



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 – FERTILIZERS



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ACRONYMS

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
ANVISA Brazilian Health Regulatory Agency
ANTT Brazilian Land Transport Agency
ASTM American Society for Testing and Materials
CAMEX Brazil Foreign Trade Chamber
CMC Common Market Council, Mercosul
CMED Regulatory Chamber of Medicines Market
CNI Brazil National Confederation of Industry
CORPROSAL Commission on Health Products
CSM Mercosul Sectorial Committees
DECEX Department of Foreign Trade Operations, Brazil 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
PROFARMA Brazil Program for Supporting the Development of the Pharmaceutical Productive Chain
PRONAF Brazil 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 – FERTILIZERS

1. OVERVIEW

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 \$ 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 billion¹.

Fertilizers have a 10-percent share of the Brazilian chemical industry. The production of fertilizers is a fundamental activity for the agriculture sector, since it also aims to increasing the productivity in the agriculture sector. Brazil also exports fertilizers and similar products to many trade partners. The most important markets for Brazilian exports of fertilizers are the North American Free Trade Area (NAFTA) and the members of Mercosul. The trade with EU is also important, Brazil imported more than USD 700 million from the countries of EU in 2016.

2. TECHNICAL REGULATIONS AND AUTHORITIES

The chemicals sector is complex and involves many different products. The technical regulation is different for each of the sub-sectors. The main regulatory agencies for fertilizers are MAPA, ANVISA, MMA and INMETRO.

Regulations for the fertilizer sector are found in a few ordinary federal laws and executive orders. The Law 6894/80 sets forth the inspection of the production and trade of fertilizers and similar products. The inspection and oversight is conducted by the MAPA (Article 2). Individuals or legal entities that produce or trade fertilizers, correctives, inoculants, stimulants or bio fertilizers, remineralizers and substrates for plants are obliged to provide its register on the Ministry of Agriculture (Article 4). The inspection is done whenever there is a requirement by the individuals or legal entities mentioned in the law (Paragraph 1 of Article 6).

The Federal Law n. 6,934/1981 establishes the need of a permanent technical assistance of an accredited professional with the consequent functional responsibility in order to obtain a register. Federal Law n. 8,522/1992 extinguished inspection fees for the production and commercialization of fertilizers, correctives, inoculants, stimulants or bio fertilizers intended for

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).

agriculture and the inspection fee of plant protection products. Federal Law n. 12,890/2013 includes the remineralizers as a category of input for agriculture.

The Decree n. 4,954/2004 establishes the regulation of Federal Law n. 6,894/1980. The most relevant chapters of the Decree for a regulatory analysis deal with register production, packaging, labeling and advertising, trade, storage and transport, inspection and oversight of fertilizers and similar products. MAPA has competence to inspect and oversee the production, importation, exportation and trade of fertilizers, correctives, inoculants, bio fertilizers, remineralizers and substrates for the plants and to edit complementary norms needed to compliance with the regulation (Article 3). There are concurrent competences of states and of the Federal District to oversee and legislate about trade and use of fertilizers, correctives, inoculants, bio fertilizers, remineralizers and substrates of plants (Article 4).

Production and trade of fertilizers and similar products must be registered in MAPA. Article 8 of the Decree also makes mandatory the registration of fertilizers, correctives, inoculants, bio fertilizers, remineralizers and substrates of plants by the productive and importing establishments on MAPA. It is worth noting that facilities, equipment and minimum systems of quality control will be defined in an administrative act of MAPA. The registry of imported products, when intended exclusively to trade, must be conceded on the basis of the analysis of certificate and of the register certificate or of free trade and current consumption provided that there is compliance with technical requirements about specifications and guarantees applied in Brazil and that the importer is registered before MAPA (Article 14). Every new product, national or imported, that does not have a history of use in the country, in any of its technical aspects, will only have its registry conceded after a conclusive technical-scientific report issued by a Brazilian body of official research or accreditation that attests the viability and efficiency of its agricultural use (Article 15).

Article 16 of Decree n. 4,954/2004, *caput*, exempts of registry the secondary material obtained in an industrial process that has plant's nutrients or other components that promote the improvement of physical, physicochemical or biological properties of the soil. Paragraph 1 of Article 16 establishes that the authorization of MAPA is necessary to trade secondary material. Paragraph 2 of article 16 provides that to use of the secondary material mentioned above as raw material to the manufacturing of products, producer establishments must: (i) prove the authorization to process the material; and, (ii) present an analytical award with the percentage of heavy toxic metals or other contaminants and the methods or processes for the preparation of the final product.

Regarding trade, storage and transport, according to article 36 of the Decree, only fertilizers and similar products that comply with the regulation and with the administrative acts of MAPA, may be traded. Article 44 foresees that, considering the regulation and administrative acts, each imported product can be sampled by MAPA and analyzed by an official or accredited laboratory². Article 45 establishes that each imported lot or consignment of inoculants, bio fertilizers, organic fertilizers, agricultural correctives of organic origin, mixtures containing organic substances or other products that may harbor pests shall, be accompanied by the corresponding phytosanitary certificate issued by the plant protection agency of the country of origin.

² The list of laboratories can be found in <http://www.agricultura.gov.br/assuntos/laboratorios/rede-nacional-de-laboratorios-agropecuarios/fertilizantes-corretivos-substratos-e-afins>

Regarding inspection and oversight, article 49 determines that the oversight body of MAPA must inspect and oversee producers, commercial establishments, importers and exporters of fertilizers, correctives, inoculants, bio fertilizers, remineralizers and substrates for plants and its products and raw material. According to article 50, procedures to audit compliance with the Technical Regulation of Good Practices of Production and Control (BPFC) in the establishments by the regulation are deemed actions of inspection and oversight. The federal agricultural supervisor is responsible for the inspection and the oversight.

Article 57 obliges producing establishments, importers and merchants to have written procedures and control and record mechanisms to ensure the quality of the products and the manufacturing processes of the products in order to guarantee the production, import and marketing of fertilizers, inoculants, correctives, bio fertilizers, remineralizers and substrates for plants with quality for the purpose of the proposed use. Paragraph 2 of the same article stipulates that the own or third-party laboratories responsible for carrying out the quality control analysis of raw materials and finished products of the establishments covered by the regulation, must be registered in MAPA. Paragraph 3 of the same article further provides that the quality control can be done through the adoption of the program of good practices of manufacturing and control.

The following table presents a list of the main infralegal norms that regulate fertilizers, correctives, inoculants, bio fertilizers, remineralizers and substrates for plants and its products.

Table 1 - List of Technical Regulations about fertilizers

Technical regulation	Provisions
Ordinance 31/1982	Approves the analytical methods in annex, which become standard, official methods for the analysis of correctives, fertilizers and inoculants subject to inspection.
Ordinance SEFIS 2/1984	Approves and makes official the "Service Manual of Inspection and Production and Trade of Fertilizers, Corrective Agents, Inoculants, Stimulants or Bio fertilizers".
Ordinance 3	Grants the tolerance of 10% of the minimum guarantee of the fertilizer Thick Magnesian Thermophosphate, in the ABNT n° 20 sieve (0,84 mm), which is dealt with in Ordinance n° 001, of May 22, 1984 of the Secretary of Agricultural Inspection.
Ordinance 415/1986	Requires the publication of administrative acts, of external effects, resulting from the inspection and control activities of the various agricultural inputs.
Ordinance 121/1995	Regulates the issuance of documents related to the supervision of correctives, fertilizers, inoculants, stimulants or bio fertilizers by computer, approving official models of documents and forms.
Normative instruction 53/2013	Regulates registers, packing and labeling. Establishes minimal requirements to the evaluation of agronomic viability and efficiency and preparation of technical-scientific report for the register of fertilizer, corrective and bio fertilizer in the condition of new product.
Normative instruction 1/2007	Establishes the criteria for accreditation, recognition, extension of scope and monitoring of laboratories in the Ministry of Agriculture, Livestock and Supply, in order to integrate the National Network of Agricultural Laboratories of the Unified System of Attention to Agricultural and Livestock Health, foreseen in the annex to the normative instruction. A technical commission is created to deliberate about concession, suspension or cancellation of accreditation or recognition of laboratories. The annex states criteria for accreditation, recognition, scope extension and monitoring of laboratories in the ministry of agriculture
Normative instruction 38/2009	Alters article 16 of normative instruction 1/2007, which will become effective with the following wording: "the results obtained by the laboratories concerning the samples of the official controls shall be issued in models established by MAPA.
Normative instruction DAS 28/2007	Approves the official analytical methods for mineral, organic, organo-mineral and corrective fertilizers.
Normative instruction 28/2004	Extends, until April 30 2005, the deadline foreseen in item "a" of subsection II of article 38 of normative instruction 10/2004 for the requirement of adequacy of the registers of products conceded before the publication of decree 4954/2004.
Normative instruction 25/2009	Approves standards on specifications and guarantees, tolerances, registration, packaging and labeling of simple, mixed, composite, organomineral and bio fertilizer fertilizers intended for agriculture.
Normative instruction 10/2006	Changes the list of microorganisms authorized for inoculant production in Brazil, contained in annex II, of normative instruction SARC n° 05, of August 6, 2004, which becomes that described in the annex of the normative instruction.
Normative instruction 34/2008	Revokes normative instruction 1/1993.
Normative instruction 5/2007	Approves the definitions and standards for specifications and warranties, tolerances, registration, packaging and labeling of mineral fertilizers, intended for agriculture. It revokes normative instruction SARC 10/2004.
Normative instruction	Approves standards on specifications and warranties, tolerances, registration, packaging and

35/2006	labeling of acidity, alkalinity and soil conditioners, intended for agriculture. Sanctions foreseen in decree 4954/2004 will be applied if the norms established in the normative instruction are violated. The normative instruction SARC 04/2004 is revoked.
Normative instruction 27/2006	Regulates fertilizers, correctives inoculants and bio fertilizers, which to be produced, imported or marketed, must meet the limits established in annexes I, II, III, IV and V of the normative instruction in which regards maximum permissible concentrations for phytotoxic agents, pathogenic to humans, animals and plants, toxic heavy metals, pests and weeds. Sanctions foreseen in decree 4954/2004 will be applied if the norms established in the normative instruction are violated.
Normative instruction 5/2004	Approves the definitions and standards on specifications, guarantees, registration, packaging and labeling of inoculants destined to agriculture, as well as the list of micronutrients authorized for the production of inoculants in Brazil.
Normative instruction 14/2004	Approves the definitions and norms on specifications and warranties, tolerances, registration, packaging and labeling of substrates for plants, listed in the annex to the normative instruction.
Service instruction SNAD 1/1992	Decentralizes the register of establishments and products. The levels of guarantee of products destined to animal feeding and fertilizers will be written in the specific annex of the register certificate of the product.
Service instruction SNAD 3/1992	Gives additional instructions to the registration of establishments and products.
Service instruction SNAD 4/1992	Details complementary instructions to the decentralization of the register of establishments and products.

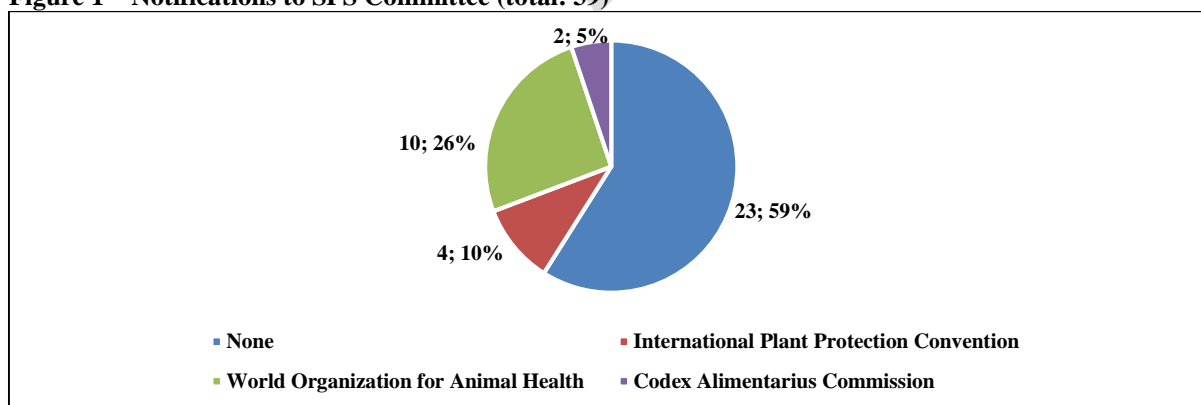
Source: ADAPAR. Prepared by CCGI-EESP/ FGV (May 2017).

The chemicals sector is complex and involves many different products. The technical regulation is different for each of the sub-sectors. The main regulatory agencies for fertilizers are MAPA, ANVISA, MMA and INMETRO.

2.1. Notifications to WTO

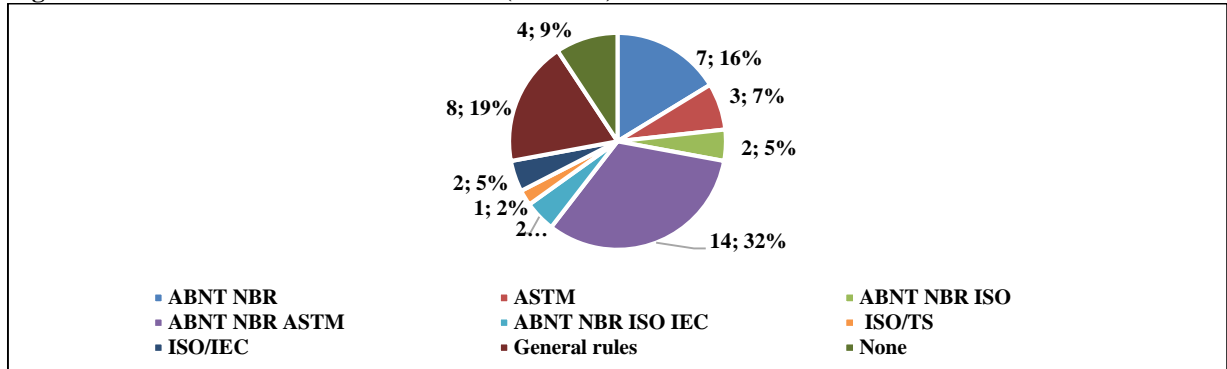
Brazil notifies regulations relating to different kinds of chemical products. In such notifications is possible to identify the standards that support such regulations. For all chemical products, Brazil notified the SPS Committee 39 times and the TBT Committee 43 times.

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



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

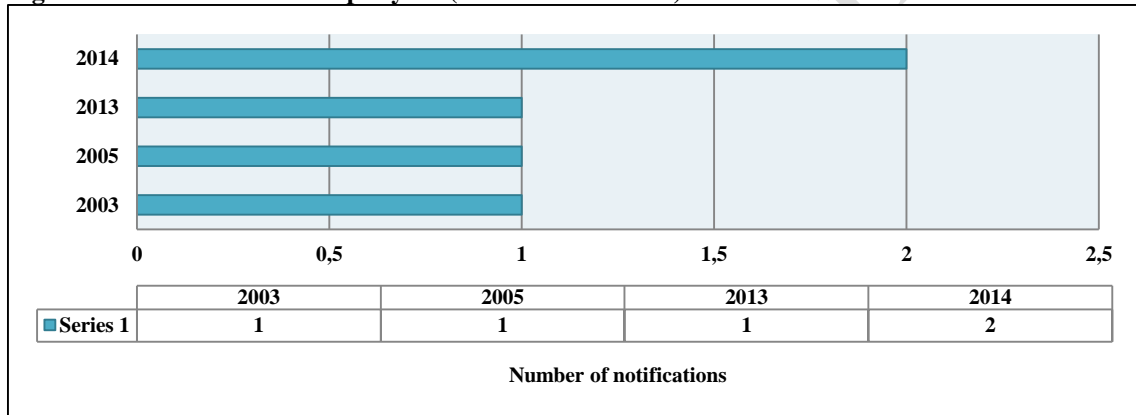
Figure 2 – Notifications to TBT Committee (total: 43)



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

Specifically, for the HS 31, fertilizers, the regulations created by MAPA are very important. Such regulations are communicated to the WTO under the agreement on Technical Barriers to Trade (TBT). In the period between 2003 and 2014, 5 notifications were made by Brazil to the TBT Committee. The graphic below shows the notifications made each year.

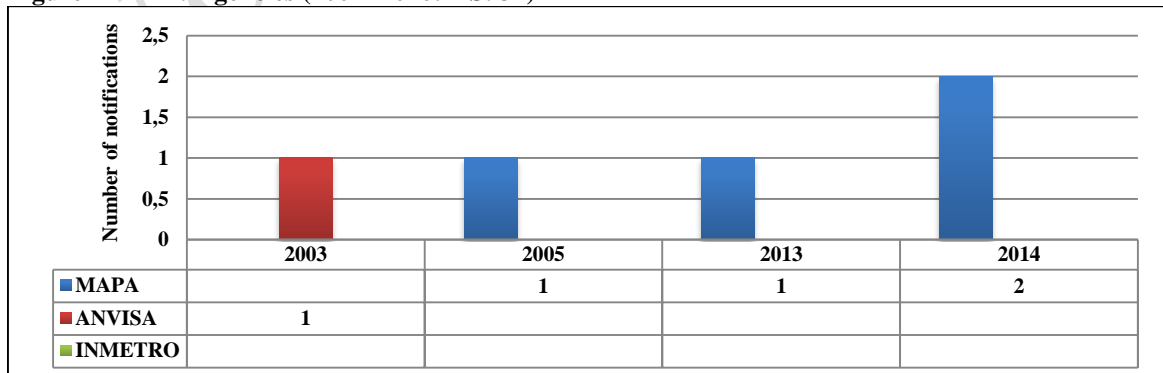
Figure 3 - TBT: Notifications per year (2001- 2016: HS: 31)



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

The graphic below reveals the main bodies that made notifications to the TBT Committee. MAPA, Anvisa and INMETRO have important roles in the technical regulation of the chemical sector.

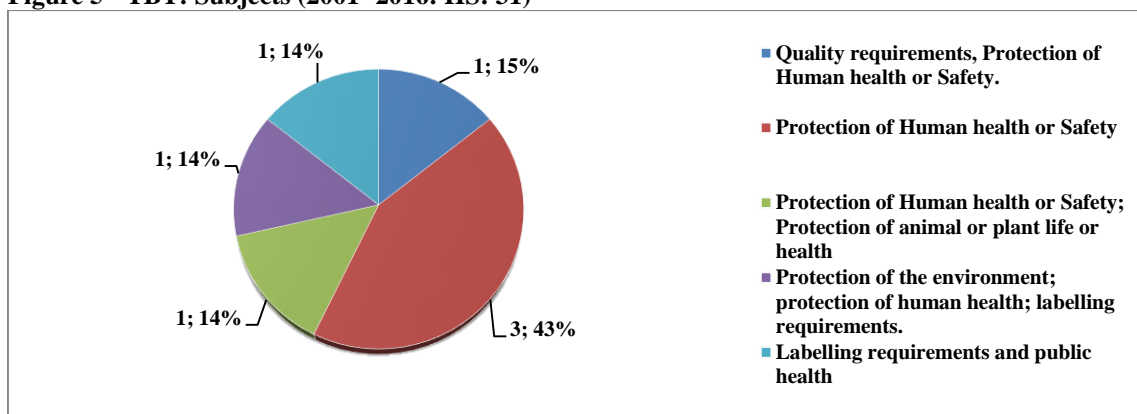
Figure 4 - TBT: Agencies (2001- 2016: HS: 31)



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

The graphic below shows the percentage of each TBT subject on the notifications. Protection of human health is the subject more frequent (it appears in 3 of 7 notifications).

Figure 5 - TBT: Subjects (2001- 2016: HS: 31)



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

The table below contains the Brazilian notifications to TBT Committee.

Working Document

Table 2 - List of Notification to TBT Committee

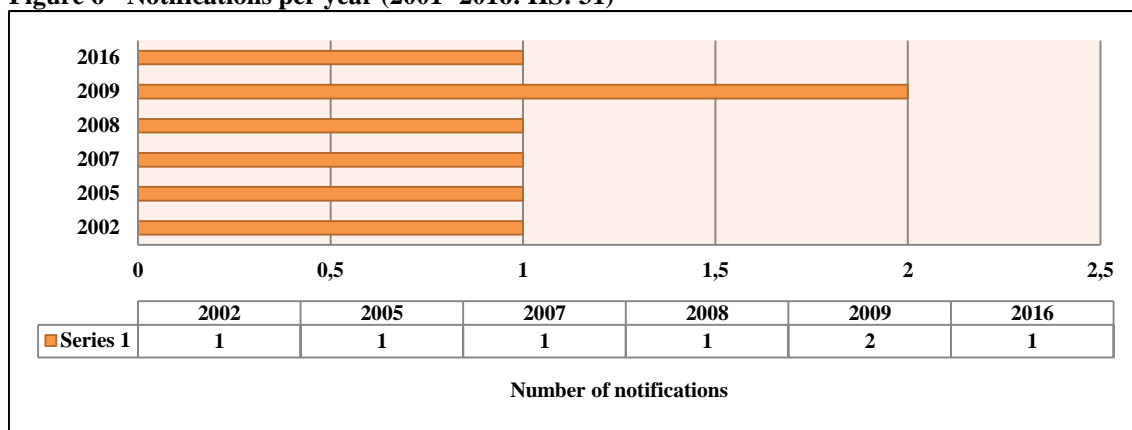
Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale	Technical Provisions/Standards
G/TB T/N/B RA/00 00009 1	2003	28-inorganic chemicals; organic or inorganic compounds of precious metals, of rare- earth metals, of radioactive 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 (Consulta Pública no. 100 de 16 de dezembro de 2002) 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.	Labelling requirements and public health	

G/TB T/N/B RA/19 4	2005	Animal or vegetable fertilizers, whether or not mixed together or chemically treated; fertilizers produced by the mixing or chemical treatment of animal or vegetable products (HS: 3101)	MAPA	Ministerial Act on definitions for organic fertilizers destined to agriculture Technical Regulation which lays down labelling and packaging requirements for organic fertilizers destined to agriculture. It also revokes the following documents: Ministerial Act number SARC N° 15, 22 December 2004 (Instrução Normativa SARC N° 15, de 22 de Dezembro de 2004).	Draft not found	Technical Regulation which lays down labelling and packaging requirements for organic fertilizers destined to agriculture. It also revokes the following documents: Ministerial Act number SARC N° 15, 22 December 2004 (Instrução Normativa SARC N° 15, de 22 de Dezembro de 2004).	Protection of the environment; protection of human health; labelling requirements.	
G/TB T/N/B RA/56 3	2013	Fertilizers, liming, inoculants, agricultural bio fertilizers or secondary materials (HS 31)	MAPA	Ordinance N° 53, 13 October 2013 (Instrução Normativa n° 53, de 23 de outubro de 2013) determines criteria for definitions, classification, establishment registration and importation of fertilizers, liming, inoculants, agricultural bio fertilizers or secondary materials Technical Regulation which lays down labelling and packaging requirements for organic fertilizers destined to agriculture. It also revokes the following documents: Ministerial Act number SARC N° 15, 22 December 2004 (Instrução Normativa SARC N° 15, de 22 de Dezembro de 2004).	In force	Technical regulation and assessment procedures establishing provisions, criteria, inspection and supervision for the production and trade of fertilizers, liming, inoculants, agricultural bio fertilizers or secondary materials. It revokes Ordinance N°. 10, 6 May 2004 and Ordinance N°. 20, 2 June 2009 (Instrução Normativa N° 10, de 6 de maio de 2004 e a Instrução Normativa N° 20, de 2 de junho de 2009).	Protection of Human health or Safety; Protection of animal or plant life or health	NBR 5426 e NBR 5427

G/TB T/N/B RA/57 2	2014 FERTILISERS (HS 31)	MAPA	Ordinance N°. 3, 9 January 2014 (Portaria N° 3, de 9 de janeiro de 2014). "The regulation lays down the analytical methods to approve Mineral, Organic and Organo-Mineral fertilizers as well as the analytical methods to approve some agricultural nutrient compounds in order to adjust the relative acidity or alkalinity of the soil" Draft Technical Regulation establishing the analytical methods to be used by the Ministry of Agriculture, Livestock and Food Supply (MAPA) Laboratories or by a third party for the fertilizers and agricultural nutrients compound evaluation, verification and assurance of conformity in order to adjust the relative acidity or alkalinity of the soil as well as to verify the chemical contaminants. INSTRUÇÃO NORMATIVA N° 3, DE 26 DE JANEIRO DE 2015	In force	Draft Technical Regulation establishing the analytical methods to be used by the Ministry of Agriculture, Livestock and Food Supply (MAPA) Laboratories or by a third party for the fertilizers and agricultural nutrients compound evaluation, verification and assurance of conformity in order to adjust the relative acidity or alkalinity of the soil as well as to verify the chemical contaminants.	Protection of Human health or Safety	General rules
G/TB T/N/B RA/57 7	2014 Mineral fertilizers	MAPA	MAPA Ordinance N°. 7, 16 January 2014: draft technical regulation providing requirements for mineral fertilizers. Draft Technical Regulation establishing the analytical methods to be used by the Ministry of Agriculture, Livestock and Food Supply (MAPA) Laboratories or by a third party for the fertilizers and agricultural nutrients compound evaluation, verification and assurance of conformity in order to adjust the relative acidity or alkalinity of the soil as well as to verify the chemical contaminants.	In force	Draft technical regulation to provide rules for product characteristics and to lay down provisions for production, registration, packaging, labelling, etc. of mineral fertilizers. It revokes MAPA Ordinance N° 21, 16 April 2008 (Instrução Normativa N° 21, de 16 de abril de 2008) notified as document G/TBT/N/BRA/279.	Quality requirements, Protection of Human health or Safety.	General rules

In the period from 2002 to 2016, seven notifications were made by Brazil to SPS Committee. This relatively low number of notifications about fertilizers is consistent with the scarcity of technical regulation about this type of product. These products are often indirectly regulated by more general rules that focus on their basic chemical components used in its process of manufacture. The following graphic illustrates the number of notifications to SPS Committee per year.

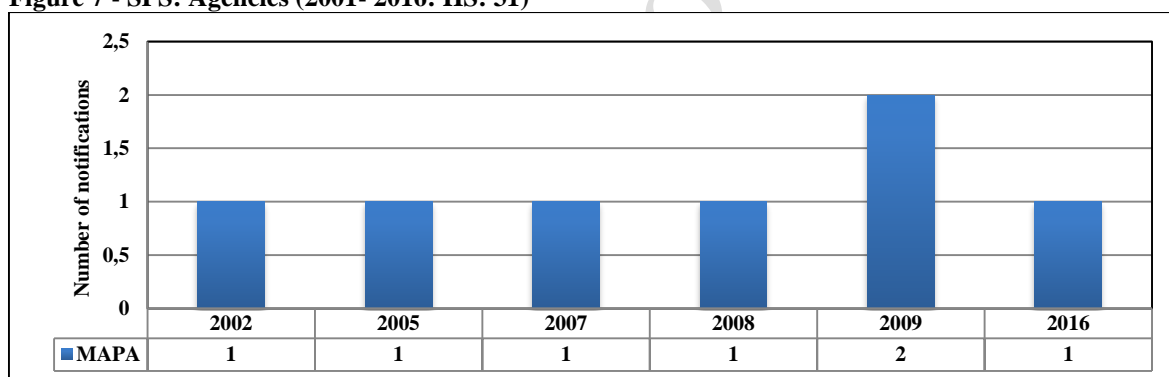
Figure 6 - Notifications per year (2001- 2016: HS: 31)



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

The graphic below shows MAPA notifications to SPS Committee per year.

Figure 7 - SPS: Agencies (2001- 2016: HS: 31)

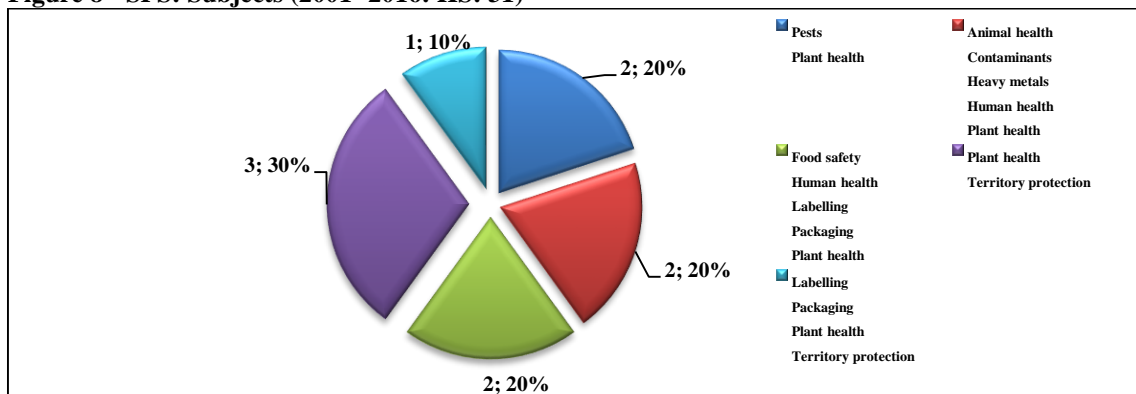


Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

The main topics foreseen in the notifications are the following: i) methods for the analysis of fertilizers; ii) specifications and warranties, inspection, registration, packaging and labelling of fertilizers; iii) publication of administrative acts resulting from the inspection and iv) control activities and accreditation, recognition, extension of scope and monitoring of laboratories.

An important part of the notifications made to SPS Committee concerns animal health, contaminants and the existence of heavy metals in the fertilizers. The following graphic reveals the percentage of each SPS subject on the notifications.

Figure 8 - SPS: Subjects (2001- 2016: HS: 31)



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

MAPA is the main body that notified technical regulations to the WTO, playing a role more important than ANVISA in this subsector. In case of fertilizers, the analysis made by MAPA as well as the registry is a condition to legally market the products.

All the notifications to SPS Committee were made by MAPA. Since 2002, MAPA notified the SPS Committee seven times.

The following table shows Brazilian notifications to SPS Committee.

Table 3 - Notifications to TBT Committee

Doc.	Year	Products covered	Agency responsible	Notified document title	Situation	Description of content	Objective and rationale
G/SPS/ N/BRA/ 111	2005	Fertilizers, Soil Correctives, Inoculants and Bio fertilizers.	MAPA	Title, language and number of pages of the notified document: "Portaria" N° 49, issued on 25 April 2005, published in the "Diário Oficial da União" (Federal Official Journal) from 27 April 2005, section 1, page 20 (available only in Portuguese, two pages). The text may be downloaded from the following Internet site: http://oc4j.agricultura.gov.br/agrolegis/do/consultaLei?op=viewTextual&codigo=11865 Description of content: The notified regulation will establish the maximum allowable level of phytotoxic agents, pathogenic to human, animals and plants, toxic heavy metals, plagues and weeds, to be contained in fertilizers, soil correctives, inoculants and bio fertilizers. It establishes a 60 days period for comments on the draft law.	The notified regulation will establish the maximum allowable level of phytotoxic agents, pathogenic to human, animals and plants, toxic heavy metals, plagues and weeds, to be contained in fertilizers, soil correctives, inoculants and bio fertilizers. It establishes a 60 days period for comments on the draft law.	animal health, plant protection, protect humans from animal/plant pest or disease	None
G/SPS/ N/BRA/ 300	2007	Mineral fertilizers used in agriculture	MAPA	Title, language and number of pages of the notified document: Normative Instruction N° 5, issued on 23 February 2007, published in the "Diário Oficial da União" N° 41 (Federal Official Journal) from 1 March 2007, section 1, pages 10 to 21. The text may be downloaded from the following Internet site: http://extranet.agricultura.gov.br/sislegis-consulta/consultarLegislacao.do?operacao=visualizar&id=17655 (available only in Portuguese, 39 pages) Description of content: The notified regulation approves the definitions and norms for specification, guarantee, tolerance, register, packaging and labelling of mineral fertilizers used in agriculture.	The notified regulation approves the definitions and norms for specification, guarantee, tolerance, register, packaging and labelling of mineral fertilizers used in agriculture.	food safety, plant protection	Codex Alimentarius Commission

G/SPS/ N/BRA/ 393	2008	Organic fertilizers - simple, mixed and compounds, mineral-organic fertilizers and bio fertilizers for agriculture	MAPA	<p>Title, language and number of pages of the notified document: "Portaria" Nº 42, issued on 5 March 2008, published in the "Diário Oficial da União" Nº 46 (Federal Official Journal) from 7 March 2008, section 1, pages 4 to 8 (available only in Portuguese). The text may be downloaded from the following Internet site: http://extranet.agricultura.gov.br/sislegis-consulta/consultarLegislacao.do?operacao=visualizar&id=18505</p> <p>Description of content: The notified regulation opens a 30-days period for public consultation on the draft normative instruction that approves the definitions and standards on the specifications, guarantees, tolerances, registration, packaging and labelling of organic fertilizers - simple, mixed, compounds, mineral-organic fertilizers and bio fertilizers for agriculture.</p>	<p>The notified regulation opens a 30-days period for public consultation on the draft normative instruction that approves the definitions and standards on the specifications, guarantees, tolerances, registration, packaging and labelling of organic fertilizers - simple, mixed, compounds, mineral-organic fertilizers and bio fertilizers for agriculture.</p>	<p>plant protection; territory from other damage from pests.</p>	None
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3. STANDARDS AND SUPPORTING STANDARDS

ABNT produces technical standards about fertilizers that are under the committee ABNT/CEE-182 Fertilizers and Soil Correctives. Most part of these standards concern the composition of the fertilizer, dealing with the amount of determined substances recommended for specific types of fertilizers. In the case of fertilizers and other agricultural correctives, the Brazilian technical norms are not produced on an explicit basis in international norms. Also noteworthy is the small number of technical standards produced for this type of product, despite the existence of a specific committee within ABNT. The following table contains ABNT standards on fertilizers.

Table 4 - Standards of ABNT

Standard
ABNT NBR 14094:2012 Fertilizers — Determination of total nitrogen content — Kjeldahl simplified method in urea
ABNT NBR 15822:2010 Fluid fertilizers – Determination of density – Method of pycnometer
ABNT NBR 16533:2016 Phosphoric acid – Determination of the fluorine content by distillation and titrimetric method
ABNT NBR 5771:2010 Solid fertilizers – Determination of free water
ABNT NBR 5772:2014 Determination of oil in anhydrous ammonia in fertilizer – Hexane method
ABNT NBR 5773:2014 Determination of water and nitrogen in anhydrous ammonia for fertilizers – Test method
ABNT NBR 5774:2010 Solid phosphate fertilizers – Determination of free acidity – Titrimetric method
ABNT NBR 5988:2012 Fertilizers – Determination of total nitrogen content – Kjeldahl method in the absence of nitrate
ABNT NBR 5990:2012 Fertilizers – Determination of nitrogen content in urea – Urease method
ABNT NBR 6305:2010 Fertilizers – Nitrate detection
ABNT NBR 6306:2012 Fertilizers – Determination of ammoniacal nitrogen content – Magnesium oxide method
ABNT NBR 7126:2012 Fertilizers – Determination of nitric and ammoniacal nitrogen content – Alloy Devarda method
ABNT NBR 7345:2013 Soil acidity correctives – Sampling in trucks and railway wagons
ABNT NBR 8908:2014 Nitric acid for industrial use – Determination of total acidity by titrations method – Test method

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

4. MANDATORY CONFORMITY ASSESSMENT PROCEDURES

Conformity assessment procedures are mainly established by technical regulations instead of standards. The Federal Law n. 6,894/1980, the Decree n. 4,954/2004 and different Normative Instructions prescribe the procedures that must be followed to produce and to trade fertilizers and similar products.

Certification is applied in the seed health test. The lots of imported seed can contain pathogens or pathotypes that can be introduced in neutral areas, which makes quarantine and certification tests necessary³.

The procedures of registration of fertilizers go through an assessment to verify if they were created and instructed with all the informative and documental elements foreseen in legal norms. This verification is done through the form PT3.2 called conformity of register of fertilizers. The document contains a list of legal requirements for the MAPA to grant the certificate of registry of a fertilizer. The analysis is done through the comparison of the procedures foreseen in PT3.2 and the documents that are in the registry process being examined⁴.

The conformity assessment of the registry processes of a fertilizer embraces the following measures: i) consultation of the control systems for registration of the product; ii) consultation of the table of reference and calculation of the size of samples of each process; iii) elaboration of the list of processes, their requisition through the drawing up of the request for information or

³ BRAZIL. MAPA. **Regras para análise de sementes**. Brasília: MAPA/ACS, 2009. Available at <http://www.agricultura.gov.br/assuntos/insumos-agropecuarios/arquivos-publicacoes-insumos/2946_regras_analise_sementes.pdf> (accessed on 26 February 2018), p. 336.

⁴ BRAZIL. MAPA. **Auditoria operacional na fiscalização de insumos agrícolas: procedimentos**. Brasília: MAPA/ACS, 2011. Available at <http://www.agricultura.gov.br/assuntos/insumos-agropecuarios/arquivos-publicacoes-insumos/auditoria_f.pdf> (accessed on 27 February 2018), pp. 97-98.

their withdrawal of the archive; iv) data collection, tabulation and calculation; v) elaboration of nonconformities ratio to be clarified; vi) drafting of the request for clarification term and sending to the auditee for elaboration of an analytic text⁵.

The conformity assessment of the register of a fertilizer is classified according to the following concepts and criteria: i) if conformity is higher than 90 per cent, the service of register of fertilizers is adequate; ii) if conformity is less or equal to 90 per cent and higher than 75 per cent, the service of register is moderately appropriate and iii) if conformity is less than 75 per cent, the service of register is inadequate⁶.

The conformity assessment of the licensing for importation of fertilizers aims to verify if the administrative processes were constituted and instructed with all the informative and documentary elements required in the legal norms. The analysis of the licensing process must be done according to the following steps: i) consultation of the register to obtain the number of processes constituted and in process; ii) consultation of the table of reference and definition of the size of the sample; iii) drawing up of the requisition term for process of information; iv) random selection of sample processes; v) collection of data, tabulation and calculation; vi) elaboration of the list of nonconformities to be clarified; vii) sending the request for clarification term and elaboration of an analytic text⁷.

The conformity assessment of the licensing for importation of fertilizers is classified according to the following criteria: i) if conformity is higher than 90 per cent, the service of licensing of fertilizers is adequate; ii) if conformity is less or equal to 90 per cent and higher than 75 per cent, the service of licensing is moderately appropriate and iii) if conformity is less than 75 per cent, the service of licensing is inadequate⁸.

Fertilizers go through private certification in Brazil and can receive the labels Bio Suisse, Demeter International and IBD. The label Bio Suisse represents the non-use of pesticides or synthetic fertilizers. Demeter is applied to biodynamic wines, which were not produced with synthetic chemical fertilizers and pesticides. IBD label indicates that mineral and/or organic fertilizers were used in agriculture.

5. MERCOSUR REGULATION

In Mercosur, Resolution MERCOSUL GMC n. 147/1996 creates the *Ad Hoc* Commission of Fertilizers, Correctives and Inoculants.

Resolution MERCOSUL GMC 28/1998 creates measures to facilitate the trade of inoculants. Examples of measures are the register of the product on the receiving State and the submission of products that were never used on the receiving State to field test and to the verification of agronomic efficiency.

⁵ *Ibid Idem* [p. 97.](#)

⁶ *Ibid Idem* [p. 101.](#)

⁷ *Ibid Idem* [p. 160.](#)

⁸ *Ibid Idem* [p. 164.](#)

6. MAIN GOVERNMENT AND PRIVATE ACTORS

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

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

Working Document