



Multiple Framework Contract FWC FPI PSF 2015
Lot 4 "Market Access and Trade & Investment Agreement Negotiation & Implementation"

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

DELIVERABLE 2
**BRAZIL – CHEMICAL SECTOR – BASIC
CHEMICAL PRODUCTS**



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Multiple Framework Contract FWC FPI PSF 2015

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



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

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BRAZIL – CHEMICAL SECTOR – BASIC CHEMICAL PRODUCTS

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TABLE OF CONTENTS

1. OVERVIEW.....	4
2. MAIN REGULATION AND AUTHORITIES.....	5
2.1. International Conventions	6
2.2. Notifications to the WTO	7
3. STANDARDS AND SUPPORTING STANDARDS	9
4. CONFORMITY ASSESSMENT PROCEDURES, CERTIFICATION, REGISTRY AND OVERSIGHT	11
5. MERCOSUL REGULATION.....	13
6. MAIN GOVERNMENT AND PRIVATE ACTORS IN THE SECTOR	13
ANNEX.....	14

List of Tables and Figures

TABLE 1 - BASIC CHEMICAL PRODUCTS (MAIN REGULATION).....	5
TABLE 2 - ABNT STANDARDS FOR CHEMICAL PRODUCTS.....	9
TABLE 3 - IMPORTANT NOTIFICATIONS TO SPS COMMITTEE.....	14
TABLE 4 - IMPORTANT NOTIFICATIONS TO TBT COMMITTEE.....	15
FIGURE 1 - NOTIFICATIONS TO SPS AND TBT COMMITTEES	7
FIGURE 2 - TBT: NOTIFICATIONS PER YEAR (2001- 2016: HS: 28 AND 29).....	8
FIGURE 3 - SPS: NOTIFICATIONS PER YEAR (2001- 2016: HS: 28 AND 29).....	8
FIGURE 4 - ABNT STANDARDS ON CHEMICAL PRODUCTS	9

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LIST OF ABBREVIATIONS

ABIQUIM Brazilian Chemical Industry Association
ABIFINA Brazilian Association of Fine Chemical Industry
ABNT Brazilian Association of Technical Standards
ACE Economic Complementation Agreement
AFFEE Authorization of Manufacture for Exclusive Purpose of Export
ALADI Latin American Integration Association
ANVISA Brazilian Health Regulatory Agency
ANTT Brazil National Land Transport Agency
ART Technical liability annotation
ASTM American Society for Testing and Materials
CAMEX Brazil Foreign Trade Chamber
CAP Mercosul Common Automotive Policy
CEN European Committee for Standardization
CENELEC European Committee for Electrotechnical Standardization
CMC Common Market Council, Mercosul
CMED Regulatory Chamber of Medicines Market
CNI Brazil National Confederation Industry
CNA Brazilian Confederation of Agriculture and Livestock
CNTT Brazilian National Thematic Tripartite Commission
CONAMA Brazilian National Environmental Council
CORPROSAL Commission on Health Products
DECEX Department of Foreign Trade Operations, MDIC
DFPC Controlled Products Oversight Board
EFTA European Free Trade Association
FDI Foreign Direct Investment
FIESP Federation of Industries of the State of São Paulo
FNDCT Brazilian Fund of Scientific and Technological Development
GHS Globally Harmonized System of Classification and Labeling of Chemicals
GMC Common Market Group, Mercosul
IAF International Accreditation Forum
IEC International Electrotechnical Commission
IBAMA Brazilian Institute of the Environment and Renewable Natural Resources
IBDF Brazilian Institute for Forest Development
ILAC International Laboratory Accreditation Cooperation
ILO International Labor Organization
INMETRO Brazilian National Institute of Metrology, Quality and Technology
ISO International Standardization Organization
MCR Adjusts the General Norms
MDIC Brazil Ministry of Industry, Foreign Trade and Services
MERCOSUL Common Market of the South
MMA Brazil Ministry of Environment
MRE Brazil Ministry of Foreign Affairs
NIP National Implementation Plan
NM Mercosul Standard
NR Regulatory Standard
PHPC Personal Hygiene, Perfumery and Cosmetics
POP Persistent Organic Pollutants
PRONAF Brazilian National Program to Strengthen Family Agriculture
RDC Resolution of the Board of Directors
SDCI Secretariat of Industrial Development and Competitiveness, MDIC
SGT Mercosul Working Subgroup, GMC, Mercosul
SIEMA Brazilian National Environmental Emergency System
SUS Unified Health System
TBT Technical Barriers to Trade
UNECE United Nations Economic Commission for Europe
WTO World Trade Organization

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

Deliverable 2

BRAZIL – CHEMICAL SECTOR – BASIC CHEMICAL PRODUCT

1. OVERVIEW

Brazil has a deficit of trade in chemical products. The value of the deficit has grown in recent years. In 2015, Brazil exported US\$ 13.1 billion in chemicals. Imports of chemicals totalled US\$ 39.6 billion. The deficit in the Brazilian trade balance of chemical products registered in the same year was US\$ 26.5 billion. In 1991, the same deficit was US\$1.5 billion¹.

Basic chemicals are important inputs to the industrial sector, representing almost half of industrial production in this sector and involving a wide range of products used in diverse sectors of the industry. Amongst economic blocs and regions, NAFTA countries are the main buyers of basic chemicals from Brazil (HS 28 and 29), with nearly US\$ 2 billion in 2016. For the European Union and Mercosul, Brazil exports, respectively, USD 525 million and USD 445 million. The largest origins of Brazilian imports of basic chemical products are, respectively, the European Union (US\$ 2,7 billion) and NAFTA (US\$ 2,5 billion) as AliceWeb data shows for 2016.

2. MAIN REGULATION AND AUTHORITIES

Regulations and standards for the basic chemicals sector deal with safe handling and transportation of these products. Brazil is a participant of important international conferences related to the sector and accepts many international standards governing these products. Brazil internalizes many of these provisions, which shows observance of international rules and guidelines in place.

The main bodies responsible for regulating the sector are the Brazilian Health Regulatory Agency (ANVISA), the Ministry of Agriculture and Livestock (MAPA), and the Ministry of Environment (MMA), the most relevant ones.

Table 1 - Basic Chemical Products (Main Regulation)

<i>Legal Requirement</i>	<i>Details</i>
Decree n. 2,657/1998	It promulgates ILO Convention No. 170 on Safety in the Use of Chemicals at Work, signed at Geneva on 25 June 1990.
Decree n. 96,044/1988	Approves the regulation of road transport of dangerous products. Determines the obligations of the carrier and the transport contractor
Resolution ANTT n. 420/2004	Approves the supplementary instructions to the regulation of the inland transport of dangerous products.

¹ BRAZILIAN CHEMICAL INDUSTRY ASSOCIATION – ABIQUIM (2017). O desempenho da indústria química em 2017, Report. Available at <https://abiquim.org.br/uploads/guias_estudos/desempenho_industria_quimica_2017.pdf> (accessed on 20 February 2018).

Federal Law n. 10,357/2001	It establishes provisions of control and inspection on chemical products that directly or indirectly can be destined to the illicit elaboration of narcotic, psychotropic substances or that determine physical or psychic dependence, and other measures.
Decree n. 4,262/2002	Regulates Federal Law N. 10,357 /2001, which establishes rules for control and supervision of chemical products that may be directly or indirectly destined to the illicit manufacture of narcotic, psychotropic substances or that determine physical or psychic dependence, and other measures.
Ordinance MJ N. 1,274/2003	The Chemicals listed in Lists I, II, III, IV and in their respective addenda, listed in Annex I, shall be subject to control and inspection by the Federal Police Department, in accordance with this ordinance.
Decree n. 38,356/1998 Federal Law n. 9,921/1993 (Rio Grande do Sul State)	Packaging, containers, wrappings and the like, when intended for the wrapping of dangerous products, shall be compulsorily returned to the manufacturer of those products. Reuse of these containers is prohibited for any other purpose.
Ordinance INMETRO n. 364/2007	Determines that chemicals and their derivatives, intended for the institutional and / or industrial line, marketed in drums or cylinders, should have their quantitative indication expressed in legal mass units, their multiples and submultiples, written in full or with the obligatory symbols in the international system of units (SI), according to metrological legislation in force.

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

However, other bodies are also important depending on the kind of product regulated. The hazard level and the purpose (primary or secondary) of the product determine the body responsible for its regulation. For example, a specific section of the Army sets regulation and oversight of dangerous and dual-use substances (civil and military). The Federal Police has the authority to inspect and annul the entry of products that are inputs for the production of psychotropic substances. The Brazilian Land Transport Agency (ANTT) and the Ministry of Transport have the authority to regulate inland transport of these goods.

2.1. International Conventions

Brazil is part of three main treaties on chemical safety: the *Basel Convention (1989)* controlling transboundary movements of hazardous wastes and their disposals; the *Rotterdam Convention (1998)* on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade; and the *Stockholm Convention* protecting human health and the environment from persistent organic pollutants. These treaties' concerns involve the quality of food, impacts of additives on human health and the occupational exposure to chemical substances.

Brazil ratified the Basel convention in 1992² and adopted measures in order to implement the rules of the treaty. The country has a national definition of waste used for the purpose of transboundary movements and adopts a definition of hazardous waste in the national legislation³. Additional wastes are regulated or controlled as hazardous pursuant to article 1(1) (b). Brazil prohibits the importation of hazardous wastes and wastes considered as rejects in article 49 of Federal Law n. 12,305/2010.

Brazil ratified the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Agrochemicals and Dangerous Chemicals International Trade Object*, in 2004. The promulgation of the Rotterdam Convention in Brazil took place through Decree n. 5,360/2005. The National Designated Authorities for matters related to the Rotterdam Convention are: the Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA), the Ministry of Foreign Affairs (MRE) and the MMA. The Convention aims to control the transboundary movement of hazardous chemicals, based on the principle of prior consent of the importing country and shared responsibility in international trade in these products.

² The agreement was fully internalized through Decree No. 875 of July 19, 1993, and is also regulated by CONAMA Resolution n. 452/2012.

³ The definition is in the Article 3 of the Federal Law n. 12,305/2010.

The *Stockholm Convention* was ratified in 2004⁴. The MMA oversees the convention implementation plan within domestic institutions respective competences. The process for developing the current National Implementation Plan (NIP) of the Convention followed the Guidance for Developing a National Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants (POPs). It sets forth the following stages: i) establishment of the mechanisms for process coordination and organization, ii) development of POP inventories and analysis of national infrastructure and capacity, iii) establishment of priorities and objectives, iv) formulation of the national implementation plan and the specific POP action plans and v) endorsement of the NIP by stakeholders⁵.

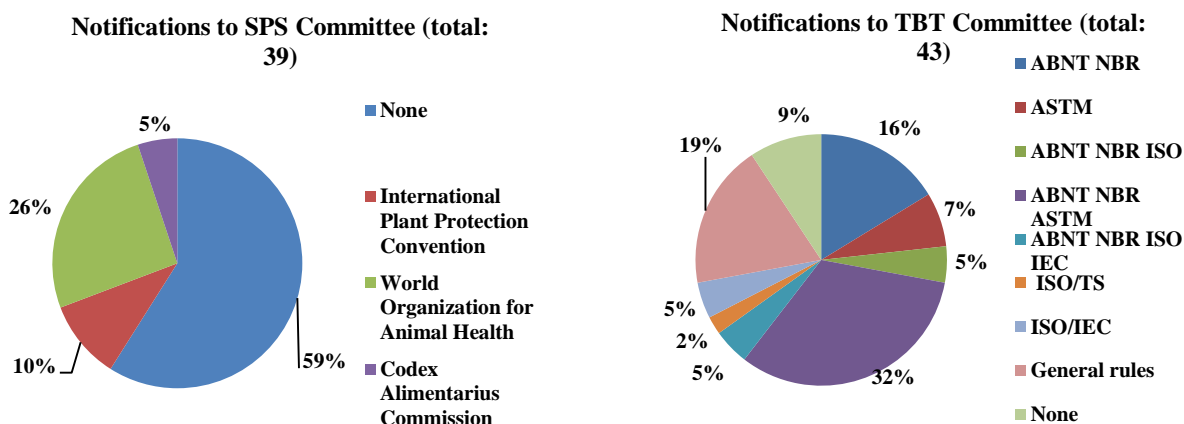
The development of the National Implementation Plan aims to meet the obligations under the Stockholm Convention for sound chemical management. They are: i) to reduce risks to human health and environment caused by POPs; ii) to contribute to improving chemicals management in Brazil, establishing broad governance on the issue; iii) to strengthen and expand the capacities of institutions for chemical management and pollution control; and iv) to raise public awareness and educate the population on the harmful effects and risks associated to chemicals so that it too can be a part of management improvement process⁶.

2.2. Notifications to the WTO

Brazil notifies the regulations on the different kinds of chemical products. In such notifications, it is possible to identify the standards that support the regulations.

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

Figure 1 - Notifications to SPS and TBT Committees



⁴ Brazil approved the text of the Convention through Legislative Decree n. 204/2004, and promulgated the text of the Convention in 2005, via Decree n. 5,472/2005.

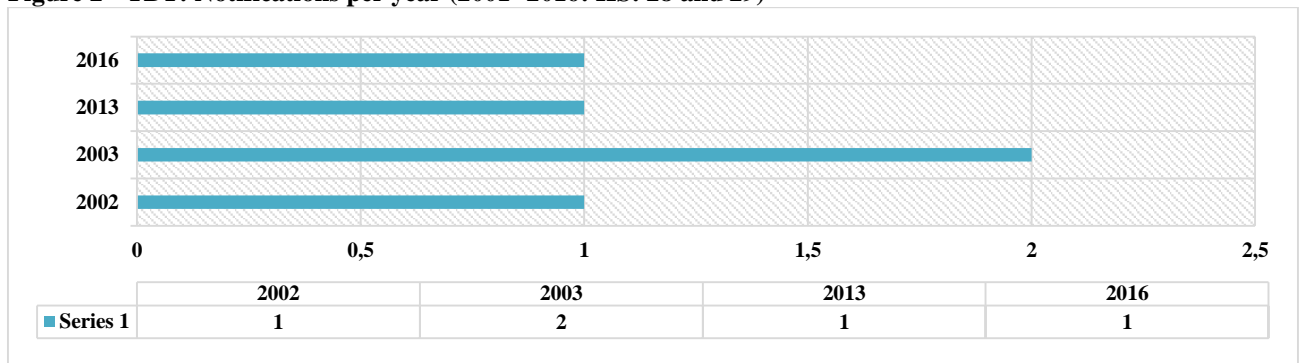
⁵ BRAZIL. MINISTRY OF ENVIRONMENT. **National implementation plan Brazil:** Convention of Stockholm. Brasília: MMA, 2015. Available at: http://www.mma.gov.br/images/arquivo/80037/Convencao%20de%20Estocolmo/Plano%20de%20Implementacao%20NIP/Plano_NIP_Ingles_impressao_final.pdf (accessed on 26 February 2018), p. 36.

⁶ *Ibid idem* p. 38.

The notifications to the SPS and TBT Committees indicate some international standard followed by the regulations. For TBT, standards used in Brazilian regulations follow international standards, especially ASTM, ISO and IEC. The standards ABNT NBR correspond to 16% of the total notified to the TBT Committee. Such standards are issued by the Brazilian organization ABNT, without explicitly endorsing any international standard.

This does not constitute the universe of regulation for the sector, but certainly indicate the main agencies that deal with the issue.

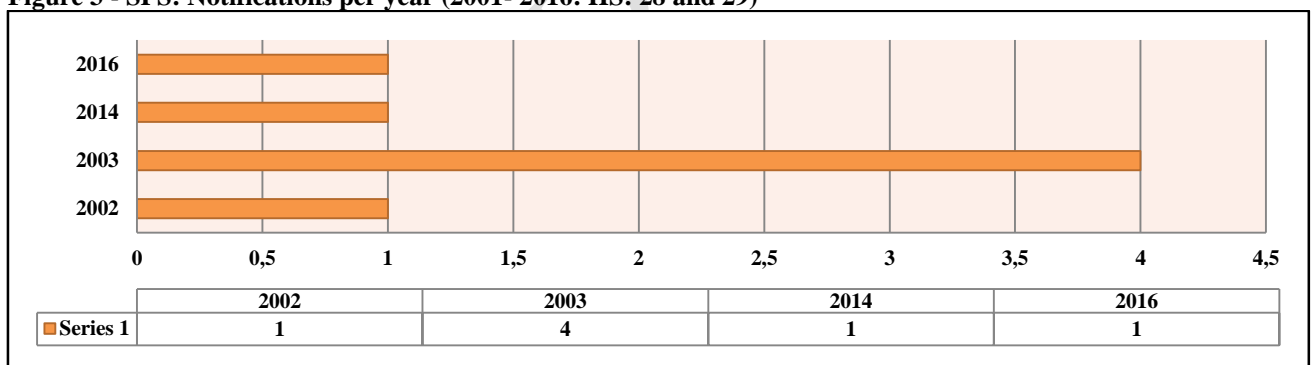
Figure 2 - TBT: Notifications per year (2001- 2016: HS: 28 and 29)



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

The SPS Committee was notified seven times since 2002. In 2003, Brazil notified four times, which differs from the pattern of less than one notification per year.

Figure 3 - SPS: Notifications per year (2001- 2016: HS: 28 and 29)



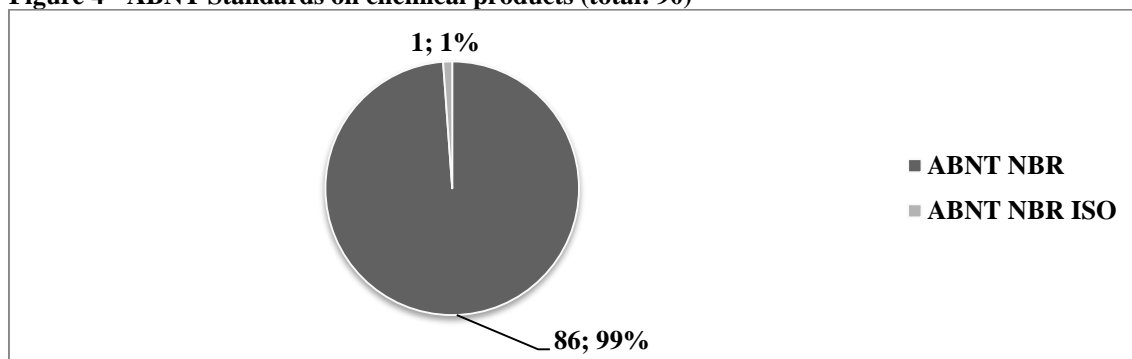
Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

Important issues are regulations that prescribe mandatory information on the packaging of the products, as well as mandatory procedures for registration at the sanitary surveillance body.

3. STANDARDS AND SUPPORTING STANDARDS

The vast majority of ABNT standards⁷ on chemical products are not explicitly based on international standards. In a list of almost 90 ABNT NBR standards, only one is directly based on an ISO standard⁸.

Figure 4 - ABNT Standards on chemical products (total: 90)



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

Table 2 - ABNT standards for chemical products

STANDARD
ABNT NBR 11589:2017 Preparation, standardization and storage solutions for chemical analysis
ABNT NBR 15784:2014 Amendment 1:2017 Chemicals used for treatment of water intended for human consumption-health effects requirements
ABNT NBR 15784:2017 Chemicals used for treatment of water intended for human consumption — health effects — requirements
ABNT NBR 8517:2017 Polyurethane flexible foam-determination of air passage through the foam
ABNT NBR 10459:2017 Adhesives-glue fluency assessment at constant temperature (<i>creep test</i>)
ABNT NBR 10790:2015 Amendment 1:2016 Lime, hydrated in aqueous suspension — application in basic sanitation — technical specification, sampling and test methods
ABNT NBR 10790:2016 Lime, hydrated in aqueous suspension — application in basic sanitation — technical specification, sampling and test methods
ABNT NBR 14961:2016 Polyurethane flexible foam-determination of ash content
ABNT NBR 8910:2016 Polyurethane flexible foam-determination of resistance to compression
ABNT NBR 9429:2016 Polyurethane flexible foam-determination of dimensions
ABNT NBR 16545:2016 High thickness coatings, polyurea system polyurea/polyurethane hybrids and-performance requirements
ABNT NBR 9223:2016 Adhesives-determination of flow time by DIN Cup
ABNT NBR 16488:2016 Polyaluminium chloride (PAC) — application in basic sanitation — technical specification, sampling and test methods
ABNT NBR 8515:2016 Polyurethane flexible foam-determination of tensile strength
ABNT NBR 9176:2016 Polyurethane flexible foam-determination of indentation force
ABNT NBR 10442:2015 Ethylenic glycols — requirements
ABNT NBR 11335:2015 Mono ethylene glycol for polyester fiber-Requirements
ABNT NBR 16430:2015 Organic compounds-determination of acidity

⁷ A relevant number of technical regulations (especially those on conformity assessment procedures) refers to supporting standards, usually issued by **ABNT**, a private body. There are different kind of supporting standards issued by ABNT that goes from a fully original standard developed under its Standardizing Committees (CB) to those based on international standards, mainly ISO and IEC. Usually, (i) If it is a standard identical to an international standard, it will appear, for example, as *ABNT NBR ISO n° XXX*; (ii) If it is based on an international standard, a reference to this international standard will be in the preamble of the standard; and (iii) If it is an original standard, it will appear as *ABNT NBR n° XXX*. ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website. ABNT Catalog with all searching tools is available [here](#). In the same way as CEN, CENELEC, ASTM and other standardizing bodies, the interested party have to pay a fee in order to have granted full access to the content of standards issued by ABNT. The costs vary depending on the standard.

⁸ ABNT NBR ISO 15605:2015 Adhesives-Sampling.

ABNT NBR 14725-3:2012 Errata 3:2015 Chemicals-information on safety, health and environment Part 3: Labelling
ABNT NBR 8537:2015 Flexible polyurethane foam--determination of density
ABNT NBR 8619:2015 Polyurethane flexible foam-determination of resilience
ABNT NBR 8797:2015 Polyurethane flexible foam — determination of compressive permanent deformation
ABNT NBR 8916:2015 Adhesives and sealants--determination of specific mass — picnometre Method
ABNT NBR 9393:2015 Melt adhesives-determination of viscosity — Brookfield viscometer method
ABNT NBR 15725:2015 Adhesives-structural bonding system in automotive glass replacement-requirements and test methods
ABNT NBR 9178:2015 Polyurethane flexible foam-determination of burning features
ABNT NBR ISO 15605:2015 Adhesives-Sampling
ABNT NBR 11887:2015 Calcium hypochlorite-application in basic sanitation-technical specification, sampling and test methods
ABNT NBR 9177:2015 Polyurethane flexible foam-determination of dynamic fatigue
ABNT NBR 9224:2015 Adhesives-determination of ash content
ABNT NBR 9683:2015 Adhesives and sealants-determination of relative density
ABNT NBR 15163:2015 Adhesives-determination of time open
ABNT NBR 8516:2015 Polyurethane flexible foam-determination of tearing resistance
ABNT NBR 8877:2015 Adhesives-determination of solids
ABNT NBR 14725-4:2012 Amendment 1:2014 Chemicals-information on safety, health and environment Part 4: material safety data sheet (MSDS) chemicals
ABNT NBR 14725-4:2014 Chemicals-information on safety, health and environment Part 4: material safety data sheet (MSDS) chemicals
ABNT NBR 7353:2014 Aqueous solutions-determination of pH glass electrode
ABNT NBR 16725:2011 Amendment 1:2014 Chemical residue-information on safety, health and Environment-Safety Data Sheet for chemical residues (FDSR) and labelling
ABNT NBR 16725:2014 Chemical residue — information on safety, health and environment — Plug safety data of chemical waste (FDSR) and labelling
ABNT NBR 9277:2014 Adhesives-determination of viscosity — Brookfield viscometer method
ABNT NBR 9424:2014 Melting adhesives-determination of the softening point--ring and ball Method
ABNT NBR 16256:2014 Determination of theoretical calculation of volatile organic compound (VOC) in adhesives and sealants — Leed Method
ABNT NBR 16257:2014 Determination of theoretical calculation of volatile organic compound (VOC) in adhesives and sealants — MIR Method
ABNT NBR 9278:2013 Adhesives and sealants-determination of flow time — pressure flowmeter method
ABNT NBR 9908:2013 Elastomeric base adhesive — determination of shear adhesion strength for
ABNT NBR 16240:2013 Rigid polyurethane foam system for in situ applications by spray on roofing
ABNT NBR 9684:2013 Adhesives-determination of time open
ABNT NBR 12014:2013 Organic compounds--determination of boiling point
ABNT NBR 11176:2013 Aluminium sulphate for use in basic sanitation — technical specification, sampling and testing methods
ABNT NBR 14725-3:2012 Errata 2:2013 Chemicals-information on safety, health and environment Part 3: Labelling
ABNT NBR 14725-3:2012 Errata 1:2012 Chemicals-information on safety, health and environment Part 3: Labelling
ABNT NBR 5764:2012 Liquid industrial chemicals at one stage — Sampling
ABNT NBR 11334:2012 Mono ethylene glycol for electrolytic capacitors — requirements
ABNT NBR 8333:2012 Glycolic Trieters — determination of dieters — gas chromatography method
ABNT NBR 9003:2012 Mono ethylene glycol — determination of diethylene glycol — gas chromatography method
ABNT NBR 7454:2012 Mono ethylene glycol — determination of resistance to voltage of 1 000 V
ABNT NBR 9906:2012 Ethyl glycol acetate — determination of ethyl glycol — gas chromatography method
ABNT NBR 14725-3:2012 corrected version 3:2015 Chemicals-information on safety, health and environment Part 3: Labelling
ABNT NBR 11590:2012 Glycolic Triéteres-determination of the freezing point
ABNT NBR 6308:2012 Industrial aromatic hydrocarbons and related materials-determination of relative density-picnômetro method
ABNT NBR 8911:2012 Solvents-determination of non-volatile material
ABNT NBR 6309:2011 Ethylene glycols — determination of aldehydes and ketones
ABNT NBR 7140:2011 Mono ethylene glycol — determination of ultraviolet transmittance
ABNT NBR 7342:2011 Mono ethylene glycol – determination of chlorides
ABNT NBR 7343:2011 Mono ethylene glycol — determination of aldehydes combined
ABNT NBR 7448:2011 Ethylene glycols and propylenic-determination of iron content
ABNT NBR 9239:2011 Adhesives-Terminology
ABNT NBR 14725-2:2009 Errata 1:2010 Chemicals-information on safety, health and environment Part 2: hazard classification system
ABNT NBR 5758:2010 Organic and inorganic liquids and solids — determination of water — General by Karl Fischer reagent Method
ABNT NBR 14725-1:2009 Errata 1:2010 Chemicals-information on safety, health and environment Part 1: terminology
ABNT NBR 14725-1:2009 EN Chemicals-Information about safety, health and environment Part 1: Terminology
ABNT NBR 14725-1:2009 corrected version: 2010 Chemicals-information on safety, health and environment Part 1: terminology
ABNT NBR 14725-2:2009 corrected version: 2010 Chemicals-information on safety, health and environment Part 2: hazard classification system
ABNT NBR 5769:2009 Clear liquids-determination of color-Platinum-cobalt scale (Pt-Co)
ABNT NBR 7141:2009 Mono ethylene glycol and diethylene glycol-determination of color after heating with hydrochloric acid-Platinum-cobalt Scale (Pt-Co)
ABNT NBR 7142:2009 Mono ethylene glycol-determination of color after heating 4:00-Platinum-cobalt Scale (Pt-Co)
ABNT NBR 7453:2009 Mono ethylene glycol-determination of electrical conductivity

ABNT NBR 8675:2008 Mono ethylene glycol and diethylene glycol-determination of permanganate time
ABNT NBR 15366-1:2006 Industrial panels with polyurethane rigid foam Part 1: requirements and test methods
ABNT NBR 15366-2:2006 Industrial panels with polyurethane rigid foam Part 2: classification with regard to reaction to fire
ABNT NBR 15366-3:2006 Industrial panels with polyurethane rigid foam Part 3: guidelines for selection and installation in buildings and cold storage
ABNT NBR 15007-1:2003 Orthopolyphosphates -based products in drinking water systems Part 1: requirements and criteria for performance evaluation
ABNT NBR 15007-2:2003 Orthopolyphosphates -based products in drinking water systems Part 2: procedures for handling, preparation and application
ABNT NBR 15007-3:2003 Orthopolyphosphates -based products in drinking water systems Part 3: methods for evaluation of performance criteria
ABNT NBR 11833:1991 Sodium hypochlorite-specification
ABNT NBR 11834:1991 Powdered activated carbon-specification
ABNT NBR 12073:1991 Powdered activated carbon-determination of iodine number-test method
ABNT NBR 12074:1991 Powdered activated carbon-determination of phenol index-test method
ABNT NBR 12075:1991 Powdered activated carbon-particle size Determination-test method
ABNT NBR 12076:1991 Powdered activated carbon-determination of the apparent density-test method
ABNT NBR 12077:1991 Powdered activated carbon-determination of moisture test method
ABNT NBR 12279:1991 Sodium hypochlorite-sampling Procedure
ABNT NBR 12280:1991 Powdered activated carbon-sampling Procedure
ABNT NBR 11735:1990 Glycol ethers-specification

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

However, it is important to note that Brazil is a party of international conventions regulating hazardous chemicals. These international commitments affect the commercial and productive activities of the sector and condition the internal technical regulation.

4. CONFORMITY ASSESSMENT PROCEDURES, CERTIFICATION, REGISTRY AND OVERSIGHT

The Brazilian Army authorizes and oversees the production and trade of military equipment (Article 21 of Brazilian Federal Constitution). It covers as many different activities as: manufacturing, import, export, customs clearance, storage, commercialization and transportation. The Controlled Products Oversight Board (*Diretoria de Fiscalização de Produtos Controlados* - DFPC) centralizes the actions of the oversight system. The Decree n. 3,665/2000 (Regulation for Controlled Product Oversight/R-105) establishes all the procedures for exercising activities with controlled products.

The purpose of the Regulation is to establish the necessary provisions for the correct oversight of the activities carried out by natural and legal persons, involving products controlled by the Army. The chemical warfare agents are substances of any physical state (solid, liquid, gaseous or intermediate physical states), with physical and chemical properties which make them suitable for military use and which have chemical properties that cause lethal or harmful permanent/temporary effects on human beings, animals, plants and materials, as well as to cause fumigant or incendiary effects. The classification of a product as controlled by the Army has as its basic premise the existence of destructive power or other risk that indicates a need for a restricted use to legally qualified natural and legal persons, technically, morally and psychologically capable of ensuring the security of society and the country itself.

Activities of manufacture, use, import, export, customs clearing, transportation and trade of controlled products, shall observe the following requirements: i) for the manufacture, the registration in the Army that will issue the competent Registration Title (*Título de Registro* – TR); ii) for industrial use, in laboratories, sports activities, as object of collection or in research, registration in the Army upon issuance of the Registration Certificate (*Certificado de Registro* – CR); iii) for import, registration in the Army through the issuance of TR or CR and the prior import license by the International Import Certificate (*Certificado Internacional de Importação* – CII); iv) for export, registration in the Army and prior export license; v) the customs clearance

will be performed by an Army military oversight agent; vi) for transportation, prior authorization; and vii) for trade, registration in the Army upon issuance of the Registration Certificate.

The registration is mandatory for natural or legal persons, whether public or private, who manufacture, industrially use, store, trade, export, import, handle, transport, maintain and recover goods controlled by the Army. The Registration Title is the document that authorizes the legal entity to manufacture products controlled by the Army, while the Registration Certificate is the document that authorizes natural or legal persons to industrial use, warehousing, trade, export, import, transport, maintenance, repair, recovery and handling of products controlled by the Army.

The Department of Foreign Trade Operations (DECEX), part of the MDIC, may only issue import licenses or export registrations of controlled products covered by the Regulation 105, after authorization from the Army. When foreign factories of controlled products wish to establish subsidiaries in Brazil or transfer their industries to the country, the Army will assess advantages and disadvantages to the domestic economic development and the improvement of the domestic industrial park.

Federal Law n. 10,357/2001 establishes control and oversight standards for chemical products that may be directly or indirectly applied to the illicit manufacture of narcotic or psychotropic substances or other substances that cause physical or psychic dependence. Division of Control and Supervision of Chemicals (*Divisão de Controle e Fiscalização de Produtos Químicos - DCPQ*) at the Federal Police shall enforce this Federal Law by means of controlling and overseeing the manufacture, production, storage, transformation, packaging, purchase, sale, commercialization, acquisition, possession, donation, loan, exchange, shipping, transportation, distribution, import, export, re-export, assignment, reuse, recycling, transfer and use of chemicals that can be used as input in the production of illicit drugs.

To carry out any of the activities subject to such control and oversight by the Federal Police, the individual or legal entity must register and request a license from the Federal Police Department, in accordance with the criteria and forms established in Ordinance n. 1,274/2003 independently of other legal requirements and Regulations.

Enabling the legal entity to carry out non-eventual activity with chemical products subject to control and oversight as well as in an assimilated manner and on an exceptional basis, the individual that develops rural protection activities, requires a Certificate of Functioning License (*Certificado de Licença de Funcionamento*). The Certificate is valid for one year, counted from the date of its issuance, and may be extended, at the discretion of the Federal Police, for up to sixty days. By the other hand, the Special Authorization (*Autorização Especial*) is the document that enables the individual or legal entity to eventually engage in activities with chemicals, which are subject to control and oversight by the Federal Police.

In order to import, export or re-export a chemical subject to control and oversight, the individual or legal entity shall apply for the corresponding Prior Authorization (*Autorização Prévia*) at the Federal Police, which expires in 60 days, counted from the date of issue, extendable once for the same period, and covering one operation per product. The application form also requires the following documents: i) *proforma* invoice, with the name, quantity (in kilograms or liters), concentration, content or degree of purity, the minimum percentage of the product, the type of packaging, the value of the goods, in addition to the identification of the exporter/importer, the manufacturer and the available transport data; ii) authorization, non-objection certificate or equivalent document issued by the competent body of the importing country and the country of the final addressee. It takes up to 60 days from the receipt by the central control body of chemical products of the Federal Police.

5. MERCOSUL REGULATION

Under Mercosul, there are specific rules on the transport of dangerous goods, including chemicals products. Particularly noteworthy is the Agreement on Facilitation of the Terrestrial Transportation of Dangerous Goods in Mercosul, internalized in Brazil by Decree No. 1,797/1996. The Agreement prescribe, among other things, a series of conditions for the safe transport of hazardous materials. Vehicles and containers shall observe rules when these products circulate in more than one country, which is a Mercosul member.

The Agreement on Facilitation of the Terrestrial Transportation of Dangerous Goods in Mercosul is based on the recommendations of the Committee of Experts of the United Nations - UN, which constitute the so-called UN Model Regulations - Orange Book. In addition, the European Agreement (ADR) for this type of transport is also an option.

It should also be noted the importance of some Mercosul regulations on chemical transportation: MERCOSUL / GMC / RES n. 10/2000 and n. 82/2000 on Road Traffic Inspection and Rail Transport of Hazardous Products, as well as the Mercosul Roadmap for Hazardous Goods: Classification of Risk Labels and Safety Panels Interface with the Globally Harmonized System of Classification and Labeling of Chemicals - GHS.

6. MAIN GOVERNMENT AND PRIVATE ACTORS IN THE SECTOR

Main government actors involved with the chemicals (basic) sector are: (1) Ministry of Defense, (2) the MDIC, more specifically with SECEX (Trade) and SDCI (Sector Policies), (3) ANVISA; and (4) INMETRO.

Main private actors involved with the chemicals sector are: (1) ABNT, (2) CNI, (3) FIESP, and (4) ABIQUIM.

ANNEX

Table 3 - Important notifications to SPS Committee

Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale
G/SPS/ N/BRA/ 86	2003	Semiochemical products HS 29	ANVISA	Public consultation n° 88, published at <i>Diário Oficial da União</i> (Official Journal) on 4 November 2003 (Available in Portuguese, 7 pages)	It establishes procedures to be adopted on the registration, toxicological and environmental evaluation of biochemical products considered as pesticides, their components and related products. This measure will also be notified under the TBT Agreement.	food safety, animal health, plant protection	None
G/SPS/ N/BRA/ 87	2003	Biochemical products HS 29	ANVISA	Public consultation n° 89 on biochemical products, published at <i>Diário Oficial da União</i> (Official Journal) on 4 November 2003 (Available in Portuguese, 6 pages)	It establishes procedures to be adopted on the registration, toxicological and environmental evaluation of biochemical products considered as pesticides, their components and related products. This measure will also be notified under the TBT Agreement	food safety, animal health, plant protection	None
G/SPS/ N/BRA/ 88	2003	Microbiological products HS 29	ANVISA	Public consultation n° 90 on microbiological products, published at <i>Diário Oficial da União</i> (Official Journal) on 4 November 2003 (Available in Portuguese, 9 pages)	It establishes procedures to be adopted on the registration, toxicological, environmental and pathogenicity evaluation of microbiological products used on population control or biological activities of another living organism that is considered harmful. This measure will also be notified under the TBT Agreement.	food safety, animal health, plant protection	None
G/SPS/ N/BRA/ 89	2003	Control products used on organic agriculture HS 29	ANVISA	Public consultation n.° 91 on control products used on organic agriculture, published at <i>Diário Oficial da União</i> (Official Journal) on 4 November 2003 (Available in Portuguese, 2 pages)	It establishes procedures to be adopted on the registration, toxicological and environmental evaluation of control products used on organic agriculture and considered as pesticides. This measure will also be notified under the TBT Agreement.	food safety, animal health, plant protection	None

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

Table 4 - Important notifications to TBT Committee

Doc	Year	Products	Agency	Notified document	Situation	Description of content
G/TBT/N/ BRA/59	2002	Food and food additives (HS Section 4, Chapters 28 and 29)	INMETRO	Draft Resolution number 68, August 22th, 2002 (<i>Consulta Pública no. 68 de 22 de agosto de 2002</i>) issued by the Brazilian Sanitary Surveillance Agency on labelling requirements for tartrazine containing foods. (1 page, in Portuguese).	Draft not found	Draft Resolution proposing the mandatory inclusion of the following message at any food or food product label containing the additive tartrazine (INS 102), - also known as yellow n.º5, Food yellow 4 and Acid yellow 23: "Este produto contém o corante TARTRAZINA que pode causar reações alérgicas em pessoas sensíveis" (This product contains the colour additive TARTRAZINE which may cause an allergic response in susceptible people). Obs: Also notified under SPS Agreement
G/TBT/N/ BRA/0000 0091	2003	28-inorganic chemicals; organic or inorganic compounds of precious metals, of rare- earth metals, of radioactive elements or of isotopes, 29-organic chemicals, 30-pharmaceutical products, 31-fertilisers, 32-tanning or dyeing extracts; tannins and their derivatives; dyes, pigments and other colouring matter; paints and varnishes; putty and other mastics; inks, 33-essential oils and resinoids; perfumery, cosmetic or toilet preparations, 34-soap, organic surface-active agents, washing preparations, lubricating preparations, artificial waxes, prepared waxes, polishing or scouring preparations, candles and similar articles, modelling pastes, "dental waxes" and dental preparations with a basis of plaster, 35-albuminoidal substances; modified starches; glues; enzymes, 36-explosives; pyrotechnic products; matches; pyrophoric alloys; certain combustible preparations, 37-photographic or cinematographic goods, 38-miscellaneous chemical products	ANVISA	Draft Resolution number 100, December 16th, 2002 (<i>Consulta Pública no. 100 de 16 de dezembro de 2002</i>) issued by the Brazilian Sanitary Surveillance Agency relative to a Mercosul Draft Resolution on nutritional labelling requirements for packaged food. Resulted in RDC36/2007	Revoked	Draft Mercosul Resolution proposing the mandatory nutritional labelling for packaged food. It establishes that the nutritional labelling must contain information on the total caloric value, protein, carbohydrate, fat, saturated fat, fibre, trans fatty acid and sodium contents. This resolution will be implemented in a two-step approach: from 31 July 2005 on, the labelling must contain information on caloric value, protein, carbohydrate, fat and fibre contents. From 31 July 2007 on, information on saturated fat, trans fatty acid and sodium contents in the labelling will be mandatory.

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