PROJECT BRASIL-ARGENTINA: The regulatory environment and its effects on Brazil-Argentina integration: technical, sanitary, phytosanitary and environmental measures and their support standards.

Product 3: Technical document containing the identification of specific practical problems in complying with regulations and mandatory conformity assessment procedures

DRAFT VERSION

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LIST OF ACRONYMS

AMN Mersocur Standards Association
ANMAT National Administration of Drugs, Foods and Medical Devices
ANVISA Brazilian Health Regulatory Agency
BGMP Certificate of Good Manufacturing Practices
BSE Bovine Spongiform Encephalopathy
BSI British Standards Institution
CAMEX Brazil Foreign Trade Chamber
CEN European Committee for Standardization
CENELEC European Committee for Electrotechnical Standardization
CMC Common Market Council, Mercosul
CNTT Thematic Tripartite National Commission
DOU Brazilian Federal Gazette
GATT General Agreement on Tariffs and Trade
HS Harmonized System
IAPG Argentine Institute of Petroleum and Gas
INMETRO National Institute of Metrology, Quality and Technology
IRAM Argentine Institute for Standardization and Certification
MDSAP Medical Device Single Audit Program
MHLW Ministry of Health, Labor and Welfare
MTE Ministry of Labor and Employment
MHLW Ministry of Health, Labor and Welfare
NM Mercosul Standard
NR Regulatory Norm
PMDA Pharmaceuticals and Medical Devices Agency of Japan
RDC ANVISA Board Resolution
SPS Sanitary and Phitossanitary Meassures
STC Specific Trade Concerns
TBT Technical Barriers to Trade
TGA Therapeutic Goods Administration of Australia
TPR Trade Policy Review
USTR United Stated Trade Representative
WTO World Trade Organization

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INTRODUCTION

In this report, the research team analyses the non-tariff difficulties to international trade of Brazil and Argentina, especially (but not limited to) the bilateral trade. The report will also identify the more problematic topics concerning the regulatory framework of Brazil and Argentina, making explicit 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 illegal 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.

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The legal framework that allows the identification of regulatory barriers to international trade imposed by Argentina is 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.

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, according to initials in Portuguese) and Latin American Association of Integration (ALADI, according to initials in Spanish) 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[1]. 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).

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

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

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 obstruction to trade. The level of obstruction, 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, specially 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.

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PART A – BRAZIL

In this part, the report analyses specific difficulties of some sectors. The purpose is to scrutinize practical problems that affect international trade in general of Brazil. The focus is the difficulties faced by those companies that export to Brazil, including Argentine companies.

In this part of the report, the team of researchers scrutinizes separately the technical barriers and sanitary and phytosanitary measures for the selected sectors. As a result, some products, such as food and agriculture products, will be approached from the perspective of TBT and SPS. Not all products in the selected group of goods have any relevant regulatory barriers. Although many of them are specially affected by the problematic performance of some specific agencies of the public administration, it is not possible to assert that they face a regulatory barrier to trade, in the sense provided in the TBT and SPS agreements of the WTO.

The barriers and problems highlighted in the following pages represent general problems for Brazil's foreign trade. Some of them directly affect bilateral trade between Brazil and Argentina, but others represent only a potential barrier that may interfere, at some point, in trade between the two countries. The identification of this potential trade obstruction results from the fact that these are systemic problems that affect other Brazilian trading partners and that have not yet been fully solved by Brazil, although many of them have been dealt with in regulatory convergence initiatives whose results have not are completely clear. In cases where the problems have been addressed through convergence schemes or through some regulatory reform project that is not yet in force, these corrective actions will be highlighted in the text.

The legal framework that allows the identification of regulatory barriers to international trade imposed by Brazil are the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade Agreement (TBT), both inserted on 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, on its turn, also aims to fulfil legitimate objectives as the ones mentioned above, national security and the prevention of deceptive practices and is applied to technical regulations, standards and conformity assessment procedures.

The barriers identified are limited to the sectors analyzed during the research project on regulatory coherence and convergence initially between Brazil, European Union and United States and later expanded to Argentina.

1. TECHNICAL BARRIERS TO TRADE

An efficient way to identify the conduct of a country concerning the imposition of barriers to trade by analyzing specific trade concerns raised by your business partners, not the WTO TBT Committee.

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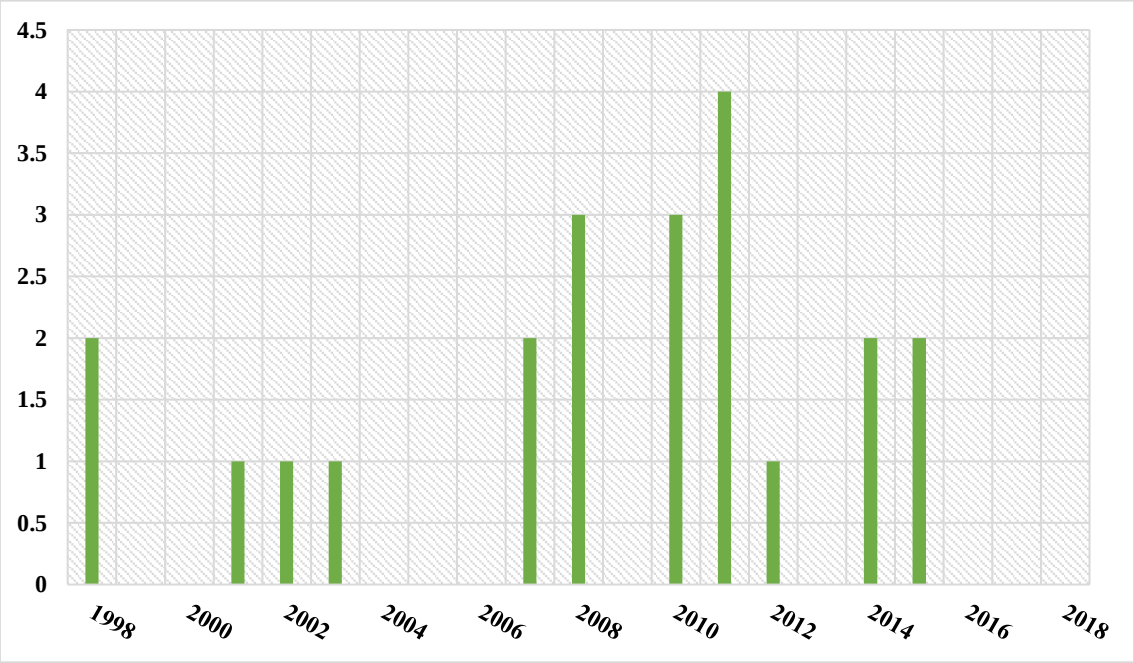
Figure 1 – STC raised against Brazil in TBT Committee

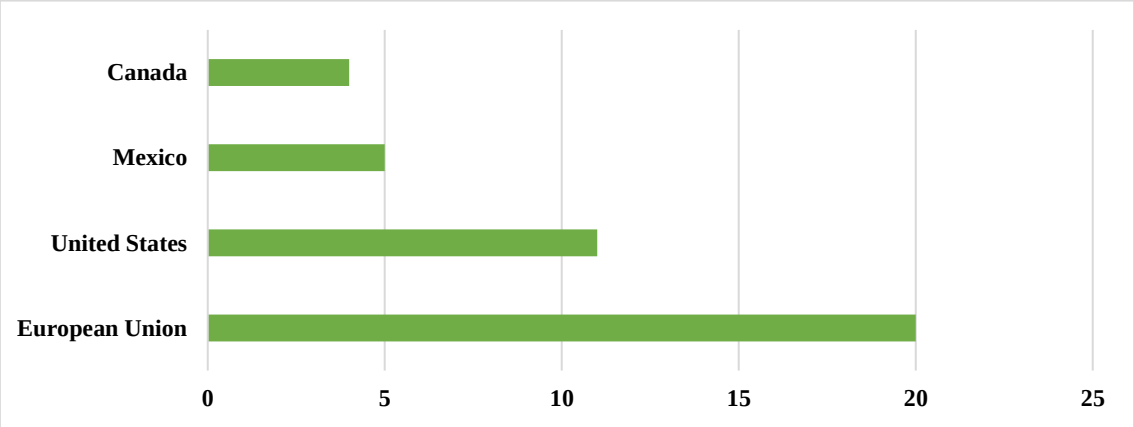


Source: WTO. Elaborated by CCGI/EESP-FGV.

The number of STCs raised against Brazil is relatively small. There are several years where no new STC was raised. The year 2011 was the year in which there were the highest number of STCs: 4.

The most part of STCs was raised by only four members: European Union, United States, Mexico and Canada. Argentina and other members of Mercosur do not raise any STC against Brazil until the present date.

Figure 2 – Members raising STCs against Brazil



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

This absence of members of Mercosur can indicate absence of divergences on issues related to TBT or the capacity to solve problems in the institutional framework of the regional bloc.

Some issues with respect to technical regulations of the sectors analyzed on this research and standards raised by domestic producers and importers are:

- International standards – The National Institute of Metrology, Quality and Technology (INMETRO, according to acronym in Portuguese) has a list of international regulation and standards and stimulates Brazilian manufacturers to follow them. However, the Brazilian productive sector often prefers to follow standards from Brazilian Association of Technical Standards (ABNT), which are not always supported by international standards.
- Complexity – The overall complexity of independent regulatory agencies and government bodies in Brazil, and the volume of technical regulation and standards dealing with energy efficiency, labor safety among other issues, required by each Ministry in its area of competence, is a serious challenge for producers and importers.
- Lack of Transparency – There is no public or private entity that gathers information on any mandatory regulation. The lack of a focal point contributes to this lack of transparency.
- Lack of Coherence – There are agencies that regulate the same sector issuing incompatible rules.
- Constant changes – The Brazilian electronic regulatory framework is characterized by a constant change, following the development of the technology and quality areas. Many resolutions are published in a quite dynamic process but they are not included immediately on the agencies websites.

These problems are not common to all sectors and therefore they not reported by all respondents. The specific problems of each sector are analyzed below. Some specific sectors, such as plastics and their products, which are still economically very relevant, did not present specific difficulties for international trade.

In the case of bilateral trade between Brazil and Argentina, some of these problems are even mitigated by the existence of regulations and institutions within Mercosur. In these situations, it can be seen that solutions partially addressed within the regional bloc can be deepened in order to accelerate regulatory convergence between the two countries.

1.1. MACHINERY SECTOR

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 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.

1.2. MEDICAL DEVICES SECTOR

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

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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).

The table below describes the auditing bodies evaluated and approved through MDSAP that received the recognition by ANVISA and the respective resolution of recognition.

Table 1 – Auditing bodies recognized by ANVISA

Auditing body	Resolution	Validity of recognition
BSI Group America Inc.	RE nº 651/2017	27/02/2021
DEKRA Certification B.V.	RE nº 193/2017	31/12/2018
DQS Medizinprodukte GmbH	RE nº 194/2017	31/12/2018
Intertek Testing Services NA Inc.	RE nº 323/2017	31/12/2020
Laboratoire National de Métrologie et d'Essais (GMED Certification Division)	RE nº 31/2017	30/06/2018
Lloyd's Register Quality Assurance Inc.	RE nº 2057/2017	16/07/2019
National Standards Authority of Ireland (NSAI)	RE nº 1783/2017	15/06/2019
TUV SUD America Inc.	RE nº 324/2017	31/12/2020
UL Medical and Regulatory Services	RE nº 2226/2017	03/08/2021
SGS United Kingdom Ltd.	RE nº 3432/2017	12/12/2021
NSF Health Sciences Certification, LLC	RE nº 3433/2017	11/12/2019

Source: ANVISA. Elaborated by CCGI.

While this is an important initiative to avoid duplication of compliance assessments, MDSAP is limited. To be more relevant, it is important that other countries participate in the initiative. The recent RDC 217/2018[2] increased the scope of the MDSAP good manufacturing practice certification, which is now opened to manufacturers that are based in South American countries and are members of Mercosur. This provision can be especially important for bilateral trade between Brazil and Argentina.

The RDC n. 185/2001 provides criteria to classify products on the aforementioned classes. The resolution provides rules for the following categories of products: non-invasive medical products, invasive medical products and active medical products. The resolution also foresees special rules.

Table 2 - categories of medical devices

TYPE		CLASS
NON INVASIVE	Non-invasive medical products	All non-invasive medical products are on class I, except the ones to which the following rules are applied.
	Medical products applied on the	All non-invasive medical products applied on the storage or conduction of blood, fluids or body tissues, liquids or gases applied

[2] See the full regulation in http://portal.anvisa.gov.br/documents/10181/3612364/RDC_217_2018_.pdf/c510c05b-5693-469e-81b4-36bbd21324e5

	storage or conduction of blood	on infusion, administration or introduction on the body are on class II if they can be connected to an active medical product of class II or of a higher class and if they are destined to conduction, storage or transport of blood or other fluids or storage of organs, parts of organs or body tissues.
	Products applied on the change of chemical or biological composition of blood	All non-invasive medical products applied on the change of chemical or biological composition of blood, of other fluids or of other liquids introduced on the body are on class III, except if the treatment consists on filtering, centrifugation or change of gases or heat. In these last cases, the products belong to class II.
	Medical products that are in contact with the injured skin	All non-invasive medical products that are in contact with the injured skin are on class I if they are applied as mechanical barrier for compression or for absorption of exudates, are on class III if they are applied on wounds that produced rupture of the skin and that can heal and are on class II on all the other cases, including medical products applied on the micro environment of a wound.
	All invasive medical products applied to the body holes	All invasive medical products applied to the body holes, except the invasive medical products on a surgery, that are not applied in connection to an active medical product are on class I if they are used transitorily. They are on class II if they are of short term use except if they are used on the oral cavity until the pharynx, on the external auditory canal until the tympanum or on the nasal cavity. In this last case, they are on class I. They are on class III if they are applied on the long term, except if used on the oral cavity until the pharynx, on the external auditory canal until the tympanum or on the nasal cavity and are not absorbed by the mucous membrane. In these cases, they are on class II.
	All invasive medical products of transitory use applied on a surgery	All invasive medical products of transitory use applied on a surgery are on class II, except in five situations. When they are applied on the diagnosis, monitoring or correction of a heart malfunction or of the central circulatory system, through direct contact with these parts of the body, they are on class IV. When the surgery instruments can be reused, they are on class I. When they are applied on the supply of energy through ionizing radiations, they are on class III. When they have biological effect or are totally or in great part absorbed, they belong to class III. When they are applied on the introduction of medicines through an infusion system or on a potentially dangerous form, considering the form of application, they are on class III.
	All invasive medical products of short term applied on a surgery are on class II (exceptions)	All invasive medical products of short term applied on a surgery are on class II, except in five situations. When they are applied specifically on the diagnosis, monitoring or correction of heart malfunction or of the central circulatory system, through the direct contact with these parts of the body, they are on class IV. When they are applied specifically in direct contact with the central nervous system, they are on class IV. When they administer energy through ionizing radiations, they are on class III. When they have biological effect or are totally or in great part absorbed, they are on class IV. When they suffer chemical alterations on the body or administer medicines, except the medical products to be put on the teeth, they belong to class III.
INVASIVE PRODUCTS	All medical products that can be implanted and the invasive medical products applied on a surgery are on class III (exceptions)	All medical products that can be implanted and the invasive medical products applied on a surgery are on class III, except on four situations. When they are put on the teeth, they belong to class II. When they are used in direct contact with the heart, the central circulatory system or the central nervous system, they belong to class IV. When they produce a biological effect or are absorbed totally or in large part, they belong to class IV. When they suffer a chemical transformation on the body or administer medicines,

		except if they are applied on the teeth, they belong to class IV.
PRODUCTS FOR DIAGNOSIS, PRODUCTS FOR DISINFECTION, PRODUCTS FOR ADMINISTRATION OF MEDICINES ETC	All active medical products for therapy applied on administration or change of energy	All active medical products for therapy applied on administration or change of energy are on class II, except if its characteristics are such that can administer or change energy with the human body on a potentially dangerous form, considering the nature, density and the place of application of energy. In this case, they are on class III. All active products applied on the control or monitoring of the functioning of active medical products for therapy foreseen in class III or applied to influence directly the functioning of these products are on class III.
	Medical active products for diagnosis or monitoring	The following medical active products for diagnosis or monitoring are on class II: (i) those applied on the administration of energy to be absorbed by the human body, except the medical products whose function is to illuminate the body of the patient on the visible specter, (ii) those applied on the production of in vivo images of distribution of radiopharmaceuticals, (iii) those applied on the direct diagnosis or monitoring of vital physiologic processes, except when applied specifically on the monitoring of vital physiological parameters, whose variations can result in immediate risk to the life of the patient, as variations on the heart functioning, the breathing or the activity of the central nervous system. In this case, they belong to class III.
	All active medical products applied on the administration of medicines, body fluids or other substances of the body or to extract them from the bod	All active medical products applied on the administration of medicines, body fluids or other substances of the body or to extract them from the body are on class II, except when the process is done on a potentially dangerous form, considering the nature of the substances, the part of the body involved and the form of application. In this case, they belong to class III.
	Medical products that incorporate a substance, that when used separately can be considered a medicine	All medical products that incorporate a substance, that when used separately can be considered a medicine, and that can exert on the human body a complementary action to these products are on class IV.
	Medical products used on the contraception or for prevention of the transmission of sexually transmittable disease	All medical products used on the contraception or for prevention of the transmission of sexually transmittable diseases are on class III, except when there are medical products that can be implanted or invasive medical products applied on the long term. In this case, they belong to class IV.
	Medical products applied specifically on disinfection, cleaning, washing and, if necessary, hydration of contact lens	All medical products applied specifically on disinfection, cleaning, washing and, if necessary, hydration of contact lens, are on class III. All medical products applied specifically on disinfection of other medical products are on class II. This rule is not applied to products applied on the cleaning of medical products that are not contact lens through physical action.
	Non-active medical products applied specifically on the registry of radiographic images for diagnosis	The non-active medical products applied specifically on the registry of radiographic images for diagnosis are on class II.
	Medical products that use tissues of animal origin or its	All medical products that use tissues of animal origin or its inert derivatives are on class IV, except when such products are applied only to enter in contact with the skin.

	inert derivatives
	The blood bags are on class III.

Source: ANVISA. Elaborated by CCGI.

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.

2. SANITARY AND PHITOSSANITARY MEASURES

By the same token, a general framework of sanitary and phytosanitary measures can be developed based on the STCs against Brazil made to the SPS Committee.

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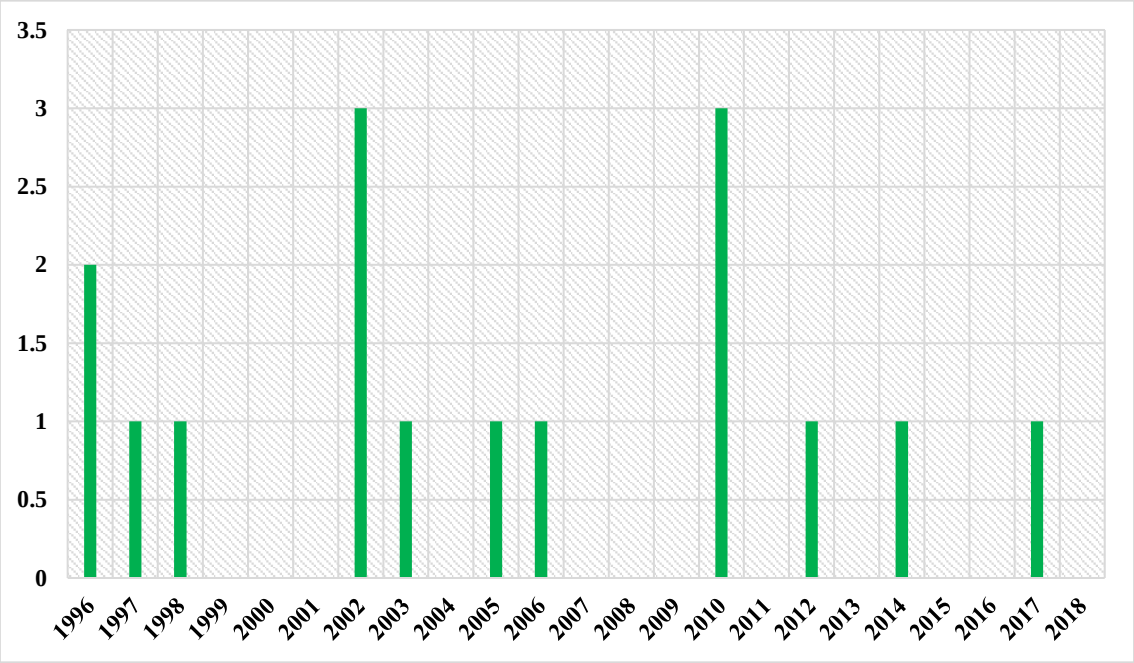
Figure 3 - STC raised against Brazil in SPS Committee



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

As observed for the case of TBTs, Brazil is not a very frequent target of STCs. The European Union (6) and Canada (3) are the two members that most raised STCs against Brazil.

2.1. PHARMACEUTICAL SECTOR

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 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[3]. 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[4] (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[5].

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.

2.2. 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[6].

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[3] The use of Portuguese language was not a spontaneous decision by ANVISA. It was determined by judicial decision, after the request of federal prosecutors.

[4] 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.

[5] *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.

[6] See all the estimate for registry in http://portal.anvisa.gov.br/fila-de-analise.

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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.

2.3. 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 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.

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- 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.

3. FINAL REMARKS

This part of the report aimed at identifying specific and practical problems in complying with regulations and mandatory conformity assessment procedures in Brazil, as well as standards in cases where they may affect the trade performance of domestic and foreign producers. Based on the conceptual dichotomy proposed in the introduction, most of the problems encountered in the regulation, standardization and conformity assessment of the sectors analyzed are short-term and cyclical difficulties, except in the case of machine control. NR 12, the main technical regulation of the machinery sector, presents challenges of a more structural nature, since NR 12 adopts safety criteria different from those found in other countries.

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PART B – AREGENTINA

In the second, the report analyses specific difficulties for trade in some Argentine sectors. The objective is to identify practical problems concerning international trade in general. The focus is the difficulties faced by foreign companies to export to Argentina, including Brazilian companies.

In this part of the report, the team of researchers evaluate the technical barriers and sanitary and phytosanitary measures for the selected sectors. As developed in the first part, some products, such as food and agriculture products, will be approached from the perspective of TBT and SPS. Not all products in the selected group of goods have any relevant regulatory barriers. Although many of them are directly affected by the performance of some specific agencies of the Argentine public administration, it is not possible to assert that they face a regulatory barrier to trade, in the sense provided in the TBT and SPS agreements of the WTO.

As clarified above for the first part, the barriers and problems described in the following pages represent general problems for Argentina's foreign trade. Some problems directly affect bilateral trade between Brazil and Argentina, but others indicate only a potential barrier that may create obstacles, at some point, in trade between the two countries. The identification of this potential trade barrier results from the fact that some of them are systemic problems that affect other Brazilian trading partners and that have not yet been fully solved by Brazil, although many of them have been dealt with in regulatory convergence initiatives whose results have not are completely clear. In cases where the problems have been addressed through convergence schemes or through some regulatory reform project that is not yet in force, these corrective actions will be highlighted in the text.

The identification of regulatory barriers to international trade imposed by Argentina are based on the compulsory provisions of the SPS and TBT Agreement, both inserted on the multilateral trade system centered WTO. As explained above, the declared aim of SPS is to protect human, animal and plant life or health. TBT also aims to fulfil legitimate objectives, such as national security and the prevention of deceptive practices. The provisions of TBT Agreement are applied to technical regulations, standards and standardization procedures and conformity assessment process. The articles of SPS Agreement apply to measures, which encompass a broader universe of governmental actions.

The barriers identified are limited to the sectors analyzed during the research project on regulatory coherence and convergence initially between Brazil, European Union and United States and later expanded to Argentina. The sectors analyzed are the following: electrical products, machinery, medical devices, pesticides, pharmaceutic products, plastic, processed food and vehicles.

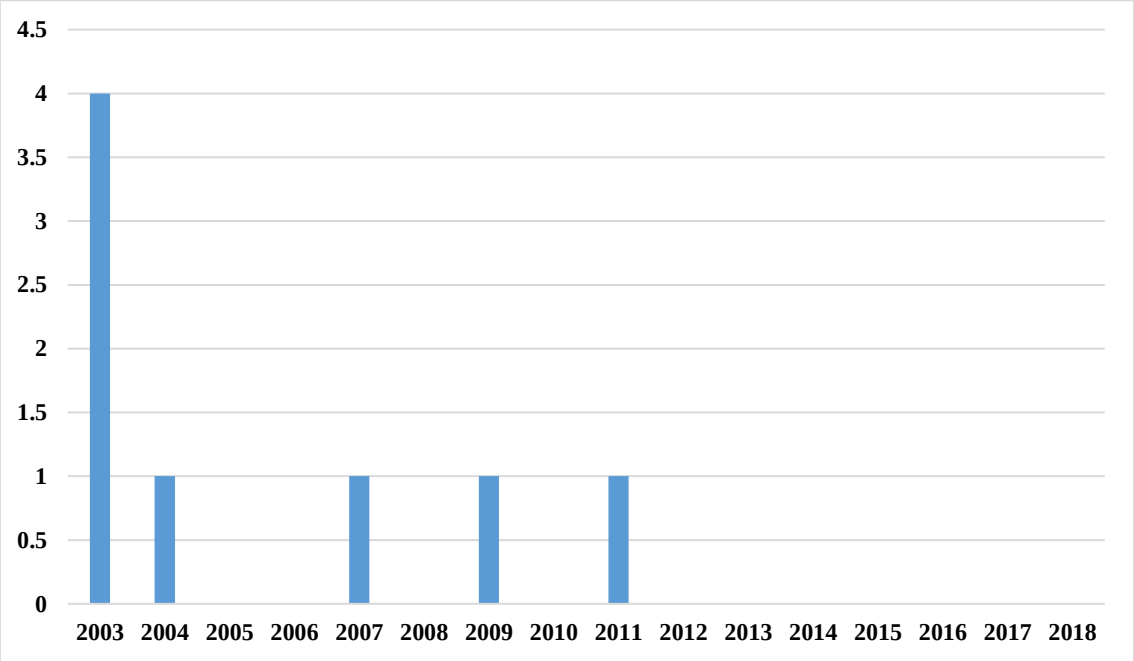
1. TECHNICAL BARRIERS TO TRADE

Argentine technical barriers to trade were identified according to the following sources: 2017 USTR report on Argentina, 2013 Trade Policy Review (TPR) of Argentina,

specific trade concerns (STCs) on the SPS Committee and on the TBT Committee and data collected on sectorial reports of the research on regulatory convergence.

The STCs raised against Argentina on the TBT Committee indicate the general framework of barriers imposed by the country against imported products. EU (7) is the member that raised the largest number of STCs against Argentina.

Figure 4 – STCs against Argentina in TBT Committee



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

The general barriers identified, present in more than one sector, are the following: conformity assessment procedures, certificates of origin and prohibition of the import of different used capital goods and the consumer goods price control. These barriers are explained on the paragraphs below.

1.1. ELECTRICAL PRODUCTS

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 Mercosur 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.

1.2. VEHICLES

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 the action on the accreditation of laboratories, the action on the committee of the automotive industry of Mercosur subgroup of work 3. These measures aim to identify coherence of positions on the sectorial fora.

1.3. MACHINERY

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. 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).

1.4. PHARMACEUTICAL PRODUCTS

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 Mercosur bilateral group, but no 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).

1.5. FOOD AND AGRICULTURE SECTOR

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 Mercosur one. This Mercosur 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).

2. SANITARY AND PHYTOSANITARY BARRIERS

The sources consulted to identify sanitary and phytosanitary barriers are the same ones consulted to identify technical barriers to trade, namely the 2017 USTR report on Argentina, the 2013 Trade Policy Review (TPR) of Argentina, specific trade concerns (STCs) on the SPS Committee and on the TBT Committee and data collected on sectorial reports of the research on regulatory convergence.

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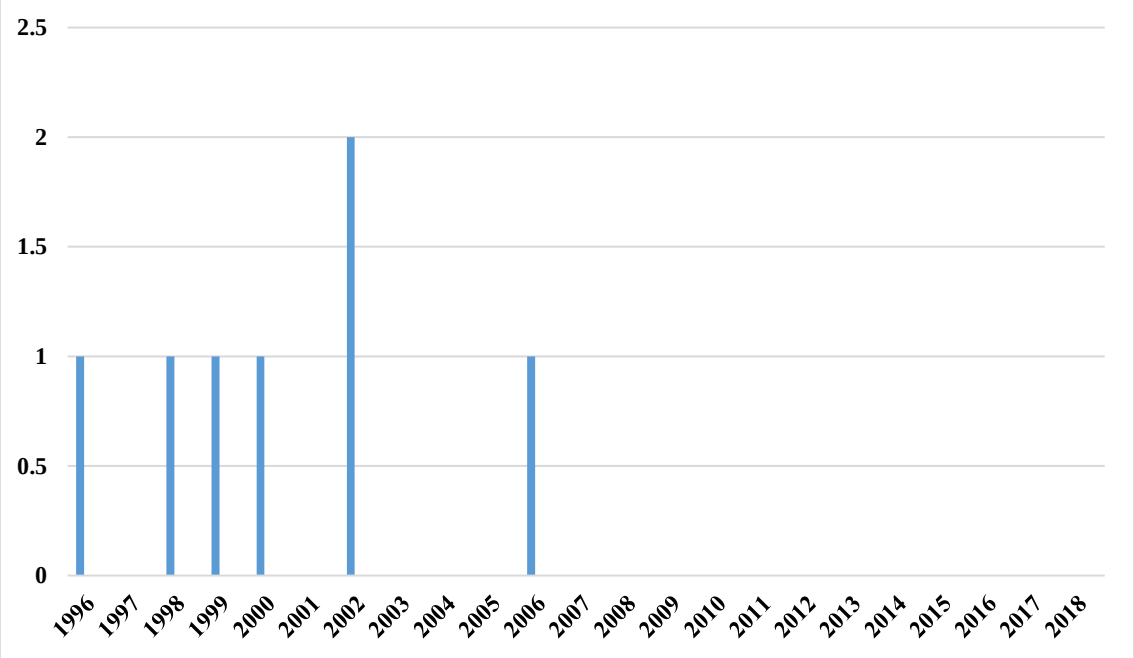
The STCs raised against Argentina in the SPS Committee indicate the general framework of barriers imposed by the country against imported products. EU (3) is the member that raised the largest number of STCs against Argentina.



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

The number of STCs against Argentina in the SPS Committee is relatively small. In addition, in recent years, no STC has been raised against the country.

Sanitary and phytosanitary barriers to trade are present on the following sectors: processed food, pesticides, vehicles and pharmaceutical products.

2.1. FOOD AND AGRICULTURE SECTOR

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 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

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Members imposing restrictions with the necessary documentation warranting their status as being BSE-free (WTO, 2001, p. 4-5)[7]. 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 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

[7] 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/

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.

On pesticides, the concession of the faculty to approve and deny allowances of production and sales of phytosanitary products on the whole country to the application authority of the registry implies a great margin of discretion and lacks objective criteria to determine the trade of phytosanitary products.

2.2. VEHICLES AND AUTO-PARTS

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.

2.3. PHARMACEUTICAL PRODUCTS

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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
- 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.

3. FINAL REMARKS

Argentina's regulatory, standardization and conformity assessment system creates some barriers to international trade. Some of these barriers are relevant even to closer trading partners. The same reasoning is valid for Brazil and its regulatory system. In the next part, these barriers will be evaluated, and the level of real convergence between Brazil and Argentina will be specified. Specific regulatory convergence initiatives will also be considered, including harmonization successes in Mercosur, as well as regional standardization work, through the work of the Mercosur Association for Standardization.

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PART C – BILATERAL CHALLENGES AND REGULATORY CONVERGENCE

At this point, the report focuses only on the international relations established between Brazil and Argentina so as to try to comprehend the possible level of convergence of their regulatory and standardization policies. This is a relevant effort since it 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.

At the end 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 standard 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 3 – 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 4 – 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 the sector, creation of standards by AMN.	Equally not internationally standardized.
Cosmetics	There is no relevant voluntary standard on	Few standards, but mainly based on ISO and	Equally not internationally

	cosmetics in Argentina.	few regional resolutions adopted by ANVISA.	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 5 – Level of convergence of regulation and standards

SECTOR	REGULATION	STANDARDS INTERNATIONALIZATION SIMILARITIES	CONVERGENCE
Electrical and electronic appliances and machinery	Partially Harmonized	Not similar.	No
Vehicles and auto-parts	Partially Harmonized	Similar: not internationalization	Low

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Cosmetics	Fully 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.

REFERENCES

BRAZIL. 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>. Accessed on: 12 jun. 2017.

BSI. Programa de Auditoria Única em Dispositivos Médicos – MDSAP. **BSI** Available at: <https://www.bsigroup.com/pt-BR/medical-devices/our-services/mdsap/>. Accessed on: 14 aug. 2018.

COMMISSION OF PRODUCTION AND TRADE BRAZIL-ARGENTINA. **I Ministerial Inform about the works of the Commission of Production and Trade Brazil-Argentina.** December/2017.

UNITED STATES TRADE REPRESENTATIVE. 2018 National Trade Estimate Report on Foreign Trade Barriers. **USTR**. Available at: < https://ustr.gov/sites/default/files/files/Press/Reports/2018%20National%20Trade%20Estimate%20Report.pdf>. Accessed on: 14 aug. 2018.

WORLD TRADE ORGANIZATION. Minutes of the meeting held on 14-15 march 2001. **WTO**. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=66296&CurrentCatalogueIdIndex=0&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 14 aug. 2018.

_____. Minutes of the meeting of 7 november 2003. **WTO**. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=52527,18658&CurrentCatalogueIdIndex=1&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 14 aug. 2018.

_____. Minutes of the meeting of 23 march 2004. WTO. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=84437,80442&CurrentCatalogueIdIndex=1&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 14 aug. 2018.

_____. Minutes of the meeting of 9 november 2007. **WTO**. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=80929,66700&CurrentCatalogueIdIndex=1&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 14 aug. 2018.

_____. Minutes of the meeting of 25-26 june 2009. **WTO**. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=75872&CurrentCatalogueIdIndex=0&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 14 aug. 2018.

_____. Minutes of the meeting of 10-11 november 2011. **WTO**. Available at: < https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=43462&CurrentCatalogueIdIndex=0&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True >. Accessed on: 14 aug. 2018.

_____. Summary of the meeting held on 12-13 march 1998. **WTO**. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=17667&CurrentCatalogueIdIndex=0&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True >. Accessed on: 14 aug. 2018.

_____. Summary of the meeting of 29-30 march 2006. **WTO**. Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=59739,57734&CurrentCatalogueIdIndex=1&FullTextHash=1&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 14 aug. 2018.

ANNEX 1 - STCs raised against Brazil in TBT Committee

Table 6 - STCs raised against Brazil in TBT Committee

IMS ID	TITLE	MEMBER(S) SUBJECT TO STC	MEMBER(S) RAISING STC	FIRST DATE RAISED	LAST DATE RAISED	NUMBER OF TIMES SUBSEQUENTLY RAISED
557	Brazil - Draft Technical Resolution n° 51, 7 April 2017 on labelling of beverages, wine, and grape derivatives (ID 557)	Brazil	European Union	20/06/2018		0
470	Brazil - Draft Ordinance Act Nº. 374, 27 November 2014 (Portaria SDA/MAPA 374/2014) Establishes quality requirements for wine and derivatives of grape and wine (ID 470)	Brazil	United States of America; European Union	17/06/2015	21/03/2018	8
478	Brazil - Toy Certification; Ordinance No. 89, No. 310 and draft administrative rule No. 321 (ID 478)	Brazil	Canada; United States of America; European Union	04/11/2015	21/03/2018	7
531	Brazil – Regulation RDC No 123 on food additives and processing aids authorised for use in wine of 4 November 2016 (ID 531)	Brazil	European Union	29/03/2017		0
443	Brazil – Draft Technical Resolution nº 69, 9 September 2014, Regarding the Requirement of Describing the Chemical Composition, in Portuguese, in the Label of Personal Hygiene Products, Cosmetics and Perfumes (ID 443)	Brazil	Canada; Mexico; European Union	05/11/2014	10/11/2016	6
429	Brazil - Higher Risk Medical Devices Good Manufacturing Practice (GMP) Certification (ID 429)	Brazil	India	18/06/2014		0
362	Brazil – Draft ANVISA Resolution on used, refurbished, rented and lent medical devices (ID 362)	Brazil	Switzerland; European Union	27/11/2012	19/03/2014	4
233	Brazil – Health Products (ID 233)	Brazil	Canada; Mexico; Singapore; Switzerland; United	25/06/2009	30/10/2013	10

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			States of America; European Union			
288	Brazil - Draft Resolution No. 112, 29 November 2010; maximum levels of tar, nicotine and carbon monoxide permitted on tobacco products and prohibition of additives (ID 288)	Brazil	Chile; Colombia; Cuba; Dominican Republic; Ecuador; Guatemala; Honduras; Indonesia; Jordan; Kenya; Malawi; Mexico; Mozambique; Nicaragua; Nigeria; Philippines; Russian Federation; Zimbabwe; Turkey; The former Yugoslav Republic of Macedonia; Tanzania; Zambia; European Union	24/03/2011	13/06/2012	4
273	Brazil - Instructions for Registration for Labels of Imported Products of Animal Origin (ID 273)	Brazil	Switzerland; United States of America; European Union	03/11/2010	20/03/2012	4
263	Brazil – Alcoholic Beverages (ID 263)	Brazil	Mexico; United States of America; European Union	24/03/2010	10/11/2011	5
290	Brazil - Canned Sardines - Ministerial Act Nº 406, 10 August 2010 (ID 290)	Brazil	Norway; Peru; European Union	24/03/2011	10/11/2011	2
308	Brazil – ANVISA Enforcement of CATEC Technical Opinions 4, 5, 6 and 7 of 21 December 2010 (ID 308)	Brazil	United States of America; European Union	15/06/2011		0
299	Brazil - Disposition (Portaria) nº 371, December 29th 2009 and Annex; INMETRO approves Conformity Assessment Requirements for Security of Electronic Appliances (ID 299)	Brazil	Mexico	24/03/2011		0
260	Brazil – Food registration and notification procedures (ID 260)	Brazil	Mexico	24/03/2010		0

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180	Brazil – Toys (ID 180)	Brazil	China; Malaysia; Thailand; United States of America; European Union	20/03/2008	05/11/2009	5
193	Brazil – Regulation on Identification and Quality Standards of Ethyl Alcohol and other Spirits (ID 193)	Brazil	Mexico; United States of America; European Union	01/07/2008	18/03/2009	2
161	Brazil – Registration requirements for medical devices (ID 161)	Brazil	Canada; Switzerland; United States of America; European Union	05/07/2007	05/11/2008	4
194	Brazil – Wines (ID 194)	Brazil	United States of America; European Union	01/07/2008	05/11/2008	1
153	Brazil – Mandatory certification of batteries (ID 153)	Brazil	European Union	21/03/2007	09/11/2007	2
102	Brazil – Decree on Beverages and Spirits (ID 102)	Brazil	Barbados; Dominican Republic; Jamaica; Trinidad and Tobago; United States of America; European Union	07/11/2003	16/06/2005	4
75	Brazil – Criteria and Procedures for the Import of Wines and Beverages Derived from Grapes and Wines (ID 75)	Brazil	European Union	20/06/2002	20/03/2003	2
62	Brazil – Labelling Disciplines for Food Products Containing GMOs (ID 62)	Brazil	United States of America	09/10/2001		0
26	Brazil – Certification of Pacifiers and Nursing Bottles (ID 26)	Brazil	European Union	15/09/1998	20/11/1998	1
27	Brazil – Technical Regulation on Labelling of Textile Products (ID 27)	Brazil	European Union	15/09/1998		0

Source: WTO. Elaborated by CCGI/EESP-FGV

ANNEX 2 – STCs raised against Brazil in SPS Committee

Table 7 - STCs raised against Brazil in SPS Committee

Number of Specific Trade Concern	Title	Member(s) raising the concern	Member(s) supporting the concern	Member(s) maintaining the measure	First date raised	Last date raised	Dates subsequently raised	Subject keywords	Status	Date reported as resolved
4	Measures related to BSE	Switzerland		Argentina; Australia; Austria; Belgium; Brazil; Canada; Chile; Czech Republic; France; Germany; Italy; Netherlands; Poland; Romania; Singapore; Slovak Republic; Slovenia; Spain; United States of America	01/05/1996	01/03/1999	10 times	Animal health; Human health; International Standards / Harmonization; Risk assessment; Zoonoses;	Resolved	01/03/1999
5	Import requirements for wine	European Union		Brazil	01/05/1996	01/03/1997	1 times	Equivalence; Food safety; Human health;	Resolved	16/10/2013
14	Restrictions on imported wheat	United States of America		Brazil	01/03/1997	01/07/2001	1 times	Plant health; Risk assessment;	Resolved	01/07/2001

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46	Import prohibition of coconut palms and related products	Philippines	Malaysia; Sri Lanka	Brazil	01/06/1998	01/09/1998	1 times	Plant health; Risk assessment;	Not reported	
126	Import requirements for seed potatoes	Canada; European Union		Brazil	01/06/2002	01/06/2004	3 times	Plant health; Risk assessment; Transparency;	Resolved	01/06/2004
140	Imports of live ostriches	European Union		Brazil	01/11/2002		0 times	Animal health; International Standards / Harmonization;	Resolved	13/10/2010
141	Pest risk assessments for imports of plant origin	Canada	Australia; European Union; New Zealand; Peru; United States of America	Brazil	01/11/2002		0 times	Plant health; Risk assessment;	Resolved	02/11/2017
156	Notification G/SPS/N/BRA/74 and G/SPS/N/BRA/75 on BSE-related measures	Canada	United States of America	Brazil	01/04/2003	01/06/2003	1 times	Animal health; Human health; International Standards / Harmonization; Risk assessment; Zoonoses;	Resolved	01/09/2004
218	Lack of recognition of regionalization and disease-free status for classical swine fever	European Union		Brazil	01/06/2005		0 times	Animal health; International Standards / Harmonization; Pest or Disease free Regions / Regionalization;	Not reported	
237	Lack of regionalization for Newcastle disease and restrictions on live birds	European Union		Brazil	01/03/2006		0 times	Animal health; Human health; Zoonoses; Pest or Disease free Regions /	Not reported	

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								Regionalization;		
308	Restrictions on bovines and bubalines for reproduction	Colombia		Brazil	20/10/2010		0 times	Animal health;	Resolved	16/10/2013
309	Labelling of products of animal origin	European Union		Brazil	20/10/2010		0 times	Food safety; Sufficiency of scientific evidence;	Not reported	
310	Measures on canned sardines	Morocco	European Union	Brazil	20/10/2010		0 times	Food safety; Technical Barriers to Trade;	Not reported	
344	Measures on shrimp	Ecuador		Brazil	18/10/2012	13/07/2017	5 times	Animal health; Risk assessment; Territory protection;	Not reported	
377	Brazil's regulation on international certificates for fish and fishery products	China		Brazil	09/07/2014		0 times	Animal health; Control, Inspection and Approval Procedures; Food safety; Undue delays;	Not reported	
423	Brazil's measures on bananas	Ecuador		Brazil	13/07/2017	02/11/2017	1 times	Risk assessment; Plant health;	Not reported	

Source: WTO. Elaborated by CCGI/EESP-FGV

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ANNEX 3 - STCs raised against Argentina in TBT Committee

Table 8 - STCs raised against Argentina in TBT Committee

IMS ID	TITLE	MEMBER(S) SUBJECT TO STC	MEMBER(S) RAISING STC	FIRST DATE RAISED	LAST DATE RAISED
325	Argentina - Resolution 453/2010 establishing mechanisms in order to eliminate dangers arising from the use of inks with a high lead content in graphic products (ID 325)	Argentina	United States of America; European Union	10/11/2011	13/06/2012
232	Argentina Testing Requirements for Imported Toys (ID 232)	Argentina	China; United States of America; European Union	25/06/2009	05/11/2009
174	Argentina Measures affecting market access for pharmaceutical products (ID 174)	Argentina	Chile; Colombia; Paraguay	09/11/2007	25/06/2009
100	Argentina Legal Appellation System for Wine Products (ID 100)	Argentina	European Union	07/11/2003	04/11/2004
107	Argentina MERCOSUR Regulation on Definitions Relating to Alcoholic Beverages other than Fermented (ID 107)	Argentina	Barbados; Cuba; Dominican Republic; Jamaica; Mexico; Trinidad and Tobago; United States of America; European Union	01/07/2004	04/11/2004
98	Argentina Amendment of the Argentine Food Code on Olive Oil (ID 98)	Argentina	European Union	07/11/2003	23/03/2004
99	Argentina Labelling of Pre-Packaged Food (ID 99)	Argentina	European Union	07/11/2003	23/03/2004
101	Argentina Resolution on Sulphate Content in Wine and Wineries (ID 101)	Argentina	European Union	07/11/2003	23/03/2004

Source: WTO. Elaborated by CCGI/EESP-FGV

ANNEX 4 – STCs raised against Argentina in SPS Committee

Table 9 - STCs raised against Argentina in SPS Committee

Number of Specific Trade Concern	Title	Member(s) raising the concern	Member(s) supporting the concern	Member(s) maintaining the measure	First date raised	Last date raised	Dates subsequently raised	Subject keywords	Status	Date reported as resolved
4	Measures related to BSE	Switzerland		Argentina; Australia; Austria; Belgium; Brazil; Canada; Chile; Czech Republic; France; Germany; Italy; Netherlands; Poland; Romania; Singapore; Slovak Republic; Slovenia; Spain; United States of America	01/05/1996	01/03/1999	10 times	Animal health; Human health; International Standards / Harmonization; Risk assessment; Zoonoses;	Resolved	01/03/1999
38	Temporary prohibition of fresh pork and products	European Union		Argentina	01/03/1998		0 times	Animal health; Pest or Disease free Regions / Regionalization;	Resolved	13/10/2010

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60	Import restrictions on bovine semen and embryos, milk and milk products	European Union	South Africa; Switzerland	Argentina	01/03/1999	01/10/2005	6 times	Animal health; Food safety; Human health; Zoonoses;	Resolved	01/02/2006
84	Import restrictions affecting BSE-free countries	Bulgaria; Croatia; Czech Republic; Estonia; Latvia; Poland; Romania; Slovak Republic; Slovenia	European Union; United States of America	Argentina; Australia; Canada; Korea, Republic of; New Zealand; United States of America	01/03/2001	01/07/2001	1 times	Animal health; Food safety; Human health; Zoonoses;	Not reported	
125	BSE related measures	Canada	United States of America	Argentina	01/06/2002	01/04/2003	2 times	Animal health; Human health; Risk assessment; Zoonoses;	Resolved	01/09/2004
138	Pest risk assessment requirements	United States of America	Canada; European Union; New Zealand	Argentina	01/11/2002		0 times	Animal health;	Resolved	16/10/2013
236	Restrictions on beef exports under the Hilton Quota	European Union		Argentina	01/03/2006		0 times	Animal health; Food safety; Human health; Other concerns; Zoonoses;	Resolved	13/10/2010

Source: WTO.

ANNEX 5 – Vehicles: Brazil and Argentina[8]

Table 10 – Number of Regulations in Brazil and Argentina

	ARGENTINE	BRAZIL
Safety	24	26
Sound	5	3
Emission	5	12
Efficiency	1	2
Total	35	43

Source: LOUREIRO.

Table 11 – Situation of regulation in Brazil and Argentina

TYPE	NUMBER OF REGULATIONS	COMPARISON	PRACTICAL REQUIREMENTS
Group 1	14 Regulations	Equivalents	Homologation in the country of origin may be accepted in the country of destination as proof of conformity
Group 2	7 Regulations	Small differences	Delivery of additional reports
Group 3	6 Regulations	Not comparable	

Source: Loureiro.

Table 12 – Differences in the regulation (Group 2)

DESCRIPTION OF REGULATION	ARGENTINA	BRAZIL
Windscreen wiper	Vibration test at 160 km / h	Vibration rate at 120 km / h
Horn	Noise limit 87 to 104 dB (A)	Noise limit 93 to 104 dB (A)
Interior and exterior rearview mirrors	Distance between the attachment and the articulation of the external mirror ≤ 50 mm	Distance between the attachment and the articulation of the external mirror ≤ 70 mm
Front impact	Applies to all categories passenger cars	Does not apply to all categories of passenger cars
Seat belt and their anchorages	3-point belt for passenger cars <2,5 ton	3-point belt for all passenger cars
Seat anchors	ECE reference standard 2017	1973 ECE reference standard
Seat anchors	Equal requirement Brazil except static test	Additional Static Testing

Table 13 - Differences in the regulation (Group 3)

DESCRIPTION OF REGULATION	ARGENTINA	BRAZIL
Anti-crushing (glass with electric drive)	No regulations	CONTRAN
Auxiliary wheel (spare tire)	No regulations	CONTRAN
Seat belt warning device	Decree 32/2018	No regulations
Rear Impact	No regulations	CONTRAN
Fuel tank and its connections	Static test	CONTRAN (dynamic test)
Lighting and signaling system	Decree 32/2018 | DRL and side direction indicator required	CONTRAN non-mandatory side direction indicator

[8] Based on presentation of José Loureiro (2018): https://ccgi.fgv.br/sites/ccgi.fgv.br/files/u5/Anais-Conferencia-Dialogo%20Regulatorio-BR-ARG-11-6-18.pdf

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