



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 – PESTICIDES



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Request for Service 2016/379494 Version 1

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BRAZIL – CHEMICAL SECTOR – PESTICIDES

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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
ALADI Latin American Integration Association
ANP Brazilian Agency of Petroleum, Natural Gas and Biofuels
ANVISA Brazilian Health Regulatory Agency
ANTT Brazilian Land Transport Agency
ASTM American Society for Testing and Materials
CAMEX Brazil Foreign Trade Chamber
CNI Brazil National Confederation of Industry
CONAMA Brazilian National Environmental Council
CORPROSAL Commission on Health Products
CSM Mercosul Sectorial Committees
DECEX Department of Foreign Trade Operations, Ministry of Defense
DFPC Controlled Products Oversight Board
EFTA European Free Trade Association
EU European Union
FDI Foreign Direct Investment
FIESP Federation of Industries of the State of São Paulo
FNDCT Brazilian Fund of Scientific and Technological Development
GMC Common Market Group, Mercosul
HS Harmonized System
IAF International Accreditation Forum
IEC International Electrotechnical Commission
IBAMA Brazilian Institute of the Environment and Renewable Natural Resources
ILAC International Laboratory Accreditation Cooperation
ILO International Labor Organization
INMETRO Brazilian National Institute of Metrology, Quality and Technology
IPI Brazilian Manufactured Products Tax
ISO International Standardization Organization
MAPA Brazil Ministry of Agriculture, Livestock and Food Supply
MCR Adjusts the General Norms
MDIC Brazil Ministry of Industry, Foreign Trade and Services
MERCOSUL Common Market of the South
MMA Brazil Ministry of Environment
MRA Mutual Recognition Agreement
NAFTA North American Free Trade Agreement
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, ANVISA
SDCI Secretariat of Industrial Development and Competitiveness, MDIC
SGT Working Subgroup, GMC, Mercosul
SIEMA Brazilian National Environmental Emergency System
SUS Unified Health System
TBT Technical Barriers to Trade
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 – PESTICIDES

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1. OVERVIEW

Pesticides are important products of the Brazilian agro-industrial complex. The production of pesticides and similar products is located upstream in the agro industrial production chain. Such products are often used in large-scale crops and increase the productivity of the farmer. Because chemicals are directly related to human health, pesticides are heavily monitored by governmental entities. These entities, pursuing a public health objective, control the production, sale and import of agrochemicals and similar agricultural pesticides.

Brazil has a deficit of trade in chemical products. The value of the deficit has grown in recent years. In 2016, Brazil exported US\$ 8.0 billion in chemicals. Imports of chemicals totalled US\$23.1 billion. The deficit in the Brazilian trade balance of chemical products registered in the same year was US\$ 15.1 billion. In 1991, the same deficit was US\$1.5 billion (Abiquim, 2017).

In 2016, Brazil exported more than US\$ 260 million of pesticides and similar products. The most important partner was the countries of ALADI, excluding Mercosul members, which bought from Brazil US\$ 89 million and the partners of Mercosul imported US\$ 130 million from Brazil.

2. MAIN TECHNICAL REGULATION AND AUTHORITIES

Pesticide sector regulation is based on two major federal laws: Federal Law n. 7,802/1989, and Federal Law n. 9,605/1998; two federal executive decrees: Federal Decree n. 4,074/2002, and Decree n. 5,981/2006; and a range of non-statutory regulations. The following table contains main federal regulation on pesticides.

Table 1 - Main Federal Regulation on Pesticides

Federal Laws			
Federal Law	n.		Provides for research, experimentation, production, packaging and labeling, transport, storage, marketing, commercial advertisement, use, import, export, final destination of waste and packaging, registration, classification, control, and inspection of pesticides, their components and the like, and other measures.
7,802/1989			
Federal Law	n.		Provides on the penal and administrative sanctions against conducts and activities harmful to the environment, and establishes other measures.
9,605/1998			
Federal Decrees			
Federal Decree	n.		Regulates Law n. 7,802/1989, which deals with research, experimentation, production, packaging and labeling, transportation, storage, commercialization, commercial advertisement, use, import, export, final destination of waste and packaging, registration, classification, control, inspection and inspection of pesticides, their components and the like, and other measures.
4,074/2002			
Decree n. 5,981/2006.			It provides new wording and includes provisions to Decree n. 4,074/2002, which regulates Federal Law n. 7,802/1989.
Ordinances			
Ordinance	SVS	n.	It sets forth specific rules for the registration of products intended for use in amateur gardening.
322/1997			

Resolutions			
Resolution 001/2011	RDC	n.	Technical regulation for the active ingredient Metamidofós as a result of toxicological re-evaluation
Resolution 028/2010	RDC	n.	Technical Regulation for the Active Ingredient Endosulfan as a result of the Toxicological Re-evaluation.
Resolution 034/2010	RDC	n.	Regulates sanitizing products for sale.
Resolution 045/2013	RDC	n.	Technical regulation for the active ingredient Acephate as a result of the Toxicological Re-evaluation.
Normative Instruction			
Normative Instruction n. 002/ 2008			It concerns the rules for the application of agrochemicals by agricultural aircraft.
Normative Instruction n. 042/2011			It changes the SDA Normative Instruction No. 36 of November 2009.
Normative Instruction n. 036/2009			It establishes the guidelines and requirements for conducting research and experimentation, for accreditation of entities that perform them and for submission of requests of registration and alteration, regarding the conduction and issuance of reports of efficiency and agronomic feasibility, phytotoxicity and field essays for the study of residues of pesticides and the like.

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

The Ordinances, Resolutions and Normative Instructions of the National Health Surveillance are particularly important, because they deal with more specific technical aspects of the products, such as composition of substances, necessary information for the consumer and potential negative effects. The tables below list ANVISA Resolutions and Normative Instructions.

Table 2 - List of ANVISA Resolutions on pesticides

Resolution of the Board of Directors - RDC n. 70/2016. Revokes Resolution of the Board of Directors - RDC no. 29, May 27, 2009
Resolution of the Board of Directors - RDC n. 60/2016. Provides for the prohibition of the use of the active ingredient Prochloraz in pesticides, as a result of its toxicological re-evaluation, and other measures.
Resolution of the Board of Directors - RDC n. 56/2015. Provides on technical regulation for the active ingredient Parationa metil due to the toxicological reevaluation
Resolution of the Board of Directors - RDC n. 12/2015. Provides technical regulation for the active ingredient Forato as a result of toxicological re-evaluation
Resolution of the Board of Directors - RDC n. 12/2014. Provides on procedure for notification to the National Agency of Sanitary Surveillance - ANVISA, of technical changes in the registration of pesticides, its components and the like and makes other provisions.
Resolution of the Board of Directors - RDC n. 45/2013. Technical regulation for the active ingredient acephate as a result of its toxicological re-evaluation.
Resolution of the Board of Directors - RDC n. 44/2013. It shall carry out the toxicological re-evaluation of the technical products formulated on the basis of the active ingredient prochloraz listed in the Annex.
Resolution of the Board of Directors - RDC n. 4/2012. Provides on the criteria for the study of pesticide residues for purposes of registration of pesticides in Brazil.
Resolution of the Board of Directors - RDC n. 1/2011. Technical regulation for the active ingredient methamidophos as a result of toxicological re-evaluation.
Resolution of the Board of Directors - RDC n. 65/2010. Reverses the Resolution of the Board of Directors - RDC No. 62, of December 22, 2010.
Resolution of the Board of Directors - RDC n. 37/2010. Technical regulation for the active ingredient Trichlorfon as a result of toxicological re-evaluation
Resolution of the Board of Directors - RDC n. 36/2010. Technical regulation for the active ingredient Fosmete as a result of toxicological re-evaluation
Resolution of the Board of Directors - RDC n. 28/2010. Technical Regulation for the Active Ingredient Endosulfan as a result of the Toxicological Re-evaluation
Resolution of the Board of Directors - RDC n. 34/2009. Proposal of Technical Regulation for the Active Ingredient Cihexatin Following the Toxicological Re-evaluation.
Resolution of the Board of Directors - RDC n. 30/2009. Provides for the repeal of RDC n. 84/2008.
Resolution of the Board of Directors - RDC n. 48/2008. Detail the administrative procedures for the toxicological reevaluation of technical products formulated on the basis of active ingredients with change of human health risks.
Resolution of the Board of Directors - RDC n. 44/2008. Amends art. 27 and its single paragraph of the RDC n. 90/2007, republished in the Official Gazette of March 28, 2008 and amended by RDC n. 32/2008.
Resolution of the Board of Directors - RDC n. 10/2008. Carry out the Toxicological Re-evaluation of the Technical Products Formulated on the basis of the Active Ingredients of Annex I and according to the Schedule of Annex II of this Regulation.
Resolution of the Board of Directors - RDC n. 9/2008 New text to §§ 1 and 2 of art. 2, of RDC n. 216/2006.
Resolution of the Board of Directors - RDC n. 46/2007. Extension of the Adequacy Period of Information Centers and Toxicological Assistance (Ciats) To the Guidelines Established by Anvisa.
Resolution of the Board of Directors - RDC n. 19/2007. Provides for registration of pesticides by equivalence.
Resolution of the Board of Directors - RDC n. 6/2007. The two-year period for adequacy to the "guidelines for the qualification of toxicological information centers" referred to in item 2 of the general provisions of rdc annex no. 19 of feb 3 2005 is extended until mar 3 2007.
Resolution of the Board of Directors - RDC n. 215/2006. The monograph of the active ingredient monocrotophos is canceled as of

November 30, 2006.
Resolution of the Board of Directors - RDC n. 188/2006. The authorization referred to in item 5 of the Annex to RDC Resolution n. 67/2006, for the emergency use of methyl bromide based agrochemicals, is hereby extended until October 27, 2007.
Resolution of the Board of Directors - RDC n. 165/2006. All uses of active Lindane Ingredient In Brazil are forbidden.
Resolution of the Board of Directors - RDC n. 164/2016. All uses of the active ingredient Pentachlorophenol (PCF) and its salts in Brazil are forbidden.
Resolution of the Board of Directors - RDC n. 111/2006. It deals with the emergency use of pesticides based on acephate in the oil palm crop.
Resolution of the Board of Directors - RDC n. 67/2006. To approve the specifications defined in the annex to this Resolution, regarding the companies interested in the commercialization of agrochemicals.
Resolution of the Board of Directors - RDC n. 347/2005. Extends the term referred to in art. 2 of the RDC n. 287/2005.
Resolution of the Board of Directors - RDC n. 287/2005. The substance is subjected to a toxicological re-evaluation of the substance p-dichlorobenzene.
Resolution of the Board of Directors - RDC n. 19/2005. The National Network of Information and Assistance Centers - RENACIAT was created.
Resolution of the Board of Directors - RDC n. 244/2003. Changes the item 1.6-Technical Monograph of the "Guidelines and requirements regarding authorization of registration, renewal of registration and extension of use of pesticides and related products - n. 1 of 09/12/91, DOU of 12/13/91
Resolution of the Board of Directors - RDC n. 226/2003. To authorize the request of registration, together with the competent organ, of the active ingredients listed in the annexes, in an emergency, according to technical recommendations.
Resolution of the Board of Directors - RDC n. 119/2003. Creates the Program of Analysis of Agrochemical Waste in Food
Resolution of the Board of Directors - RDC n. 98/2003. Repeals art. 2 of RDC n. 135/2002, published in the Official Gazette of May 22, 2002.
Resolution of the Board of Directors - RDC n. 97/2003. Repeals RDC 132/2001, which constitutes the permanent technical commission responsible for the implementation and monitoring and evaluation of the National Program for the monitoring of agrochemical residues in food.
Resolution of the Board of Directors - RDC n. 17/2003. The importation of reference standards, including standards for pesticides, may only be carried out, upon request of bodies, entity (ies) or interested company (ies) and approval by the National Sanitary Surveillance Agency
Resolution of the Board of Directors - RDC n. 5/2003 To change the monograph, referring to the Active Ingredient P-46 Piraclostrobina, published through Resolution-RDC n. 347/2002, DOU of 12/31/02.
Resolution of the Board of Directors - RDC n. 347/2002 The publication of the "List of Monographs of the Active Ingredients of Pesticides and Preservatives of Wood", whose use is authorized as described, according to annexes, is determined.
Resolution of the Board of Directors - RDC n. 252/2002 To revoke the Collegiate Board Resolution - RDC n. 19/2000, published in the DOU No. of March 8, 2000, which prohibits the use of Methyl Bromide in the treatment of wood, throughout the national territory.
Resolution of the Board of Directors - RDC n. 135/2002 Toxicological re-evaluation of technical products formulated on the basis of the previously mentioned active ingredients.
Resolution of the Board of Directors - RDC n. 57/2002 To establish the criteria for the preliminary toxicological evaluation for research and experimentation with genetically modified organisms that perform the function of agrochemicals and the like, as provided for in Federal Law n. 7,802/1989.
Resolution of the Board of Directors - RDC n. 6/1999 Suspend approval and toxicological evaluation for registration of new technical products and / or formulations of agrochemicals based on Paration Methyl and Metamidofos.
Resolution of the Board of Directors - RDC n. 5/1999 Suspend the approval and toxicological evaluation for registration of new formulations of pesticides with the mixture of active principles considered potentially carcinogenic.

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

Table 3 - List of ANVISA Normative Instructions (in force)

Joint Normative Instruction - INC n. 2/2015 Purpose: Authorizes the use of methyl bromide in Brazil exclusively in phytosanitary treatment with quarantine purposes in the import and export operations, in the form of this Joint Normative Instruction.
Joint Normative Instruction - INC n. 11/2015 Purpose: Establishes criteria and procedures for the registration of pesticides, their components and the like for use in sanitary or environmental emergencies.
Joint Normative Instruction - INC n. 1/2014 Purpose: Establishes the guidelines and requirements for the registration of agrochemicals, their components and the like for crops with insufficient plant protection, as well as the maximum residue limit allowed.
Normative Instruction - IN n. 6/2013 Mention: The use of the substances listed in the Annex to this Normative Instruction in smoke-based products derived from tobacco is authorized for an exceptional period of 12 (twelve)
Joint Normative Instruction - INC n. 1/2013 Purpose: Joint Normative Instruction Map, Anvisa and Ibama on alteration of formulation of pesticides and related.

Joint Normative Instruction - INC n. 2/2006 Purpose: The re-evaluations of pesticides, their components and the like will be carried out in the situations described in this INC.
Joint Normative Instruction - INC n. 1/2006 Purpose: For the purposes of registration of technical products, premixtures, agrochemicals and similar products intended exclusively for export, the interested party must submit a registration application, accompanied by the relevant documents.
Joint Normative Instruction - INC n. 3/2006 Purpose: Establish procedures to be adopted for the purpose of recording microbiological agents used in the control of a population or biological activities of another living organism considered to be harmful.
Joint Normative Instruction - INC n. 32/2005 Purpose: Establish procedures to be adopted for the purpose of registration of biochemical products that are characterized as technical products, agrochemicals and the like, according to the definitions established in Decree No. 4,074/2002, art.1.

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

Federal Law No 7,802/1989, is the federal statute that provides general regulation for pesticides. The law regulates the manufacture, research, experimentation registry, importation, advertisement and inspection, of pesticides. The Federal Law n. 7,802/1989 also regulates matters regarding the research, testing, production, packaging and labeling, transport, storage, marketing, commercial advertisement, use, import and export, of pesticides. The Law also regulates the final destination of waste, the classification, control, inspection and inspection of pesticides and their components.

The definition of pesticides is set forth in Article 2 of the same Federal Law. This norm lists the substances to be considered as pesticides. The law covers both end products used as agricultural pesticides and active substances used for the manufacture of biocides.

To be sold, substances classified as pesticides must be registered as determined by Article 3 of Federal Law n. 7,802/1989.

Federal Law n. 7,802/1989 is regulated by the following Decrees: Federal Decree n. 4,074/2002 and Decree n. 5,981/2006. Article 1 of the Federal Decree n. 4,074/2002 defines terms such as additives, biological agents, agrochemicals, and recognition center. For their turn, Articles 3, 4, 5, 6 and 7 provide the competence of ministries about chemicals.

According to article 3, the MAPA is responsible for the monitoring of residues derived from pesticides and other products used as plant defensive t. This provision leaves unclear if the monitoring shall be made directly by the Ministry or can be delegated to bodies of the decentralized administration. Differently, the registration of chemical substances of pesticides must be made also by the Ministry of Environment, as set forth in article 4.

The competence of each governmental body is specified by law. The following table describes the competences of three ministries that regulate pesticides.

Table 4 - Specification of regulatory competence

Governmental Body	Competence
The Ministry of Agriculture, Livestock and Supply shall (Article 5)	I - to evaluate the agronomic efficiency of agrochemicals and the like for use in the production, storage and processing of agricultural products, in planted forests and pastures; and II - to grant registration, including RET, of agrochemicals, technical products, premixtures and the like for use in the production, storage and processing of agricultural products, in planted forests and pastures, in accordance with the guidelines and requirements of the Ministries of Agriculture Health and the Environment.
The Ministry of Health shall (Article 6)	I - to assess and classify toxicologically the agrochemicals, their components, and the like; II - to evaluate pesticides and similar products intended for use in urban, industrial, household, public or collective environments, water treatment and use in public health campaigns, regarding the efficiency of the product; III - carry out preliminary toxicological evaluation of pesticides, technical products, premixtures and the like, intended for research and experimentation; IV - to establish interval of reentry in environment treated with pesticides and the like; V - to grant registration, including RET, of pesticides, technical products, premixtures and the like intended for use in urban, industrial, home, public or collective environments, water treatment and use in public health campaigns attended to Guidelines and requirements of the Ministries of Agriculture and the Environment; and

	VI - monitor the residues of pesticides and the like in products of animal origin.
The Ministry of the Environment shall (Article 7)	I - to evaluate agrochemicals and related products intended for use in water environments, in the protection of native forests and other ecosystems, as to the efficiency of the product; II - carry out the environmental evaluation of pesticides, their components and the like, establishing their classification as to the potential of environmental hazard; III - carry out the preliminary environmental assessment of pesticides, technical product, premixtures and similar products for research and experimentation; and IV - to grant registration, including RET, of agrochemicals, technical products and premixes and similar products intended for use in water environments, in the protection of native forests and other ecosystems, in accordance with the guidelines and requirements of the Ministries of Agriculture, Livestock and Supply and Health.

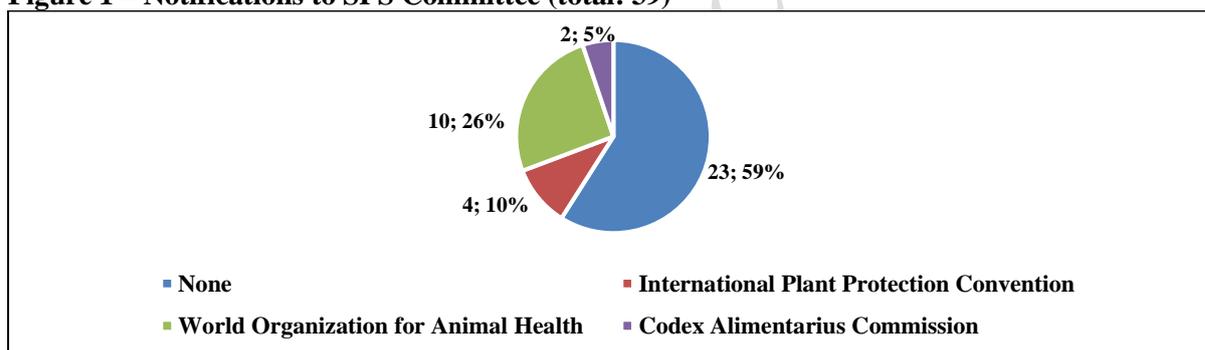
Source: MAPA. Prepared by CCGI-EESP/ FGV (May 2017).

2.1. Notifications to WTO

The interaction of such bodies with the WTO system, regarding the notifications made to SPS and TBT Committees, offer a good instrument to analyze the interaction of Brazilian Law and international instruments.

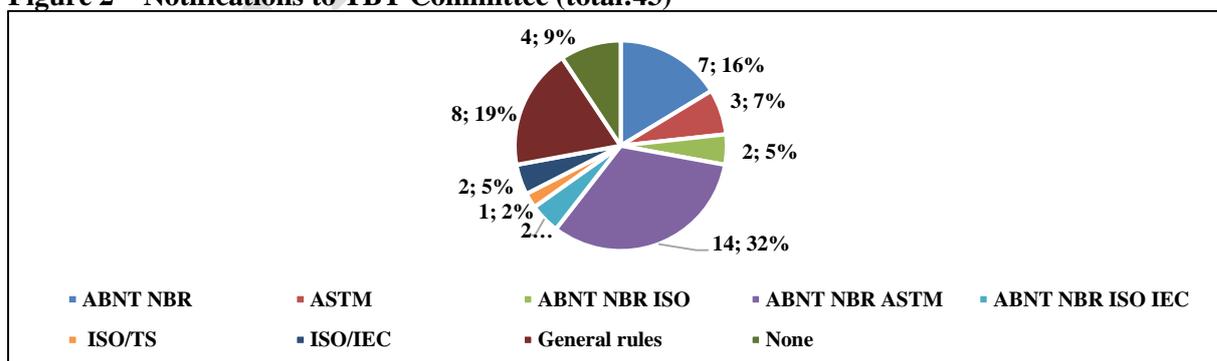
The following figure gives the big picture of the international standards adopted by the Brazilian technical regulation on chemical sector. To the SPS Committee, Brazil notified 39 times; to the TBT Committee, the country notified 43 times diverse regulations on chemical sector.

Figure 1 – Notifications to SPS Committee (total: 39)



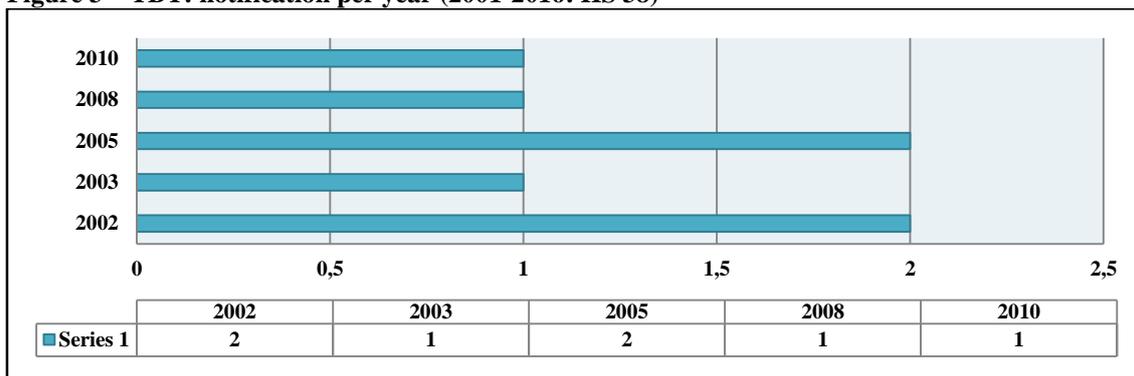
Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

Figure 2 – Notifications to TBT Committee (total:43)



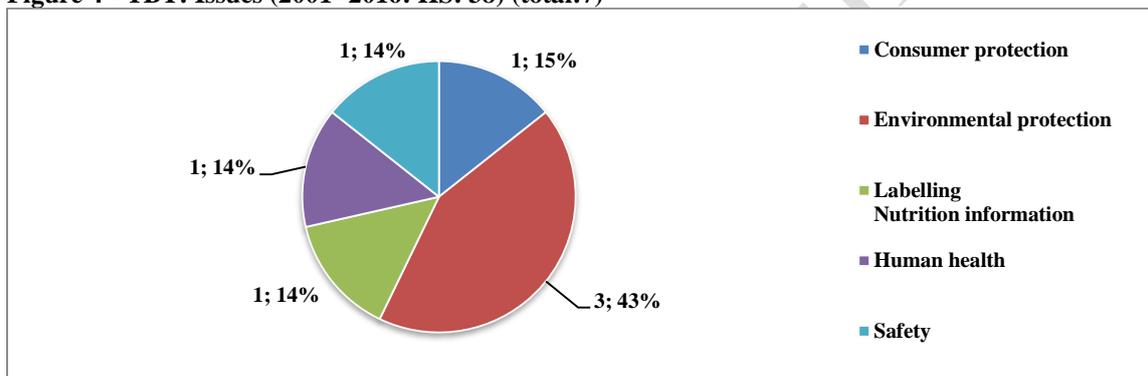
Source: WTO database. Prepared by CCGI-EESP/ FGV (May 2017).

Specifically, for pesticides and similar products, since 2002, Brazil has made 7 notifications about pesticides to the TBT Committee. In 2002 and 2005, two notifications were made; in 2003, 2008 and 2010, only one notification was made each year.

Figure 3 – TBT: notification per year (2001-2016: HS 38)

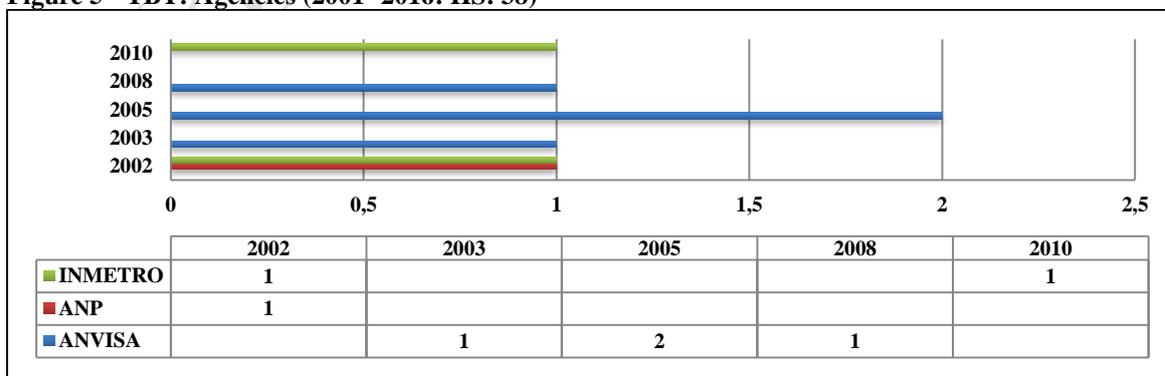
Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

The most frequent issue in the notifications to the TBT Committee is the protection of the environment. Other important topics are consumer protection, labels with nutritional information and human health.

Figure 4 - TBT: Issues (2001- 2016: HS: 38) (total:7)

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

ANVISA is the Brazilian government agency that most notifies the TBT Committee. Among the seven notifications that Brazil made to the TBT Committee, ANVISA performed more than half. ANP and INMETRO also made notifications.

Figure 5 - TBT: Agencies (2001- 2016: HS: 38)

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

The table below describes Brazilian notification to the TBT Committee.

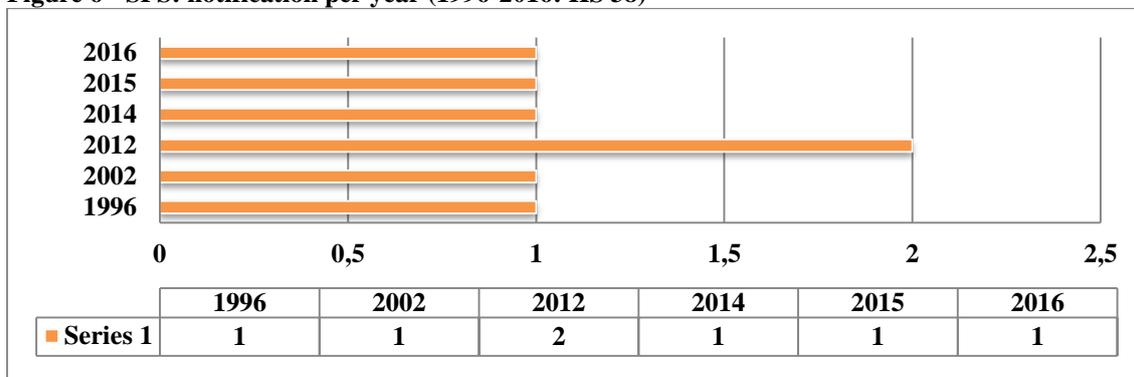
Table 5 – Notifications to TBT Committee

Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale	Technical Provisions/Standards
G/TBT/N/BRA/00000188	2005	3808-Insecticides, rodenticides, fungicides, herbicides, anti-sprouting products and plant-growth regulators, disinfectants and similar products, put up in forms or packings for retail sale or as preparations or articles (for example, sulphur-treated bands, wicks and candles, and fly-papers).	ANVISA	Draft Resolution issued by the Brazilian Sanitary Surveillance Agency for garden products <i>Consulta Pública n. 46/2005</i>	Draft not found	This draft technical regulation lays packaging and labelling requirements for garden products.	Protection of human health	None
G/TBT/N/BRA/00000290	2008	3808-Insecticides, rodenticides, fungicides, herbicides, anti-sprouting products and plant-growth regulators, disinfectants and similar products, put up in forms or packings for retail sale or as preparations or articles (for example, sulphur-treated bands, wicks and candles, and fly-papers).	ANVISA	Draft n. 21/2008	Resolution In force	This draft technical regulation opens for public consultation the modification of Resolution RE n. 165/2003. It includes on the list of active components in pesticides, sanitary products and wood preservation agents the use of etridiazole (soil application) in the culture of tobacco.	None	None

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

The number of notifications to the SPS Committee is the same: only seven. Brazil therefore has regularity in the number of notifications. This relatively low number of notifications is consistent with the scarcity of specific technical regulations on pesticides, pesticides and related products.

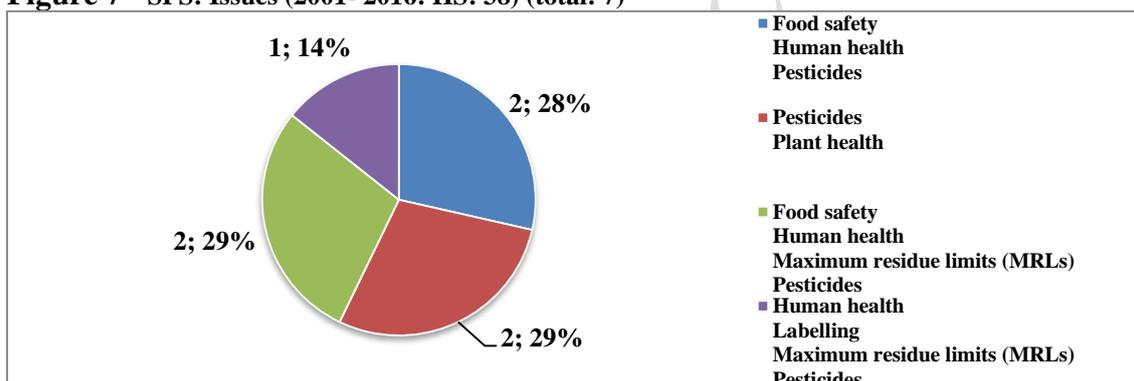
Figure 6 - SPS: notification per year (1996-2016: HS 38)



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

In the SPS Committee, plant health and food safety related to the use of pesticides are the main issues reported.

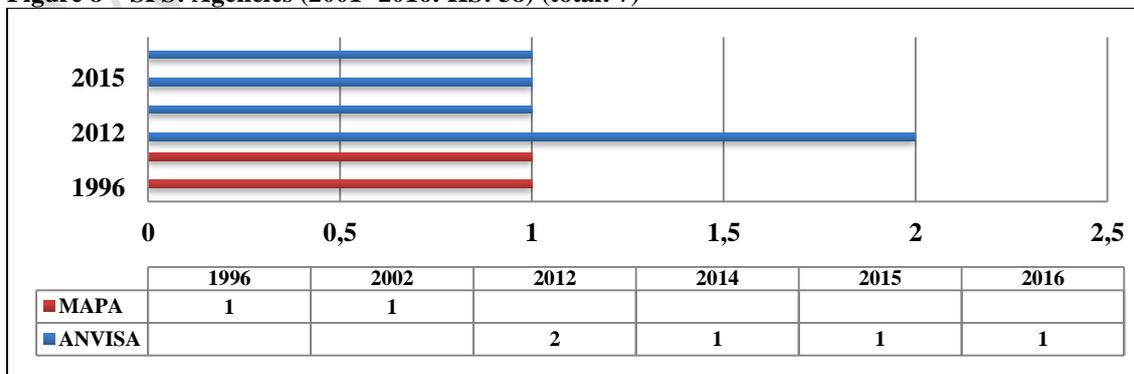
Figure 7 - SPS: Issues (2001- 2016: HS: 38) (total: 7)



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

This same prevalence of notifications made by ANVISA is also observed in the SPS Committee. Since 1996, ANVISA notified five times the SPS Committee and MAPA notified only twice.

Figure 8 – SPS: Agencies (2001- 2016: HS: 38) (total: 7)



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

The following table details the Brazilian notification to the SPS Committee.

Table 6 - List of Brazilian Notification to SPS Committee

Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale
G/SPS/ N/BRA/ 4	1996	Insecticides, fungicides, herbicides (3808)	MAPA	Portario n. 182, de 21 de março de 1996, do Diario Oficial da União de 25 de março de 1996 (Official Journal of 25 March 1996).	Describes the procedures to be followed by the inspectors to supervise pesticide manufacturers, exporters and importers.	Plant health	None
G/SPS/ N/BRA/ 86	2003	Semiochemical products HS 29	ANVISA	Public consultation n° 88, published at Diário Oficial da União (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 Diário Oficial da União (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/ 89	2003	Control products used on organic agriculture HS 29	ANVISA	Public consultation n.°91 on control products used on organic agriculture, published at Diário Oficial da União (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

G/SPS/ N/BRA/ 927	2014	Insecticides: sale to the general public: liquids and aerosols (maximum allowed concentration: 0.6% p/p); liquid repellent (maximum allowed concentration: 0.88% p/p); repellent tablets and strips (maximum allowed concentration: 15mg/each); spirals (maximum allowed concentration: 0.06% p/p); anti moth paper (maximum allowed concentration: 1.0% g/m2); gel repellents (maximum allowed concentration: 39.5% p/p); long lasting repellents, tablets and discs (maximum allowed concentration: 330 mg/each). (*) Label or package leaflet must contain the following wording: Do not use in poorly ventilated environment, especially in the presence of children. This product cannot be used by asthmatic persons, with respiratory problems or allergic to pyrethroids.	ANVISA	Draft resolution regarding the active ingredient TRANSFLUTRINA of the monograph list of active ingredients for pesticides, household cleaning products and wood preservers, published by Resolution - RE n° 165 of 29 August 2003, Brazilian Official Gazette (DOU Diário Oficial da União) of 2 September 2003.	Draft resolution regarding the active ingredient TRANSFLUTRINA of the monograph list of active ingredients of pesticides, household cleaning products and wood preservers. This resolution proposes to increase the maximum allowed concentration from 280 to 330 mg/each for use in household cleaning products: Sale to the general public: liquids and aerosols (maximum allowed concentration: 0.6% p/p); liquid repellent (maximum allowed concentration: 0.88% p/p); repellent tablets and strips (maximum allowed concentration: 15mg/each); spirals (maximum allowed concentration: 0.06% p/p); anti moth paper (maximum allowed concentration: 1.0% g/m2); gel repellents (maximum allowed concentration: 39.5% p/p); long lasting repellents, tablets and discs (maximum allowed concentration: 330 mg/each).	protect humans from animal/plant pest or disease	None
G/SPS/ N/BRA/ 1053	2015	Draft Resolution regarding a technical regulation to the active ingredient Prochloraz due to its toxicological re-evaluation	ANVISA	Draft resolution regarding the active ingredient PROCHLORAZ of the monograph list of active ingredients for pesticides, household cleaning products and wood preservers, published by Resolution - RE n°165 of 29 August 2003, Brazilian Official Gazette (DOU Diário Oficial da União) of 2 September 2003	Draft Resolution regarding a technical regulation to the active ingredient Prochloraz due to its toxicological re-evaluation.	food safety	None
G/SPS/ N/BRA/ 1191	2016	Pesticides, its components, related products and wood preservers. ICS Code(s): 13, 65, 79	ANVISA	Draft resolution regarding the criteria and requirements for the toxicological evaluation of pesticides, its components (additives and other ingredients), related products and wood preservers.	Draft Technical Resolution no. 260, 10 October 2016, to establish procedures for the toxicological evaluation (criteria and requirements) of pesticides, its components, related products and wood preservers for authorization and post-authorization purposes.	food safety	None

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

3. STANDARDS AND INTERNATIONAL CONVENTIONS

The Brazilian Standards are developed by Brazilian Association of Technical Standards (ABNT). There are almost 40 standards on pesticides and agrochemical, produced by different committees. These standards are listed on the table below.

Table 7 - List of Standards for Pesticides

STANDARD
ABNT NBR 13227:2016 Errata 1:2017 Agrochemicals and the like-determination of nonvolatile residue
ABNT NBR 13227:2016 corrected version: 2017 Agrochemicals and the like-determination of nonvolatile residue
ABNT NBR 14029:2016 Agrochemicals and the like-validation of analytical methods
ABNT NBR 13074:2016 Errata 1:2016 Agrochemicals and the like-water-preparation for tests
ABNT NBR 13074:2016 corrected version: 2016 Agrochemicals and the like-water-preparation for tests
ABNT NBR 13826:2016 Agrochemicals and the like-determination of density
ABNT NBR 13313:2015 Agrochemicals and the like-determination of suspension
ABNT NBR 13875:2014 Agrochemicals and related evaluation of physico-chemical compatibility
ABNT NBR 13238:2014 Agrochemicals and the like — determination of volatility
ABNT NBR 13827:2014 Agrochemicals and the like-determination of stability of dispersion
ABNT NBR 8510:2013 Errata 1:2014 Agrochemicals and the like-physical characteristics
ABNT NBR 13242:2014 Agrochemicals and the like — determination of wettability
ABNT NBR 16065:2012 Agrochemicals and the like — determination of residue
ABNT NBR 10436:2008 Agrochemicals and the like-nomenclature
ABNT NBR 13075:2007 Handling of pesticides and related lab-safety requirements
ABNT NBR 13073:2003 Cleaning laboratory glassware for use in product testing chemicals and allied products
ABNT NBR 13452:2016 Pesticide and the like — determination of emulsion stability
ABNT NBR 13451:2016 Pesticide and the like — determination of persistent foam
ABNT NBR 13450:2013 Pesticide and the like — determination of adhesion in dry seeds — test method
ABNT NBR 12679:2013 Pesticide and related technical Products, concentrated and formulations — terminology
ABNT NBR 8510:2013 corrected version: 2014 Pesticide and the like — physical characteristics
ABNT NBR 9843-4:2013 Pesticide and related Part 4: storage in laboratories
ABNT NBR 9843-2:2013 Pesticide and related Part 2: commercial Storage in distributors and cooperatives
ABNT NBR 9843-1:2013 Pesticide and related Part 1: storage in warehouses, general stores or distribution centers
ABNT NBR 13229:2009 Pesticide-Determination of mobility
ABNT NBR 15683:2009 Pesticide and related-determination of viscosity
ABNT NBR 13828:2006 Pesticide and related-determination of the particle size, granumetric range
ABNT NBR 13237:2006 Pesticide and related-determination of the particle size by wet sieving-test method
ABNT NBR 13228:2005 Pesticide and related-determination of solubility in water at 30° C
ABNT NBR 13240:2004 Pesticide and related-determination of the miscibility 30° C
ABNT NBR 14975:2003 Pesticide-determination of melting point
ABNT NBR 14935:2003 Empty packaging of pesticide-final destination of package washed-procedure
ABNT NBR 14719:2001 Rigid packaging empty of pesticide-final destination of washed-packing Procedure
ABNT NBR 13968:1997 Rigid packaging empty of pesticide-washing procedures
ABNT NBR 13241:1994 Pesticide-determination of surface tension-test method

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

Such standards concern to different aspects of these chemical products. Some of them deal with the proper handling of dangerous chemical products, others concern the storage and the nomenclature. All of these standards are Brazilian and they are not explicitly based on international standards.

3.1. International conventions

Brazil is part of three main treaties that regulate chemical safety: the *Basel Convention* controlling transboundary movements of hazardous wastes and their disposals, the *Rotterdam*

Convention 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 reveal the preoccupation with the quality of food, impacts of additives on human health and the occupational exposure to chemical substances.

Brazil ratified the Basel convention in 1992 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 legislation. Additional wastes are regulated or controlled as hazardous pursuant to article 1(1) (b). The country, for example, prohibits the importation of used tires in article 6 of CONAMA resolution n. 452 and prohibits the importation of hazardous wastes and wastes considered as rejects in article 49 of law 12305/10.

Brazil ratified the Rotterdam Convention in 2004. The country notified the final regulatory action on non-annex III chemicals and on annex III chemicals. The following tables show the notifications of final regulatory actions on non-annex III chemicals and on annex III chemicals.

Table 8 - Notifications of final regulatory action – Non-annex III chemicals

Chemical	Category	Final regulatory action	Date published
Cyhexatin	Pesticide	Banned	12/12/2012
Methamidophos (Soluble liquid formulations of the substance that exceed 600 g active ingredient/l)	Pesticide	Severely Restricted	12/12/2004
Methyl parathion	Pesticide	Severely Restricted	12/12/2004
Monocrotophos (Soluble liquid formulations of the substance that exceed 600 g active ingredient/l)	Pesticide	Severely Restricted	12/12/2004
Phorate	Pesticide	Banned	12/6/2017
Phosphamidon	Pesticide	Banned	12/12/2004
Trichlorfon	Pesticide	Banned	12/12/2011

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

Table 9 - Notifications of final regulatory action – Annex III chemicals

Chemical	Category	Final regulatory action	Date published
2,4,5-T and its salts and esters	Pesticide	Banned	12/12/2004
Actinolite asbestos	Industrial	Banned	12/6/2005
Aldrin	Pesticide	Banned	12/12/2004
Amosite asbestos	Industrial	Banned	12/6/2005
Anthophyllite	Industrial	Banned	12/6/2005
Binapacryl	Pesticide	Banned	12/12/2004
Captafol	Pesticide	Banned	12/12/2004
Chlordane	Pesticide	Banned	12/12/2004
Chlordimeform	Pesticide	Banned	12/12/2004
Chlorobenzilate	Pesticide	Banned	12/12/2004
Crocidolite	Industrial	Banned	12/6/2004
Crocidolite	Industrial	Banned	12/6/2005
DDT	Pesticide	Banned	12/12/2004
Dieldrin	Pesticide	Banned	12/12/2004
Dinitro-ortho-cresol (DNOC) and its salts (such as ammonium salt, potassium salt and sodium salt)	Pesticide	Banned	12/12/2004
Dinoseb and its salts and esters	Pesticide	Banned	12/12/2004
Dustable powder formulations containing a combination of benomyl at or above 7%, carbofuran at or above 10% and thiram at or above 15%	Pesticide	Banned	12/12/2004
EDB (1,2-dibromoethane)	Pesticide	Banned	12/12/2004
Endosulfan	Pesticide	Banned	12/12/2011
Ethylene dichloride	Pesticide	Banned	12/12/2004
Ethylene oxide	Pesticide	Banned	12/12/2004
Fluoroacetamide	Pesticide	Banned	12/12/2004

HCH (mixed isomers)	Pesticide	Banned	12/12/2004
Heptachlor	Pesticide	Banned	12/12/2004
Hexachlorobenzene	Pesticide	Banned	12/12/2004
Lindane (gamma-HCH)	Pesticide	Severely Restricted	12/12/2004
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds	Pesticide	Banned	12/12/2004
Methamidophos	Pesticide	Banned	12/12/2012
Monocrotophos	Pesticide	Severely Restricted	12/12/2004
Parathion	Pesticide	Banned	12/12/2004
Pentachlorophenol and its salts and esters	Pesticide	Severely Restricted	12/12/2004
Polychlorinated Biphenyls (PCBs)	Industrial	Banned	12/6/2005
Toxaphene (Camphechlor)	Pesticide	Banned	12/12/2004
Tremolite	Industrial	Banned	12/6/2005

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

The Stockholm Convention was ratified in 2004. The MMA manages the convention's implementation plan with the participation of the country's institutions inside the structure of their respective competences. The process for developing the current national implementation plan (NIP) of the convention followed the guidelines of the Guidance for Developing a National Implementation Plan for the Stockholm Convention on Persistent Organic Pollutants (POPs) and included 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 stakeholders¹.

As part of the set of actions for sound chemical management in Brazil, the development of the National Implementation Plan aims to meet the obligations under the Stockholm convention: i) reduce risks to human health and environment caused by POPs; ii) contribute to improving chemicals management in Brazil, establishing broad governance on the issue; iii) strengthen and expand the capacities of institutions for chemical management and pollution control and iv) 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 process².

4. MANDATORY CONFORMITY ASSESSMENT PROCEDURES

According to Decree No. 4,074/2002, pesticides, their components and similar products may only be produced, handled, imported, exported, marketed and used in the national territory if previously registered in the competent federal agency.

To obtain registration in Brazil, the pesticide must be evaluated by three federal government agencies: the MAPA, the IBAMA and ANVISA.

Each of these bodies performs a particular type of evaluation of the product independently of the others. IBAMA carry out an environmental dossier, in which the pollutant potential of the product is evaluated. The MAPA is assigned the responsibility of evaluating the efficiency and potential of use in agriculture, through an agronomic dossier. ANVISA performs the

¹ 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_impresao_final.pdf> (accessed on 26 February 2018), p. 36.

² *Ibid idem* p. 38.

toxicological dossier, evaluating how toxic the product is to the population and under what conditions its use is safe. The agency responsible for providing the record of pesticides in Brazil is the MAPA. ANVISA is responsible for Toxicological Evaluation of the product.

For information on the Register of Pesticides, see Decree n. 4,074/2002. For information on registration procedures, refer to the Manual of Procedures for Registration of Agrochemicals.

The registration of agrochemicals, its components and the similar products is prohibited in the following cases: i) For the products that, in Brazil, no methods are available for deactivating its components; ii) For the products that there is no antidote or effective treatment in Brazil; iii) For the products considered teratogenic (with sufficient evidences in this sense, from observations in the human species or from studies in experimental animals); iv) For the products considered carcinogenic (that sufficient evidence in this sense, from observations in the human species or from studies in experimental animals); v) For the products considered mutagenic, capable of inducing mutations observed in at least two tests, one to detect gene mutations, including using metabolic activation, and the other to detect chromosomal mutations; vi) For products that cause hormonal disorders, damages to the reproductive system, according to procedures and experiences updated in the scientific community. There are different types of registries in Brazil:

Table 10 - Types of Registry for Pesticides in Brazil

Type of Registry	Product
Temporary Special Registry For Research And Experimentation (Ret)	The company that wishes to develop activities with pesticides (registrant) must initiate the procedure through a Special Temporary Registry (RET), to assign the right to use a pesticide, component or related For specific purposes in research and experimentation, for the time of 3 years, renewable for the same period.
Technical Product	Product obtained directly from raw materials by chemical, physical or biological process, to obtain formulated products or premixes and whose composition contains defined content of active ingredient and impurities, and may contain stabilizers and related products, such as Isomers. For industrial use only.
Technical Product By Equivalence	The technical products of different manufacturers or different manufacturing processes of the same manufacturer shall be considered equivalent if the evaluation of the production process used, the profile of impurities and, if necessary, the evaluation of the toxicological / ecotoxicological profiles, meet The requirements described in Annex X of Decree No. 4074 of 2002.
Pre-mixed	Product obtained from technical product, through chemical, physical or biological processes, exclusively destined to the preparation of formulated products. The registration of premixes is only necessary for those cases in which the premix is to be transported from one plant to another and is unnecessary if it is a step in the formulation process within the same plant.
Product formulated	It is defined by Decree No. 4.074 / 2002 as the pesticide or related product obtained from technical product or premix, through the physical process, or directly from raw materials by means of physical, chemical or biological processes. Those destined to the agricultural use are registered by the Map for commercialization and use in agricultural environments, being forbidden its use in urban or domissanitary environments.
Biological product	Living organism, naturally occurring or obtained by genetic manipulation, introduced into the environment for the control of a population or biological activities of another living organism considered to be harmful.
Microbiological product	Living organism, naturally occurring or obtained by genetic manipulation, introduced into the environment to control a population or biological activities of another living organism considered to be harmful.
Semiochemical product (pheromones and allelochemicals) -	Those constituted by chemical substances that evoke behavioral or physiological responses in the recipient organisms and that are used for the purpose of detection, monitoring and control of a population or biological activity of living organisms, being able to be classified , Depending on the action they cause, intra or interspecifically, as pheromones and allelochemicals, respectively.
Formulated biochemical products	(hormones, growth regulators and enzymes) - are those constituted by naturally occurring chemical substances with a nontoxic mechanism of action, used to control diseases or pests as agents that promote chemical or biological processes, including: hormones and regulators Growth; and enzymes.

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

5. MERCOSUL REGULATION

There are few Mercosul rules on pesticides. This is not a central issue in the regional organization, not even in the framework of the production of technical standards, which is a responsibility of Mercosul Association of Standardization (AMN). The only Working Paper available is the WP 02/2016 is related to the maximum limits of pesticides in fresh vegetables.

Working Subgroup 8 of Mercosul had an important role in the creation of phytosanitary criteria applied in chemical products that are used to guarantee that agricultural goods are free of diseases and pests. Just one CMC decision and 32 GMC resolutions were created from 1999 until 2007. Brazil incorporated 24 of the regulations above mentioned. The norms regulate a variety of topics, being some of the most recurrent the phytosanitary certificate, quarantine requirement and free movement of active substances and/or its formulations. The following table describes these regulations.

Table 11 - Mercosul regulation on chemical products applied to agriculture

Norm	Theme
Decision CMC 1/99	Cooperation and facilitation agreement about the protection of plant varieties in member States of Mercosul
Resolution GMC 30/93	Single phytosanitary certificate
Resolution GMC 55/93	Quarantine requirements for peach, tobacco, vine, garlic, onion, tomato, pepper, citrus, potato, apple and pear
Resolution GMC 56/93	Norms and procedures for the declaration of a country or zone as free of communicable diseases
Resolution GMC 60/94	Phytosanitary inspection on destination point
Resolution GMC 71/94	Phytosanitary control in free zones
Resolution GMC 73/94	Technical requirements for the evaluation of active substances and agrochemical formulated products for Mercosul
Resolution GMC 118/94	Positive list of products that must not be submitted to a phytosanitary intervention
Resolution GMC 47/96	Register of cultivars
Resolution GMC 48/96	Requirements for free movement of phytosanitary products in the current stage of integration of Mercosul
Resolution GMC 87/96	Procedures of registration for free movement of active substances and/or its formulations
Resolution GMC 156/96	Second list of active substances and its formulations of free trade between State countries of Mercosul
Resolution GMC 28/98	Provisions for the trade of inoculants
Resolution GMC 71/98	Third list of active substances and its formulations of free movement between State parties of Mercosul
Resolution GMC 60/99	Principles, guidelines, criteria and parameters for the agreements of equivalence of sanitary and phytosanitary control systems between State parties of Mercosul
Resolution GMC 75/99	Derogation of standard 7.1 "Accreditation of phytosanitary diagnostic laboratories" (modifies res. GMC n. 59/94)
Resolution GMC 2/00	Derogation of res. GMC n. 43/96 and derogation of standard 2.2 of res. GMC n. 59/94
Resolution GMC 55/01	Requirements for the establishment of pest free areas
Resolution GMC 56/01	Glossary of phytosanitary terms
Resolution GMC 34/02	Standard "Regime of Certification and Check on Border Points of Origin/Destination"
Resolution GMC 52/02	Standard 3.7. Phytosanitary requirements harmonized by category of risk for the entry of vegetable products. 2 nd Revision
Resolution GMC 33/03	Derogates resolution GMC n. 74/99 "Phytosanitary Standard: Guidelines for the Identification of Regulated Non-quarantine Pests (PNCR) and Establishment of its Phytosanitary Requirements"
Resolution GMC 44/05	Derogation of res. GMC n. 44/92
Resolution GMC 45/05	Derogation of res. GMC n. 70/94 relative to "single phytosanitary requirement and phytosanitary certification of reexport"
Resolution GMC 46/05	Derogation of res. GMC n. 78/00
Resolution GMC 47/05	Derogation of res. GMC n. 54/01
Resolution GMC 48/05	Integrated system of phytosanitary measures for the risk management of <i>Xanthomonas Axonopodis Pv. Citri</i> in citrus fruits
Resolution GMC 49/05	Procedures for the approval of quarantine treatments (derogation of res. GMC n. 88/96)
Resolution GMC 50/05	Mercosul quarantine treatments
Resolution GMC 16/06	Revocation of res. GMC n. 61/92
Resolution GMC 17/06	Revocation of res. GMC n. 59/94
Resolution GMC 18/06	Revocation of res. GMC n. 62/94
Resolution GMC 41/07	Derogation of res. GMC n. 55/93

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

6. MAIN GOVERNMENT AND PRIVATE ACTORS

The main actors from government areas related to the sector are: (1) the MAPA; (2) the MDIC, more specifically SECEX (Trade) and SDCI (Sector Policies); (3) the MMA; (4) ANVISA; and (5) INMETRO.

From the private sector: (1) ABNT, (2) CNI; (3) FIESP; (4) ABIQUIM; and (5) ABIFINA.

Working Document