



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 –
COSMETICS**



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

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Multiple Framework Contract FWC FPI PSF 2015

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



Request for Service 2016/379494 Version 1

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Deliverable 2:

BRAZIL – CHEMICAL SECTOR – COSMETICS

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LIST OF ABBREVIATIONS

ABIQUIM Brazilian Chemical Industry Association
ABIFINA Brazilian Association of Fine Chemical Industry
ABNT Brazilian Association of Technical Standards
ACE Economic Complementation Agreement
AFFEE Authorization of Manufacture for Exclusive Purpose of Export
ALADI Latin American Integration Association
ANVISA Brazilian Health Regulatory Agency
ANTT Brazilian Land Transport Agency
ART Technical liability annotation
ASTM American Society for Testing and Materials
CAMEX Brazilian Foreign Trade Chamber
CAP Mercosul Common Automotive Policy
CMC Common Market Council, Mercosul
CMED Regulatory Chamber of Medicines Market
CNA Brazilian Confederation of Agriculture and Livestock
CNI Brazil National Confederation of Industry
CNTT Brazilian National Thematic Tripartite Commission
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
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
IAF International Accreditation Forum
IEC International Electrotechnical Commission
IBAMA Brazilian Institute of the Environment and Renewable Natural Resources
IBDF Brazilian Institute for Forest Development
ILAC International Laboratory Accreditation Cooperation
ILO International Labor Organization
INMETRO Brazilian National Institute of Metrology, Quality and Technology
IPI Brazilian Manufactured Products Tax
ISO International Standardization Organization
MCR Adjusts the General Norms
MDIC Brazil Ministry of Industry, Foreign Trade and Services
MERCOSUL Common Market of the South
MMA Brazil Ministry of Environment
MRA Mutual Recognition 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 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
UNECE United Nations Economic Commission for Europe
WTO World Trade Organization

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

Deliverable 2

BRAZIL – CHEMICAL SECTOR – COSMETICS

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 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 billion¹.

This chemical sector usually includes personal hygiene, perfumery and cosmetics (PHPC) products, all under Chapter 33 of the Harmonized System (2017). Differently from what happens in other chemical sub-sectors, Brazil has a surplus in the cosmetics trade. In 2016, Brazil experienced a surplus of US\$ 100 million (Aliceweb, 2017). There was an important participation of Argentina and other Latin American as importers of cosmetics. Currently, Brazil would also be the fourth biggest PHPC products consumer market in the world².

2. MAIN REGULATIONS AND AUTHORITIES

Brazilian provisions are derived from a general Federal Law, two federal decrees, about 30 ANVISA resolutions and ordinances, about 9 INMETRO resolutions, and 48 Mercosul resolutions.

Federal Law n. 6,360/1976 sets basic rules for the PHPC sector. It also establishes basic guidelines and rules for sanitary surveillance to medicine and the requirements for PHPC products that are to be sold in the Brazilian market all in the same text of law. Article 3 of such Federal Law determines legal concepts of perfumery, cosmetics and hygiene products, raw materials, labelling, packaging, batch or lot of a product and establishes their registry number and product quality control.

PHPC products have an external use, therefore, as determined by the aforementioned Federal Law, they do not have to go through the same quality procedures, restrictions and surveillance requirements as drugs and medicines, which means that if your product is classified under the law as a PHPC product, there will be no need to go through additional procedures established to

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).

² ABIHPEC (*Associação Brasileira da Indústria de Higiene Pessoal Perfumaria e Cosméticos*). *Panorama do setor 2017* (report). Available in: <https://abihpec.org.br/publicacao/panorama-do-setor-2017/>

medicine and drugs. However, the Brazilian Health Regulatory Agency (ANVISA)³ still has to authorize and to register all PHPC products. Federal Law n. 6,360/1976 Article 26 defines which products will be classified as PHPC goods under Brazilian law and, therefore, can benefit from PHPC registration instead of having to comply with all requirements for registering medicines or drugs. The major difference is defined under Article 27, which establishes that PHPC goods can be composed of innocuous formulas. This status will be legally recognized by their inclusion in the Brazilian Ministry of Health's list of substances declared innocuous or by making prove of the innocuity of the formula through a conclusive technical and analytic opinions provided by the Brazilian Ministry of Health's competent authorities.

Federal Law n. 6,360/1976 sets general provisions for PHPC goods in Brazil and Decree n. 8,077/2013 regulates this law and implements it. This Decree puts forward conditions for the operation of companies subject to sanitary licensing, and the registration, control and monitoring, within the scope of health surveillance, of all the products referred to in Federal Law n. 6,360/1976, especially PHPC products. It also mandates ANVISA to conduct the registry, control and monitoring of PHPC products. These regulations establish that if the a PHPC product do not produces any harm or creates any risk to human health, it can be subject to a simplified registration procedure before ANVISA.

It is important to highlight that the Federal Law n. 9,782/1999, which creates the ANVISA, foresees that, products under Federal Law n. 6,360/1976 may not go through the registry procedures. There are, currently, 2,613 PHPC companies in activity, certified and audited by ANVISA.

A relevant share of the Ordinances of ANVISA internalizes Mercosul technical regulations. Other Ordinances provides deadlines for expiration of the registry, labeling and other technical aspects of the products.

Table 1 - List of ANVISA Ordinances on Cosmetic Products

Subject	RDC n°	Data
Labeling for SUS	131	05/12/2016
Internalization of Mercosul Regulation	83	17/06/2016
Internalization of Mercosul Regulation	69	23/03/2016
Internalization of Mercosul Regulation	15	24/04/2015
Internalization of Mercosul Regulation	7	10/02/2015
Internalization of Mercosul Regulation	48	25/10/2013
Internalization of Mercosul Regulation	19	10/04/2013
Internalization of Mercosul Regulation	15	26/03/2013
Internalization of Mercosul Regulation	44	09/08/2012
Internalization of Mercosul Regulation	30	01/06/2012
Internalization of Mercosul Regulation	29	01/06/2012
Internalization of Mercosul Regulation	3	18/01/2012
Time extension	54	25/10/2011
Internalization of Mercosul Regulation	38	04/08/2011
Formaldehyde	36	17/06/2009
Desregulation (Degrees 1 e 2)	92	09/12/2008
Internalization of Mercosul Regulation	176	21/09/2006
Time extension	172	08/09/2006
Time extension	78	10/05/2006
Cosmetovigilance system	332	01/12/2005
Time extension	108	27/04/2005
Toothbrushes	13	17/01/2003

³ ANVISA Regulatory framework can enact resolutions by the decision of its Board of Directors (RDCs) and ordinances. There are currently 3 ordinances and 27 RDCs in force regarding PHPC.

Inclusion of www.anvisa.gov.br website	254	12/09/2002
Definition of PHPC	79	28/08/2000
Training program on good governance for auditors and inspectors	74	07/08/2000
Pacifiers and other items	10	21/10/1999
Microbiological control of PHPC	Res. 481	23/09/1999
Adoption of Mercosul classification system	Ord. 296	16/04/1998
	Ord. 295	16/04/1998
Toothbrushes	Ord. 97	26/06/1996

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

Table 2 - List of Hygiene, Perfumery and Cosmetics products with registry in ANVISA

Products Subject to Registry in ANVISA		
Child lip lipstick	Capillary infantile mouthwash	Insect repellent
Sunscreen	Enamel for child	Children's Soap
Suntan lotion	Child Hair Fixer	TALC/child starch
Children's colony	Antiseptic gel for hands	Shampoo/Conditioner childish
Children's Conditioner	Baby wipes for child hygiene	Children's shampoo
Children's Toothpaste	Children's sunscreen	
Children's play buccal mouthwash	Sunscreen	

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

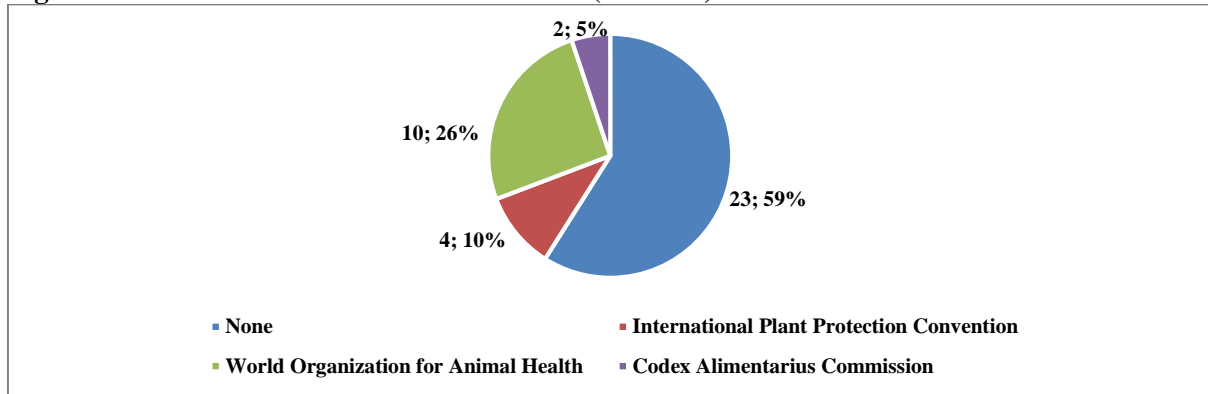
ANVISA is the main regulatory agency responsible for regulating cosmetics in Brazil. However, INMETRO also sets forth relevant provisions, e.g. nine ordinances in force or awaiting publication enlisted below:

- Ordinance INMETRO n. 115/2001 is about pre-measured cosmetics and toilet products.
- Ordinance INMETRO n. 69/2001 sets provisions for PHPC goods in the following states: solid, semi-solid, gel, solid and liquid form; and which are physically characterized by lack of fluidity.
- Ordinance INMETRO n. 228/2005 creates the Evaluation Regulation of Social Responsibility Management System.
- Ordinance INMETRO n. 108/2005 establishes rules for toys under the Brazilian System for Conformity Assessment (SBAC). It requires SBAC shall take into account Mercosul Technical Regulation on toy safety of 08/10/2004. It includes PHPC products for children.
- Ordinance INMETRO n. 197/2002 revises the Technical Metrological Regulation establishing the minimum conditions thermometers used in the determination of the temperature of petroleum have to meet as much as their liquid derivatives.
- Ordinance INMETRO n. 146/2001 creates a Technical Metrological Regulation that establishes the conditions portable and non-portable ethylometers for evidentiary purposes have to meet.
- Ordinance INMETRO n. 100/2000 establishes requirements for the liquid-flow glass thermometers, internal scale and total immersion type EIL and EIC.
- Ordinance INMETRO n. 126/1999 establishes criteria for commercialization, indication of the net content and methodology of verification of the liquid content of soap and bar soap.
- Ordinance INMETRO n. 87/1999 establishes the conditions the packaging of soap and bar soap products commercialized in the domestic market have to meet.

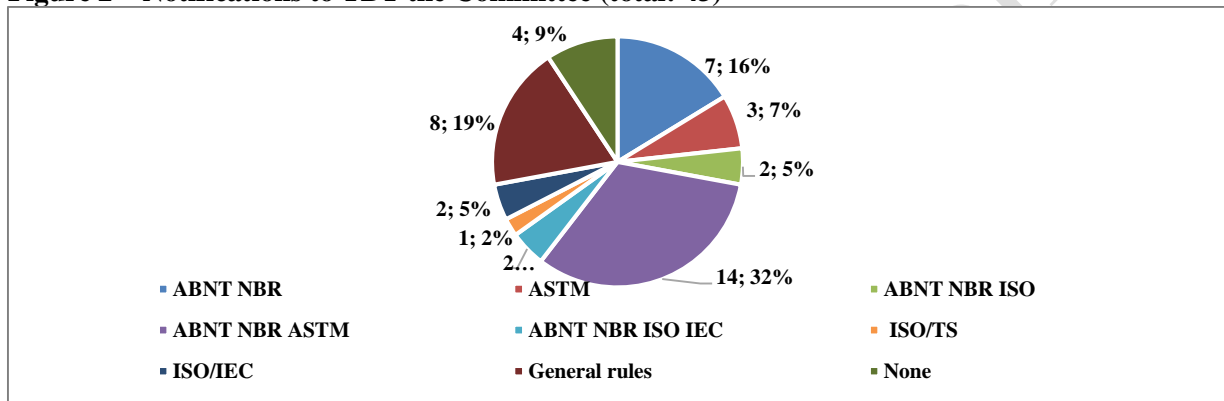
2.1. Notifications to WTO

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

For all chemical products, the big picture of the international standards adopted by the Brazilian technical regulation is as follows. To the SPS Committee, Brazil notified 39 times; to the TBT Committee, the country notified 43 times diverse regulations on chemical sector.

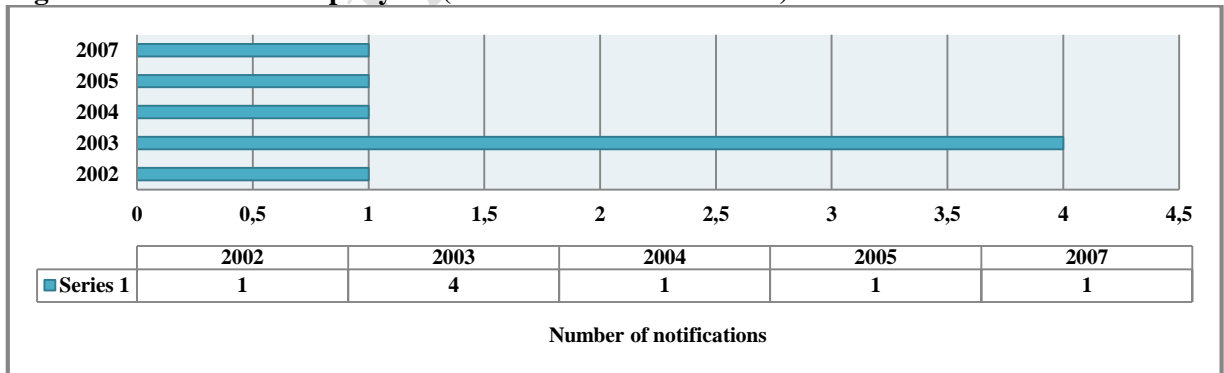
Figure 1 – Notifications to the SPS Committee (total: 39)

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

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

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

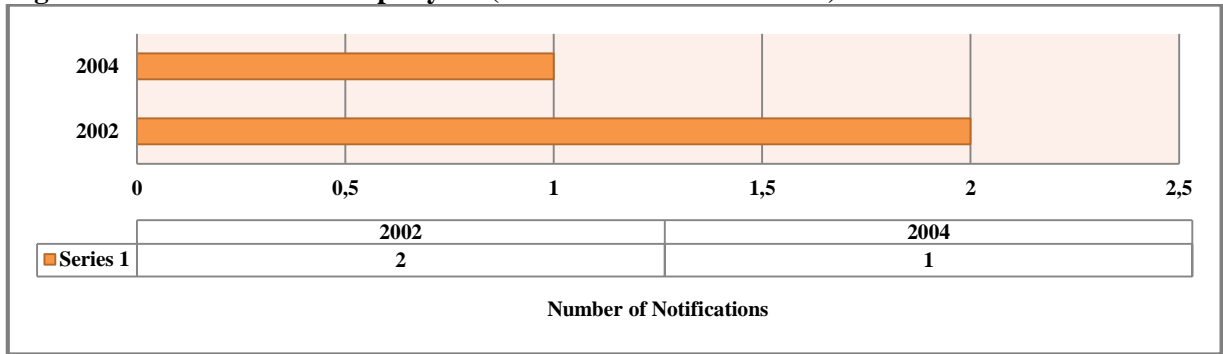
Specifically, for the cosmetic sector, from 2002 to 2016, Brazil notified the TBT Committee eight times based on HS 33 and 34. In 2003, the country notified 4 times.

Figure 3 - : Notifications per year (2001- 2016: HS: 33 and 34)

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

The number of notifications to the SPS Committee was smaller: only three times.

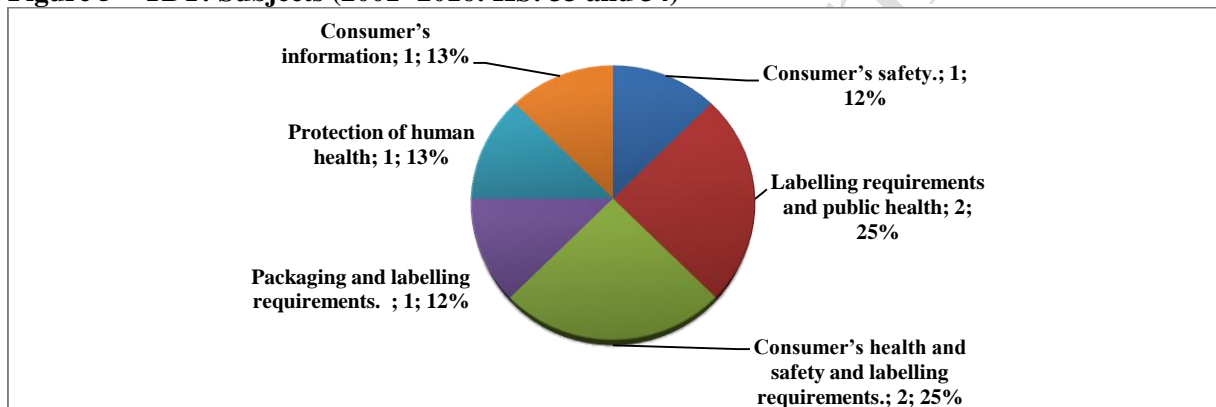
Figure 4 – SPS: Notifications per year (2001- 2016: HS: 33 and 34)



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

Most part of the notifications of HS 33 and 34 to the TBT Committee concern product labeling (5 notifications). The labelling must obey some rules, informing the consumer of some elementary characteristics of the product. Other important themes are consumer safety, consumer information, protection of human. Each one were subject of 1 notification.

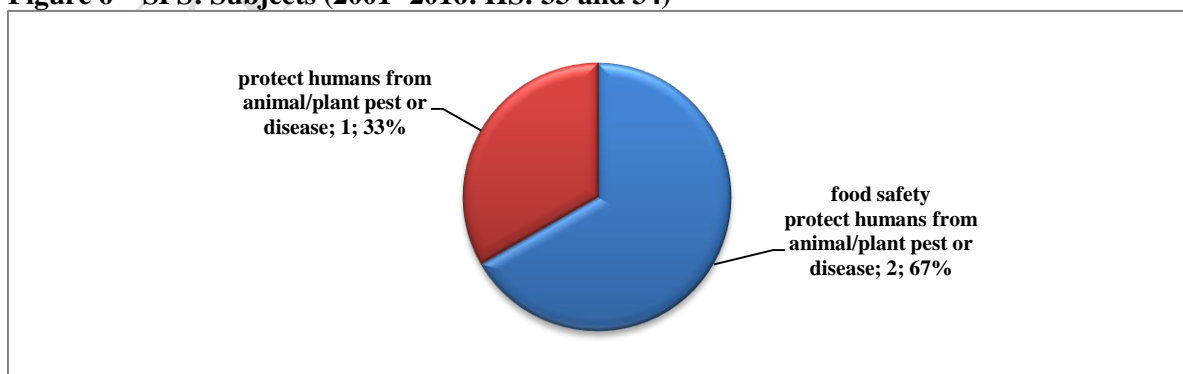
Figure 5 – TBT: Subjects (2001- 2016: HS: 33 and 34)



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

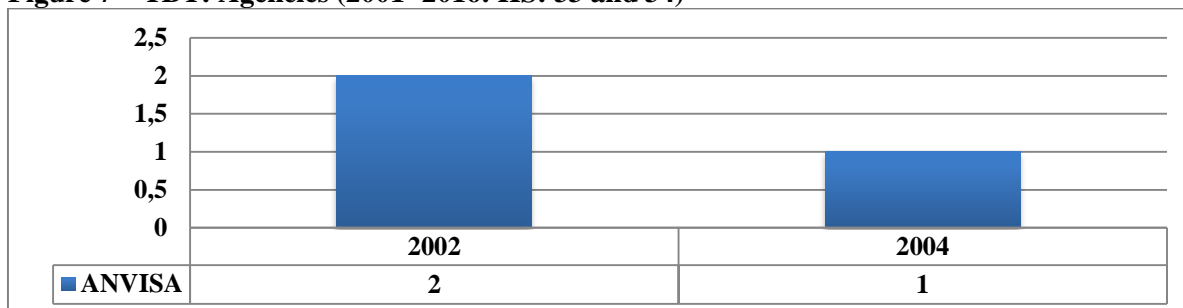
The most important topics of the Brazilian notifications to SPS Committee are food safety and protection of humans from animal/plant pest or disease.

Figure 6 – SPS: Subjects (2001- 2016: HS: 33 and 34)



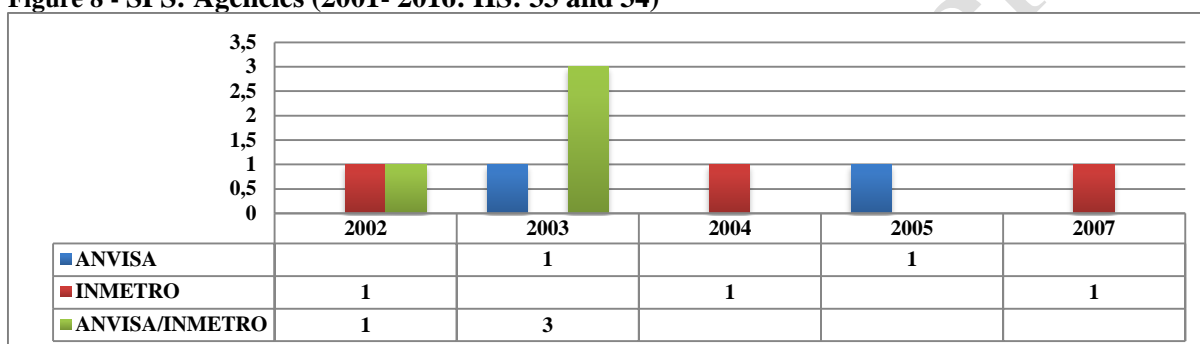
Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

In the notification of PHPC products the two most important agencies are ANVISA and INMETRO, with almost equal distribution of the notifications from 2001 to 2016.

Figure 7 – TBT: Agencies (2001- 2016: HS: 33 and 34)

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

ANVISA and INMETRO are the two agencies that most notify the SPS Committee. Joint notifications by these two agencies should be highlighted.

Figure 8 - SPS: Agencies (2001- 2016: HS: 33 and 34)

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

3. STANDARDS AND SUPPORTING STANDARDS

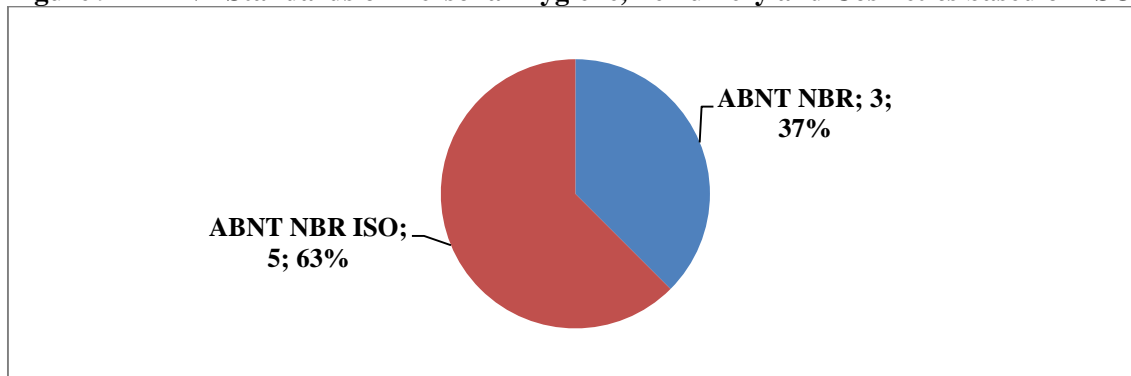
There are a few standards on cosmetics and similar products issued by ABNT. Moreover, ABNT has based its standards for detection of microorganisms on ISO standards.

Table 3 - ABNT Standards on Personal Hygiene, Perfumery and Cosmetics

Standard
ABNT NBR 16483:2016 Beauty salon — people skills who work in beauty salons
ABNT NBR 16383:2015 Beauty salon-requirements of good practice in the provision of services
ABNT NBR 16283:2015 Beauty salon-Terminology
ABNT NBR ISO 21149:2008 Cosmetics-microbiology-detection and Count of aerobic mesophilic bacteria
ABNT NBR ISO 21150:2008 Cosmetics-microbiology-detection of Escherichia coli
ABNT NBR ISO 22717:2008 Cosmetics-microbiology-detection of Pseudomonas aeruginosa
ABNT NBR ISO 22718:2008 Cosmetics-microbiology-detection of Staphylococcus aureus
ABNT NBR ISO 21148:2008 Cosmetics-microbiology-general instructions for microbiological research

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

Figure 9 - ABNT Standards on Personal Hygiene, Perfumery and Cosmetics based on ISO



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

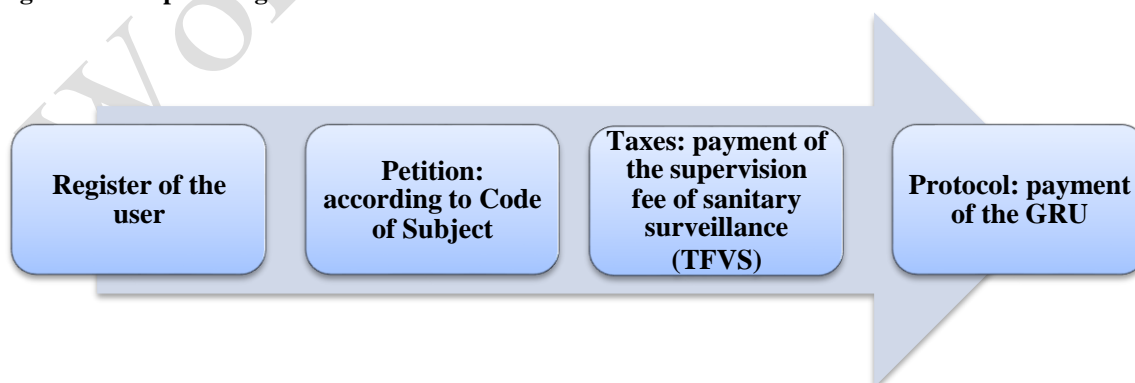
4. CONFORMITY ASSESSMENT PROCEDURES AND CERTIFICATION

The registration, issued by ANVISA, is a legal act recognizing that a product is adequate to be commercialized domestically. For products subject to health surveillance, it is necessary to meet the criteria set forth in laws and the specific rules established by health surveillance authorities. These criteria aim to minimize potential risks associated with the product. The Resolution ANVISA, RDC n. 07/2015, a technical regulation, establishes technical requirements for the regularization of toiletries, cosmetics and perfumes.

The registration shall comply with the following steps: i) registry of the user or the company registration, ii) petition or identification of the code of subject related to the petition as it is from this code that any transaction request will develop, iii) taxes including a payment bill (GRU) for the payment of the supervision fee of sanitary surveillance (TFVS) related to the subject chosen, iv) the protocol with all the documentation that must be presented to ANVISA.

ANVISA shall publish the results in Brazil's Official Gazette (DOU), which serves as proof to the applicant of the given registry. After that, the product has clearance to be commercialized throughout the country for five years, when it expires. This procedure is receiving some criticism because, allegedly, it can have an impact on shipping costs as well as a time-consuming activity because of several deadlines set forth in order to register a given PHPC good.

Figure 10 - Steps to Register the Product in ANVISA



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

5. MERCOSUL

Mercosul Working Subgroup n. 11 issued 30 resolutions involving PHPC regulation. In Brazil, ANVISA usually adopts these resolutions. Until 2017, ANVISA have adopted 14 of these resolutions by referring to them on ANVISA's own regulations. The remaining 16 resolutions are not mentioned by ANVISA. Five of them refer to small adaptation deadlines extensions to comply with other provisions or other formal requirements, while 11 resolutions deal with specific issues related to PHPC regulation that are currently not in force in Brazil.

The most recent and relevant Resolution is RDC n. 07/2015, which internalizes the following Mercosul resolutions:

- Resolution GMC MERCOSUL n. 110/1994 related to the "Definition of Cosmetic Products";
- Resolution GMC MERCOSUL n. 07/2005 about "Classification of Personal Hygiene Products, Cosmetics and Perfumes";
- Resolution GMC MERCOSUL n. 26/2004 to "Specific Technical Requirements for Toiletries, Cosmetics and Perfumes";
- Resolution GMC MERCOSUL n. 36/2004 to "Compulsory Labelling General for Personal Care Products, Cosmetics and Perfumes ";
- Resolution GMC MERCOSUL n. 36/1999 "Specific Labelling for Personal Care Products, Cosmetics and Perfumes "; and
- Resolution GMC MERCOSUL n. 24/1995 to "Requirements for the Registration of Mercosul and Extra-Zone Cosmetic Products and for Business Entities Registration Holders and Importers".

ANVISA RDC 07/2015 provides a legal definition for PHPC goods: preparations made of natural or synthetic substances, for external use in various parts of the human body, skin, capillary system, nails, lips, external genitals, teeth and mucous membranes of the oral cavity, with the sole or primary purpose of cleaning, perfuming, altering and correcting body odours and/or protecting or keeping them in good condition. It also sets forth procedures for labelling and packaging, electronic registry and authorization of products and classifies products in Grades 01 or 02.

Grade 01. Personal hygiene products, cosmetics and perfumes characterized by having basic or elementary properties, the proof of which is not initially necessary, and hence it does not require detailed information on how to use it and its restrictions on use due to the intrinsic characteristics of the product.

Grade 02. Products with specific indications, whose characteristics require proof of safety and/or effectiveness, as well as directions, information, care, mode and restrictions of use.

The criteria behind these categories lie on the probability of occurrence of unwanted effects, or adverse reactions due to inappropriate use of the product, its formulation, purpose of use, areas of the body to which it is intended and care to be observed when use.

The Common Market Group (GMC) manages several working groups, which includes one for health issues (WG #11). The Commission on Health Products (CORPROSAL)⁴ coordinates an Ad Hoc group on Cosmetics (GAHCOSME). There are discussions, led by Brazil, on updating

⁴ Subgroup in the SGT 11. See: http://bvsm.s.saude.gov.br/bvs/publicacoes/metodologia_trabalho_sgt_n11.pdf

Resolution GMC n. 24/1995 on "Requirements for Registration of Cosmetic Products MERCOSUL and extra-zone for the qualification of companies that are holders of the Registry in the Receiving State and importers" and Resolution GMC n. 26/2004 on "Specific technical requirements for personal hygiene products, cosmetics and perfumes".

6. MAIN GOVERNMENTAL AND PRIVATE ACTORS

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

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

Main private actor involved with this sector is the Brazilian Association of the Cosmetic, Toiletry and Fragrance Industry (ABIHPEC).

Working Document

ANNEX

Table 3 – Important notifications to SPS Committee

Doc	Year	Products covered	Agency Responsible	Notified document title	Description of content	Objective and rationale	Technical Provisions/Standards
G/SPS/N/BRA/92	2004	Drugs, cosmetics, medical devices and food for human consumption containing tissues or fluids from bovine, ovine, caprine and wild ruminants species Pulmonary surfactants, by-products of milk and live animal wool are excluded from the restrictions provisioned for in the notified Resolution.	ANVISA	Draft Resolution N° 10, published in the Federal Official Journal (Diário Oficial da União) on 2 March 2004.	<p>This resolution defines the requirements for countries exporting the above-mentioned products to Brazil, according to their geographical risk and to the tissue infectivity level of the exported product. It also bans the import of high risk products. This Resolution does not apply for In Vitro Diagnostic Products. For these products, the Resolution RDC N° 305 determines that they should advertise about the risks inherent to the products made of ruminant's tissues/fluids.</p> <p>This measure also defines the importing procedures of the products containing tissues derived from ruminants. This rule reinforces the prohibition, throughout the Brazilian territory, of the entrance, trade and display of the above-mentioned products that come from countries of certain regions, according the classification specified in the notified Resolution.</p> <p>When entering into force, this measure will revoke Resolution RDC N° 305 (notified as G/SPS/N/BRA/305) and Resolution RDC N° 68.</p>	food safety protect humans from animal/plant pest or disease	World Organization for Animal Health (OIE)

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

Table 4 - Important 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/142	2003	Cosmetics, perfumes and personal hygiene products. (HS 33)	ANVISA	Draft Ministerial Act number 93, 4 November 2003 (<i>Consulta Pública número 93 de 4 de novembro de 2003</i>) issued by the Brazilian Sanitary Surveillance Agency on cosmetics, perfumes and personal hygienic products	Draft not found	This Draft Technical Regulation defines those cosmetics, perfumes and personal hygienic products that can be fractionated and directly sold to consumers, as well as their minimum labelling requirements. It also lays down good fractionating practices for companies, stores and/or shops that fraction out cosmetics, perfumes and personal hygienic products directly sold to consumers	Human health and safety protection. Labelling requirements.	
G/TBT/N/BRA/185	2005	Cosmetics, perfumes and personal hygiene products (HS: 3300)	ANVISA	Draft Resolution issued by the Brazilian Sanitary Surveillance Agency for cosmetics, perfumes and personal hygiene products	Draft not found	This draft technical regulation proposes a new procedure for the notification of personal hygiene products, cosmetics and perfumes and sets up criteria for the notification of products classified as Degree 1 and Degree 2. It also establishes that the notification must be mandatory and must be made by means of the "On line System of Attendance and Collection" (<i>Sistema de Atendimento e Arrecadação</i> On-line) available on the electronic address of ANVISA. Products notified under the validity of Resolution 335/99 must have its Notification brought up to date on the available electronic simplified procedure in the "On line System of Attendance and Collection".	Protection of human health	

G/TBT/ N/BRA/ 232	2007	Cosmetics (HS: 3300)	INMETRO	Draft Ministerial Act Number 330, 13 December 2006 (<i>Portaria n° 330, de 13 de dezembro de 2006</i>)	Draft not approved.	This Mercosul Draft Technical Regulation (P. Res. GMC n° 07/2006 lays down technical quantitative requirements for cosmetics. It also revokes the Mercosul Resolution GMC n° 50/00.	Consumer's information	
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Source: WTO. Prepared by CCGI-EESP/ FGV (May 2017).

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