2, II of ordinance 397/2003: the previous consent will be required through the use of the non-automatic licensing module of Siscomex.</p> <p>Art. 1 of law 10743/2003: the System of Certification of the Process of Kimberley (SCPK) – international mechanism of certification of origin of rough diamonds intended for exportation and importation – is instituted, in Brazil, in the terms of the requirements established in the Process of Kimberley.</p> <p>Art. 1, § 3° of law 10743/2003: On importation, the Process of Kimberley aims to avoid the enter of the shipping of rough diamonds without the regular certificate of Process of Kimberley of the country of origin.</p> <p>Art. 3 of law 10743/2003: the importation activities of rough diamonds originated from countries non-participants of the Process of Kimberley are forbidden.</p> <p>Art. 7 of law 10743/2003: the importation of rough diamonds will be accompanied by the Certificate of Process of Kimberley, emitted by the competent authorities of the country of origin, being mandatory its presentation during the non-automatic licensing through DNPM.</p>	<p>25, 71</p>

	<p>Art. 2 of ordinance 209/2005: the previous consent for importation of rough diamonds will be required through a requirement addressed to the director-general of DNPm.</p> <p>Annex I of ordinance 209/2005: the following data of the importer are required: (i) name or social name of the importer, (ii) number of CNPJ/CPF/ME, (iii) address and (iv) telephone, fax and e-mail.</p> <p>Art. 2 of decree 2350/97: the importation of asbestos of the variety chrysotile, in any of its forms, can only be made after the authorization of “Departamento Nacional de Produção Mineral” (DNPm) of the Ministry of Mines and Energy and with the following requirements met: registration on DNPm of importing companies of asbestos of the variety chrysotile, in any of its forms, conditioned to the presentation, by the importing company, of an environmental license and the register on the user registration of the Ministry of Labour, presentation, until November 30 of each year, to the DNPm a forecast of importation, in the following year, of asbestos of the variety chrysotile and compliance with the established conditions by federal, state and municipal legislation of environmental control, of health and safety at work and of public health, being relevant the storage, manipulation, utilization and processing of asbestos, as well as waste generated in this operation, which includes its final disposition.</p> <p>Art. 4 of decree 2350/97: DNPm and the Secretary of Safety and Health at Work of the Ministry of Labour will forward, on each semester, to the Secretary of Foreign Trade of the Ministry of Industry, Trade and Tourism an updated list of registered companies and able to carry out imports of asbestos.</p> <p>Art. 5 of decree 2350/97: all the imported products that have asbestos of the variety chrysotile can only be traded if they have mark of conformity of the Brazilian System of Certification.</p> <p>Art. 5 of ordinance 41/98: the company interested in importation operations must, until 30 days before the day foreseen to the landing of the good, require specific authorization to the operation, through a requirement addressed to the director-general of DNPm with the following information about the origin of the asbestos of variety chrysotile: (i) country and city of origin, (ii) port of shipment, (iii) name of the provider and its complete address, (iv) state, municipality and port of landing and (v) amount and value effectively imported of asbestos of variety chrysotile.</p>	
<p>Brazilian Institute of Environment and Renewable Natural Resources (<a href="#">Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis - IBAMA</a>)</p>	<p>Art. 3 of ordinance 93/98: the importation will only be made by a legal person governed by public or private law and registered in IBAMA. In an exceptional case, the importation by physical person can be authorized, by means of a favorable opinion.</p> <p>Art. 4 of ordinance 93/98: the importation of live animals is also subjected to the Ministry of Agriculture and Food Supply, that will analyze animal health issues.</p> <p>Art. 5 of ordinance 93/98: the importation of agents of biological control will depend on the compliance of IBAMA normative ordinance 131/97 and complementary legislation.</p> <p>Art. 9 of ordinance 93/98: the legal person that imports live animals, products or subproducts of wildlife must compulsorily register in IBAMA with the presentation of the documents/information foreseen in law.</p> <p>Art. 11, b of ordinance 93/98: the imported living animals will only enter the country if marked in the origin with a proper dialing system, recognized by IBAMA (washer, tattoo and electronic identification).</p> <p>Art. 2, § 1 of CONAMA resolution 23/96: In case of a situation of necessary importation of hazardous waste, this exceptionality is conditioned to the appreciation and previous deliberation of CONAMA.</p> <p>Art. 4, single paragraph of resolution 23/96: CONAMA can amplify the list of inert waste – class III subject to a restriction on importation.</p> <p>Art. 5 of resolution 23/96: the importation of items of the category non-inert waste – Class II will only be made to the goals of recycling or reuse after the environmental authorization of IBAMA, preceded by the consent and the technical advice of the state organ of the environment.</p> <p>Art. 5, § 1 of resolution 23/96: the consent and the technical advice mentioned in the <i>caput</i> of the article refer to each type of residue that can be imported.</p> <p>Art. 5, § 2 of resolution 23/96: the companies that wish to import residues to recycling or reuse by third parties are allowed to import if they are registered on IBAMA, if they forward to IBAMA, each semester, the form of notification of importation, mentioning the cross-border movement of residues during the period, if there is a presentation to IBAMA, until November 30 of each year, a form of prediction of importation of residues for the following year and if they inform the IBAMA the reprocessing companies that will be responsible, formally, for the recycling or reuse of the imported residue, presenting a copy of the contract.</p> <p>Art. 8 of resolution 23/96: the list of residues described according to “Nomenclatura Comum do MERCOSUL baseada no Sistema Harmonizado de Designação e Codificação de Mercadorias” (NCM-SH) is specified in Annex 10 and the authorization of its importation by SECEX/MICT depends of a previous authorization of IBAMA.</p> <p>Art. 2, § 1 of resolution 297/2002: only the configurations of new moped, new and similar motorcycles, in the whole national territory, with the license</p>	<p>01, 02, 03, 04, 05, 06, 15, 16, 25, 26, 27, 28, 29, 30, 33, 34, 35, 38, 40, 41, 42, 43, 44, 51, 56, 57, 60, 61, 62, 63, 64, 65, 67, 70, 71, 78, 79, 81, 84, 85, 87, 88, 89, 91, 92, 94, 95, 96, 97</p>

	for the use of configurations of new moped, new and similar motorcycles (LCM) can be imported.	
National Agency of Petroleum, Natural Gas and Biofuels ( <a href="#">Agência Nacional do Petróleo, Gás Natural e Biocombustíveis - ANP</a> )	<p>Art. 8, XVI of law 9478/97: ANP must regulate and authorize activities related to importation of biofuels, as well as conformity assessment and certification of quality, supervising it directly or through covenants with other organs of the Union, States, Federal District or Municipalities.</p> <p>Art. 8, XVII of law 9478/97: ANP must require from the regulated agents the sending of information related to importation operations of products subject to its regulation.</p> <p>Art. 60 of law 9478/97: any company or group of companies can receive authorization of ANP to do the activity of importation of oil and byproducts and of natural gas and condensate.</p> <p>Art. 1 of ordinance 43/98: the importation of natural gas can only be made through previous and express authorization of ANP.</p> <p>Art. 7 of ordinance 43/98: after 31/12/2001, the authorizations to the importation of natural gas will comply with the specific guidelines of the “Conselho Nacional de Política Energética” (CNPE).</p>	22, 27, 29, 34, 38
National Council for Scientific and Technological Development ( <a href="#">Conselho Nacional de Desenvolvimento Científico e Tecnológico - CNPq</a> )	<p>Art. 1, § 1 of law 8010/90: the CNPq importations of machines, equipments, appliances and instruments, as well as its parts and spare parts, accessories, raw material and intermediate products that are applied in scientific and technological research are exempt of the similarity exam, of the emission of importation guidelines or document of equivalent effect and prior controls to customs clearance.</p> <p>Art. 2, § 2 of law 8010/90: the global quota of importations will be distributed and controlled by the CNPq that will forward, on each month, to the Brazilian Secretariat of Federal Revenue the list of importation entities as well as the authorized goods, values and quantities and to the Foreign Trade Portfolio of the Brazilian Bank (Cacex), for statistical purposes, the list of importers and the global value, by entity, of authorized importations.</p>	CNPq does not allow the importation of goods.
Brazilian Post and Telegraph Company ( <a href="#">Empresa Brasileira de Correios e Telégrafos - EBC</a> )	<p>“Importa Fácil” is a logistics solution to Brazilian importers that need to import diverse goods, whose customs value does not exceed US\$ 3000,00 or in equivalent foreign currency.</p> <p>The supplier/exporter must do the post abroad in one post modality in which the importation arrives directly in Brazilian “Correios”.</p> <p>In order for objects to be accepted and nationalized by “Importa Fácil”, dimensions and weights must meet specific conditions.</p> <p>The ECT uses as reference for the preparation of the clearance note, the selling price of the Tourism Dollar published in the previous day.</p>	84
National Institute of Metrology, Standardization and Industrial Quality National Institute of Metrology, Standardization and Industrial Quality – ( <a href="#">Instituto Nacional de Metrologia, Normalização e Qualidade Industrial Instituto Nacional de Metrologia, Normalização e Qualidade Industrial - INMETRO</a> )	Art. 3, XVII of law 9933/99: INMETRO must agree in the process of importation of products that it regulates and that are subject to a regime of non-automatic licensing or to other measures of administrative control previous to the dispatch for consume.	31, 32, 34, 35, 36, 38, 39, 40, 42, 44, 48, 49, 63, 65, 70, 72, 73, 74, 76, 82, 84, 85, 87, 90, 94, 95, 96
Ministry of Agriculture, Livestock and Food Supply ( <a href="#">Ministério da Agricultura, Pecuária e Abastecimento - MAPA</a> )	Art. 1 of normative instruction 51/2011: the importation of animals, vegetables, their products, derivatives and parts, by-products, waste of economic value and agricultural inputs included in the Annex to this Normative Instruction shall comply with the regulatory criteria and procedures for inspection, quality control and systems of risk analysis established by the Ministry of Agriculture, Livestock and Food Supply (MAPA).	01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 38, 39, 40, 41, 43, 44, 45, 46, 51, 52, 53, 81, 84, 87, 94, 96, 97
Ministry of Science and Technology ( <a href="#">Ministério da Ciência e Tecnologia - MCT</a> )	Ordinance MCT n. 436/2012: It establishes the MCT as the Brazilian regulatory body for importing procedures of chemicals enlisted and described on the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (Chemical Weapons Convention – CWC), adopted in Brazil under the Decree n. 2,977/1999.	28, 29, 30, 38, 39

<p>Superintendence of the Manaus Free Trade Zone <a href="#">Superintendência da Zona Franca de Manaus - SUFRAMA</a></p>	<p>Art. 3, <i>caput</i>, of law decree 288/67: the entry of foreign goods into the Free Zone, destined for domestic consumption, industrialization to any degree, including processing, farming, fishing, installation and operation of industries and services of any nature and storage for re-export, shall be exempt from import taxes, and on industrialized products.</p> <p>Art. 4 of law 8210/91: the entrance of foreign goods in the free trade area of ALCGM will be done with the suspension of import tax, that will be converted in exemption when the goods are destined to consumption and internal sales in ALCGM, processing, in the territory of ALCGM, of fish, mineral resources and of raw material of agricultural or forestry origin, agriculture and pisciculture, installation and operation of tourism and services of any nature, stocking for trade in the external market, shipbuilding and repair activities and in the case of baggage accompanied by travelers, observed the limits established by the Executive Branch, through the Federal Revenue Secretariat.</p>	<p>SUFRAMA does not allow the importation of goods.</p>
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Source: Camex. Elaborated by: CCGI – EESP/FGV.

*Working Document*