http://dx.doi.org/10.18623/rvd.v20.2543-ing

CLEANING PRODUCTS REGULATION IN THREE WORLD MARKETS: THE BRAZILIAN CASE EFFECTIVENESS

REGULAÇÃO DE SANEANTES EM TRÊS MERCADOS MUNDIAIS: A EFETIVIDADE DO CASO BRASILEIRO

Article received on: 03/15/2023
Article accepted on: 10/31/2023

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The authors declare no conflict of interest.

Abstract
The cleansers technological sophistication accompanied scientific, technological and market developments to meet the criteria for cleaning the environments. In addition to specific safety criteria for users, such products need to be safe for the environment, which requires

Resumo
A sofisticação tecnológica dos saneantes acompanhou os desenvolvimentos científicos, tecnológicos e mercadológicos para atender os critérios de higienização dos ambientes. Além dos critérios específicos de segurança para os usuários; tais produtos precisam ser seguros para o ambiente, necessitando de

appropriate regulations for society effective protection. This work aimed to identify the strengths and improvement points of the Brazilian regulatory procedures regarding household cleaning products compared to those applied in the US and Europe, based on the regulations imposed on such products and the administrative organization of the responsible agencies in each location. It was raised the Brazilian legislation referring to cleaning products and producers and their regulatory agency. It was searched the regulations for items similar to cleansers, which are pesticides and hazardous substances for the US and chemical substances for Europe. The collected information was analyzed through the comparative law method. The Brazilian regulatory procedures have the same technical and scientific rigor and regulatory practices to the USA and the European Union, in aspects such as the regulations curating and the issuing operation authorizations for companies. The lack of translation of the standards and an environment labeling program are improvement points.

Keywords: comparative legislation; regulation; cleaning products; health surveillance.

regulamentações apropriadas para a efetiva proteção da sociedade. Este trabalho buscou identificar os pontos fortes e de melhoria dos procedimentos regulatórios brasileiros, acerca dos saneantes de uso doméstico, em comparação com os aplicados nos Estados Unidos e na Europa, com base nas regulamentações aplicadas a esses produtos e na organização administrativa das agências responsáveis em cada local. A legislação brasileira, as empresas do setor e a agência reguladora, referentes aos saneantes, foram levantadas. Também, foram realizadas buscas relacionadas às regulamentações dos itens congêneres aos saneantes, sendo os pesticidas e as substâncias perigosas para os Estados Unidos e as substâncias químicas para a Europa. Foi utilizado o método de direito comparado para analisar as informações. Verificou-se que os procedimentos regulatórios brasileiros apresentam o mesmo rigor técnico-científico e as mesmas práticas regulatórias que os dos Estados Unidos e da União Europeia, em aspectos como a curadoria das regulamentações e a emissão da autorização de funcionamento de empresas. Por outro lado, a falta de tradução das normas e a ausência de um programa de rotulagem ambiental são aspectos a serem melhorados.

Palavras-chave: *legislação comparada; produtos de limpeza; regulação; vigilância sanitária.*

Introduction

Cleaning products have been used since prehistoric times when Egyptians and Greeks produced the first soaps for personal hygiene. The products, as they are known today, resulted from a development process that reflected the fight against epidemics in the Middle Ages and the demands of the masses occupying the cities with the industrial revolutions. Currently, they are widely used in cleaning and conservation. These must follow the regulations required by the National

Health Surveillance Agency (ANVISA) in Brazilian territory to guarantee standardization, mitigation of consumer safety risks, and control by said body.

The regulation of cleaning products is crucial, given their risks to public health and the environment. These products can permanently affect users if their usage guidelines are not followed. These products can be harmful to the aquatic environment and its life forms. Unregulated products are worrying, as the precautionary and preventive aspects of regulation are not considered. Thus, the representativeness and expected growth of the cleaning products market in Brazil make government control even more critical.

In this context, the regulation of cleaning products must have indicators and standards to guarantee the population's safety, systematization of the sector before government bodies, an adequate environmental assessment of their impacts, and scientific evidence that the product fulfills its function. Through scientific findings, objective decision-making is possible according to the most up-to-date information from the agencies.

This study intended to identify the strengths and improvement points in the regulatory procedures for cleaning products for domestic use in Brazil compared to American and European procedures for similar products. The importance of regulations and environmental issues in the transition to sustainable development was addressed so that government entities need to adapt product regulation requirements as new demands for environmental protection and human health arise from market changes.

The analysis considered the requirements imposed on cleaning products for domestic use by Brazilian, American, and European legislation to identify the strengths and those that could be improved in the regulations of these territories regarding environmental and human safety aspects. Furthermore, the administrative organization of the agencies responsible for controlling such products, as part of the government structure of Brazil, the United States, and the European Union, was analyzed to identify how their structure can influence regulatory procedures.

1 Cleaning products: brief definition, risks, and market

In Brazil, any substance or preparation for cleaning and similar purposes, disinfection, disinfestation, sanitization, deodorization, odorization, and disinfection of water for human consumption, fruit and vegetables, and swimming pools, is considered a cleaning product. The same legislation covers a wide range of products, although they vary in use and application. The application of these products

can cover objects and surfaces, differentiating which products can be considered sanitizing agents and cosmetics. Cleaning products are classified according to potential risk (1-low risk or 2-high risk), purpose (general cleaning, disinfection, or disinfestation), and sale and use (free sale or restricted sale for professional use) (ANVISA, 2010).

Based on this classification, the regulatory agency establishes different criteria for each type of product, acting to mitigate its main risks. If handled inappropriately, poisoning, skin and eye irritation, and damage to the gastrointestinal system can occur. Standardizing labels and packaging with information such as keeping out of the reach of children, not mixing with other products, and a lid with a safety lock can mitigate risks (SALOMON *et al*., 2021). From an environmental perspective, cleaning products can harm ecosystems, for example, causing water pollution due to the release of effluents containing cleaning products rich in nutrients (nitrogen and phosphorus) (USA, 2019).

The household chemicals market is promising, given that, in 2021, it was responsible for 27.7% of the American Gross Domestic Product, 10% of all United States exports, more than half a million jobs in the United States, and almost 11% of global chemical production (ACC, 2022). The global market for household cleaning products grew 8.4% compared with 2020 due to the increased demand generated by the pandemic. In Brazil, the sector saw an increase in sales in 2020, even with a negative GDP, because 30% of the emergency aid was allocated to purchasing cleaning products. Given this, the sector closed the year with production equivalent to the pre-pandemic period (2019) (ABIPLA, 2021). Additionally, in 2021, the sector grew 0.4%, with growth projections of up to 2% in the coming years (ABIPLA, 2022).

2 Methodology

A survey of sanitation regulations in Brazil, the United States, and the European Union was conducted. The search considered the legislation for cleaning products and producers and the body responsible for their regulation in each country/block considered in this research. Brazilian legislation was searched on the ANVISA website[1], where the agency organizes and periodically updates them in thematic libraries. The cleaning product and transversal themes library compiles all current standards for products and enterprises of such a nature. Furthermore, the laws that created the National Health Surveillance System and provided

1 Available from https://www.gov.br/anvisa/pt-br

for the health surveillance to which cleaning products are subject were identified.

Concerning the United States, products similar to sanitizing agents were searched in the US Environmental Protection Agency (US EPA), the Consumer Product Safety Commission (CPSC), and the US Food and Drug Administration (US FDA). The search found that Brazilian rodenticides and insecticides are similar to pesticides regulated by the US EPA. These products aim to prevent, destroy, repel, or mitigate any pest (insects, rodents, fungi, viruses, bacteria, and microorganisms, among others) (USA, 1947).

The other categories of cleaning products (disinfectants and detergents) are similar to hazardous substances, being regulated by the CPSC. These are substances or mixtures with toxic, corrosive, irritating, highly sensitizing, flammable, or combustible characteristics or that generate pressure through decomposition or heat and with the potential to cause substantial personal injury or illness during or as an immediate result of handling or habitual use (USA, 1960).

While the US FDA is considered the American agency similar to the Brazilian ANVISA, its legislation only concerns drugs, medicines, and cosmetics. Therefore, the abovementioned agency does not cover cleaning products like in Brazil. Therefore, pesticide products and dangerous substances were considered in this study. A search was conducted on the American agency/commission[2,3] websites about its history, creation law, responsibilities, and current legislation for products and companies.

For the European Union, the search for sanitation legislation occurred on the "EUR-Lex"[4] website, which offers a legal database for Europe. The search identified that the general regulation of chemical substances and specific product standards covers cleaning products. The Council of the European Union and the European Parliament (EP) approved the aforementioned general regulation, becoming mandatory for all member states.

The sections of this article present the researched regulations, and their similarities and differences are indicated to discuss the current status of Brazilian legislation on cleaning products compared with American and European legislation. The comparative law method was used to identify the strengths and areas that could be improved in the Brazilian context for regularizing these products and companies.

2 Available from https://www.epa.gov/

3 Available from https://www.cpsc.gov/

4 Available from https://eur-lex.europa.eu/homepage.html?locale=pt

3 Cleaning product regulatory agencies

3.1 Brazil: National Health Surveillance Agency

Brazilian health surveillance dates back to the promulgation of the Federal Constitution (CF) of 1988, which recognized the right to public health and allowed the creation of the Unified Health System (SUS). The Brazilian Constitution incorporated essential elements of the Universal Declaration of Human Rights and represented a significant change in health coverage and organization in the country (CASTRO *et al.*, 2019).

The CF delegated to the State the role of public health provider (Art. 196), which must be guaranteed through social and economic policies to reduce disease risk. Considering the risks of cleaning products, their regulation is necessary and performed within the scope of public health. Actions from this perspective, combined with public policies, insert such products into the field of action of authorities in the area (BRASIL, 2016).

Following CF, Federal Law No. 8,080/1990 regulates health actions and services, defining the SUS's objectives, competencies, and administrative structure. From this perspective, health surveillance is part of its activities, with a "set of actions capable of mitigating or preventing health risks and intervening in health problems arising from the environment, production, and circulation of goods of health interest" (BRASIL, 1990).

After that, Federal Law No. 9,782/1999 created the National Health Surveillance System (SNVS), responsible for regulating, standardizing, controlling, and inspecting health surveillance, working cooperatively with states and municipalities (BRASIL, 1999). This represented the peak of the area in the country since its history included a Health Police and a federal body with National Secretariat status that had less coverage.

The law mentioned above also created the National Health Surveillance Agency (ANVISA) as a national body of the SNVS, linked to the Ministry of Health (MS), with administrative independence and financial autonomy (BRASIL, 1999). Its independence guarantees that decision-making is less susceptible to influence, as the body's decisions produce social and economic effects and directly affect production and consumption relations (SETA *et al.*, 2017).

ANVISA regulates, controls, and inspects products and services that involve public health risks, including cleaning products (BRASIL, 1999). These actions aim to mitigate the adverse effects of these products, given the consumer's inability to identify them and the balance of failures in the health market (SETA

et al., 2017). Federal Law No. 6,360/1976 defined sanitizing agents as substances/preparations intended for hygiene, disinfection, or disinfestation at home, in collective and/or public environments, in places of common use, and in water treatment (BRASIL, 1976), with regulation and control being part of the SNVS.

The institutional organization of the Brazilian State to deal with health surveillance went through a legal construction process, generating comprehensive action throughout the national territory, security in decision-making, and a broad set of regulations. Therefore, ANVISA's actions must guarantee the population's safety, as in the decisions taken during the COVID-19 pandemic.

3.2 United States: US Environmental Protection Agency and the Consumer Product Safety Commission

3.2.1 US Environmental Protection Agency

The intense discussions in the 1970s about the natural environment and the impacts caused by man resulted from the disasters that occurred in previous years. The book *Silent Spring* (1962) denounced the damage related to chemical compounds, the formation of the Club of Rome (1968) warned about the problems of the current economic model, and the Biosphere Conference (1968) and popular pressure from social movements influenced changes in perception regarding the environment (POTT; ESTRELA, 2017).

American President Richard Nixon signed the National Environmental Policy Act (NEPA), which declared the National Environmental Policy and established the Council on Environmental Quality (CEQ). Thus, the federal government aimed to encourage harmony, prevent and mitigate environmental damage, and required the federal administration's proactivity to consider the environmental variable in planning and decisions (USA, 1969).

The CEQ, created by NEPA, was responsible for implementing environmental policy, advising the President, and developing policies and regulations on the topic (USA, 2023). The Environmental Council supported the proposal to create the US Environmental Protection Agency. This agency would centralize environmental issues, so far spread across various government agencies and departments until then. Decentralization made it difficult to respond effectively to growing environmental demands. In this way, the US EPA was born, taking on functions previously carried out by the Departments of the Interior, Agriculture, Health, Education, and Welfare and the Bureaus of Solid Waste Management and Water Hygiene (NIXON, 1970).

The US EPA does not have department status but has autonomy and covers the entire national territory. Its functions include creating protection standards, preventing pollution, developing research, and collecting information (NIXON, 1970). In addition, it has a pesticide office, linked to the administrator, responsible for regulating and registering pesticides (RUCKELSHAUS, 1970). The US EPA regulates pesticides to mitigate health and environmental risks, as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Its functions include registration, classification, banning, and revoking pesticides (SCHWINGL *et al.*, 2021).

3.2.2 Consumer Product Safety Commission

The Consumer Product Safety Commission was created in 1972 through the Consumer Product Safety Act to ensure the safety of consumer products in the United States. The Commission mentioned above works to define mandatory and voluntary standards for products, research potential hazards, and educate consumers, manufacturers, and importers about current regulations, product recalls, and prohibition of dangerous items without an approved standard (USA, 2022a).

In addition to consumer products, the CPSC inherited some functions from other departments. These involve the hazardous substances law, the poisoning prevention packaging law, and the food, medicine, and cosmetics law, previously allocated to the Department of Health, Education, and Welfare. Furthermore, the law on flammable fabrics and the Federal Trade Commission, previously in the Department and the Federal Trade Commission (USA, 1972).

The Consumer Product Safety Act considers consumer products to be any article or parts thereof produced or distributed to a consumer for domestic, institutional, or personal use, which includes domestic and institutional cleaning products. As a result, some cleaning products are classified as consumer products and as dangerous substances (by the FHSA, under the responsibility of the CPSC). It is noteworthy that, despite the scope of consumer products, these do not include pesticides, which are already regulated by the US EPA, and medicines and cosmetics, which are regulated by the US FDA (USA, 1972).

It is noteworthy that soaps have different concepts in American and Brazilian legislation. For an item to be considered soap in the United States, it must be produced with alkaline salts of fatty acids (a mixture of fats/oils with an alkali) and intended for application to surfaces and objects, being regulated by the CPSA. If there is a synthetic surfactant in its composition, the product will be classified as

cosmetic by the US FDA (USA, 2022b). Despite the differences, the products can be called soap in both cases. In Brazil, regardless of whether the soap has synthetic surfactants in its composition, it will be regulated as a cleaning product if it is intended for cleaning surfaces and objects.

The CPSC is a federal government agency with independent status. It reports directly to the President, as it is not linked to any department, and maintains close relations with Congress to avoid overlapping laws. Its independence allows it to deal impartially with products available on the American market. It is essential in light of commercial globalization and the intense development of new products during the Cold War (USA, 2022a).

3.3 European Union: European Chemicals Agency

Technological advances have made it possible to understand the potential risks of chemicals to the environment and human health, warning about indiscriminate use and regulations (WILLIAMS *et al.*, 2009). In the European market, until 2006, each country determined its own legislation, restricted substances, and evaluation, registration, and authorization processes for products sold in their territories.

Given the limited information on the risks of chemicals (SOBANSKA *et al.*, 2018), combined with the lack of regulatory obstacles, there was a disincentive for the industry to research its products (WILLIAMS *et al.*, 2009). As a result, the need for a single regulation for all countries in the bloc emerged, which approved the Regulation for Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) in 2006, a legal milestone.

The European Commission (EC) proposed the abovementioned legislation within the bloc. This body is the arm of the European executive to defend common interests concerning individual ones (countries or sectors). Therefore, before proposing legislation to the EP and the Council, the EC is advised by the European Economic and Social Committee (representatives of civil society) and the European Committee of the Regions (representatives of cities and regions) to listen to different stakeholders (UE, 2021).

After the Commission's proposal, the legislation goes to the bloc's legislature, EP, and the Council in the bicameral model. Parliament comprises representatives elected by the people who will vote on the proposal, approved with the majority of votes cast. The Council comprises ministers from the member states of the European Union, who will vote on the proposal after the Parliament, which is

approved by a majority vote of the member countries and the population (UE, 2021).

After the legislature approves chemical product regulations, the European Chemicals Agency (ECHA) will manage and enforce them to ensure their application. The agency has its own legal personality; its regulations are binding on member states and do not need to be transposed into national legislation (UE, 2021). The ECHA maintains a chemical product database, allowing European citizens access to information and supporting companies that will sell their products in the bloc.

3.4 Comparison between agencies

The organizational structure of institutions that regulate cleaning products has different characteristics. Table 1 presents the differences and similarities based on the evaluated criteria.

Table 1 – Institutional comparison

Criteria	Brazil	United States		European Union
		US EPA	CPSC	
Senior management of the regulatory body	Collegiate board of directors, comprising the CEO and four members.	Administrator and 11 executive directors.	President and four commissioners.	Executive Director and the Board of Directors with 35 members from countries, EC, EP, and stakeholders.
Nomination for senior management	Nominated by the President of the Republic and approved by the Federal Senate.	Nominated by the President of the United States and approved by the Senate.	Nominated by the President of the United States and approved by the Senate.	The executive director is pre-selected by the EC, selected by ECHA, and approved by the Parliament.
Duration of senior management mandate	Five years without renewal.	It is not pre-defined.	Seven years.	Four years; only one renewal is allowed.
Approval of regulations	By the absolute majority of the board of directors.	By the administrator after popular consultation.	By the President of the Commission after popular consultation.	Simple majority by the Parliament.

Popular participation mechanisms	Public Hearing and Consultation, Webinar, Directed Consultation, Sectoral Dialogue, Parliament, and others.	Public agenda announced in the Federal Register.	Public agenda announced in the Federal Register, opinion polls, Ombudsman, and Forum.	MEPs.

Source: adapted from ANVISA, ECHA, US EPA, and CPSC (2023).

In Brazil, cleaning products are regulated within the scope of public health (part of the SUS), whereas, in the United States, it occurs under environmental protection combined with consumer protection. In turn, the European Union does this through a specific agency for all chemical substances, which is something positive, given the scope of the topic.

In the United States, the legal framework for what is considered a cleaning product becomes segmented into different bodies, namely the US EPA, the US FDA, and the CPSC, unlike Brazil and Europe, which present centralization of agencies. This makes it difficult to understand the regulations when registering/notifying products by entrepreneurs. The case of the soaps mentioned above reinforces this idea, being covered by the CPSC or US FDA. In Brazil, cleaning products, cosmetics, and medicines are regulated only by ANVISA.

In Brazil, only cleaning products intended for animal/agricultural areas are not regulated by the health surveillance agency. In the case of a disinfectant for domestic/institutional use, regulation occurs with ANVISA, and for a disinfectant for domestic animals, with the Ministry of Agriculture. This differentiates Brazil from the United States, where centralization can facilitate understanding of the agency's activities among the public.

The European body also promotes centralization in the registration of cleaning products, managing to create databases with product and company information available to all member states. If adopted in Brazil, this could avoid the request for new regulations for products with similar uses, facilitate the consultation of regulatory processes for requesting registration, and allow the agency a global view of the items available in the country.

Another aspect that deserves to be highlighted is the senior management of the bodies, given their decision-making power. Only the European Union guarantees the high participation of different sectors of society in the committees through the Board of Directors, which has representation from parties such as the population, universities, and companies. At US EPA, CPSC, and ANVISA, proximity to the President, who appoints the administrator/commissioner/general director, can influence decisions.

At US EPA and ANVISA, there is a greater possibility that the heads of institutions will be occupied by people without technical training and with a solid political-ideological position, as there is no legal impediment to appointments of people without training in the area. Thus, votes may suffer political and economic influences regarding regulating sensitive topics. For example, Brazil's ruralist movement has gained more strength in recent years. At the same time, ANVISA has facilitated the issuance of favorable toxicological classification for previously banned pesticides.

The law creating the CPSC requires that the nominee have experience in consumer products and public protection areas, a fact that Federal Law no. 9,782/99 did not establish for ANVISA. Despite this, both agencies provide in their creation laws forbidding the appointment of directors and commissioners related to people, companies, and institutions dedicated to business or employment in the same area of interest as the agencies. For the CPSC, there is a requirement that no more than three of the commissioners be affiliated with the same political party, whereas, for ANVISA, Brazilian legislation goes further, prohibiting anyone related to party-political activity and making it impossible for a former director to represent a person or company with an interest before the agency up to one year after leaving office (USA, 1972; BRASIL, 1999).

Despite efforts, the existence of political-ideological bias may mean that the person responsible for the vote does not put on the agenda issues that are contrary to the political position of the President who nominated them or to the party that has a majority in the legislature. Thus, there is subjectivity in the actions of the agencies, which can leave social interests in the background and hinder the institution in the face of market development. Another aspect to be considered is the term of office of its senior management. If a term of office is fixed by law, management instability and changes in command are prevented due to the President's influence (ANVISA, CPSC, and ECHA). At US EPA, the mandate is not pre-defined, and strategic planning is essential to meet the country's most necessary interests.

Regulations are curated clearly and objectively in Brazil and the European Union. ANVISA publishes the cleaning product library (document with current legislation), and ECHA has the "legislation" tab on its website (with regulations and explanations about them). The recovery of norms is difficult in the United States because they are dispersed in the US Code, with some on the US EPA and CPSC websites.

A good organization of regulations facilitates public access and knowledge of the role of entrepreneurs, resellers, and consumers in ensuring everyone's safety.

Different audiences (consumers, patients, industry, healthcare professionals, and authorities) demand different forms of communication. Thus, it is noteworthy that US EPA and ECHA did not have these different forms of communication. ANVISA stood out for publishing guides and booklets[5] with simplified language (entertaining resources such as comics and images). The CPSC provides an automatic questionnaire that indicates whether the product will be regulated by the agency, in addition to a guidance program for small businesses. Thus, ANVISA and CPSC guarantee access to information using didactic language not found in legislation.

The European bloc was identified as not having forms of direct popular participation. In Brazil and the United States, one can give their opinions on agency regulations through online protocols and deepen their knowledge in webinars and workshops. Agencies allow contact with different opinions from industrial sectors, users, civil society organizations, and other administrative bodies.

The lack of translation of Brazilian regulations makes access difficult for non-Portuguese speakers, a worrying fact given that Brazil is the only one to have the language mentioned above as official in Latin America. This idea is supported through a search in the Comex Stat – Comex Vis[6] database, using the filter for products "Soap, cleaning, and polishing preparations" (ME, 2023). In 2022, Spanish-speaking countries, such as Argentina, Paraguay, Chile, and Colombia, represented more than 60% of the sector's exports, while countries where English is widely used, such as the United States (the "official" language), Germany (working language of the European Union), China (co-official language in some territories), and India (official language of the federal administration), are responsible for more than 50% of imports. The language barrier becomes a challenge for trading with Brazil. The unavailability of translation also happens in the United States, which has regulations only in English. The European Union has all its regulations available in twenty-four languages, including Portuguese.

The Brazilian agency has characteristics that reinforce and hinder its operations in the country's context. The centralization of a diversity of cleaning products under the responsibility of a single agency and the availability of popular participation tools reinforce the agency's performance. This is a lesson that Brazil can teach the United States, which has two agencies on the subject, and the European Union, which has no mechanisms for direct popular action. Despite the mechanisms made available by ANVISA, a distance was noticed between companies

5 ANVISA website, where it is possible to retrieve the available guides and booklets on cleaning products: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/saneantes/guias-e-manuais

6 Comex Stat website: http://comexstat.mdic.gov.br/pt/home

and the agency during visits to small local manufacturers[7]. Producers reported an interpretation of the regulation as a threat to their business, but they did not use participation tools to contribute to the debate.

Brazil can combat ideological bias in the nomination for agency president. However, as for the CPSC, it could require technical training and proven experience in the area. The organization of regulations by type of product by ANVISA facilitates their access compared with the US EPA and CPSC, which is something that Brazil can teach the United States. The Brazilian agency could follow ECHA's example and translate the legislation available, enabling access for foreigners. Thus, the curation and translation of legislation can result in better effectiveness in regulatory actions in Brazil.

4 Cleaning product regulations

Table 2 presents the principal regulations regarding cleaning products in the locations researched, which depend on the internal context of each country.

Table 2 – Cleaning product legislation in Brazil, the United States, and the European Union

Location/ Body	Norm	Content	Year
Brazil / Presidency of the Republic	Law No. 6,360	Provides for the Health Surveillance to which Medicines, Drugs, Pharmaceutical Inputs and Related Products, Cosmetics, Cleaning Products and Other Products are subject, and provides other Measures.	1976
	Law No. 6,437	Defines infractions of federal health legislation, establishes the respective sanctions, and provides other measures.	1977
United States / Congress	Public Law No. 92-516	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	1947
	Public Law No. 86-613	Federal Hazardous Substances Act (FHSA)	1960
European Union / Parliament and Council	Regulation No. 648	Detergents Regulation	2004
	Regulation No. 1907	Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)	2006
	Regulation No. 1272	Regulation on Classification, Labelling, and Packaging (CLP)	2008
	Regulation No. 528	Biocidal Products Regulation (BPR)	2012

Source: prepared by the authors.

7 Visits were made to small local manufacturers as part of the data collection stage of one of the authors' master's thesis. This collection was used to develop an environmental assessment of the products.

According to Federal Law No. 6,360/76, cleaning products are subject to Health Surveillance. Therefore, any substance for cleaning, disinfection, or disinfestation must comply with this law and the Collegiate Board Resolutions (RDCs) approved by ANVISA. The RDC aims to complement the law concerning technical requirements and procedures for regulation (BRASIL, 1976).

The American government has FIFRA and FHSA, which define pesticides and hazardous substances and establish general guidelines for their regulation. These laws provide requirements on registration, packaging, and labeling in a more specific way than Brazilian law, which leaves this responsibility to the regulatory agency. The US EPA can act on the issue of pesticides by defining requirements in a complementary way (USA, 1947), while the CPSC can prohibit products whose dangerousness cannot be prevented (USA, 2022c).

The European Union has two pieces of legislation that cover cleaning products. The Detergents Regulation defines detergents as any substance containing soap and/or other surfactants for washing and cleaning (EU, 2004). The Biocidal Products Regulation defines biocidal products as any substance to prevent, destroy, repel, neutralize, or control a harmful organism (disinfectants, preservatives, harmful animal control products, and others) (UE, 2012). These regulations are complemented by two others, the Registration, Evaluation, Authorization, and Restriction of Chemicals and the Regulation on Classification, Labeling, and Packaging, regarding aspects of registration, packaging, and labeling.

Leaving it to ANVISA to define requirements for companies and their products has positive and negative points. The positive thing is that the approval or update of a regulation will not need to face the bureaucracy of the legislative process for approving a law, as occurs in the United States and the European Union. Furthermore, the RDCs are evaluated by the agency's technical staff, which does not always happen with bills in the legislature. The negative point is the excess of regulations to complement the SNVS law.

Federal Law No. 6,437/77 complements Federal Law No. 6,360/76, establishing violations of Health Surveillance with penalties ranging from warning, fine, product seizure, and others, without prejudice to civil and criminal sanctions (BRASIL, 1977). There is no specific law like the Brazilian one in the United States to establish infractions, as FIFRA and FHSA already do in a chapter (USA, 1938; 1947).

Regulations at the level of the European bloc leave the definition of sanctions for non-compliance to organizations in each country, with each member state having to define a body to establish and apply them. This represents an

improvement point because if the requirements to be followed are the same for all members, the same should happen with the sanctions. The norms should, at least, suggest appropriate sanctions for non-compliance with the law and let member countries decide which to apply in each case.

The completeness of American law is seen as positive, as a single law covers the various aspects related to the regulation of pesticides (such as definitions, requirements for companies, and infractions, among others). This represents a challenge for the Brazilian context, which has a specific RDC for each product type, labeling, registration, and packaging, generating the need to consult several documents to regularize a product. Despite this, Brazilian laws and ANVISA resolutions guarantee that no aspect of cleaning products is uncovered by legislation.

5 Regularization of companies and cleaning products

Figure 1 shows the stages of company and product regularization in Brazilian health surveillance. The first is the Operating License, issued by health surveillance authorities at the municipal or state level. These will define the risk level of the economic activity (high, medium, or low), determining when the health inspection and license issuance will be carried out (BRASIL, 2013; ANVISA, 2017).

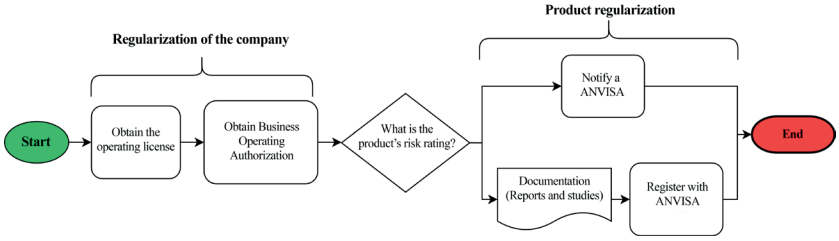

Figure 1 – Flowchart of regularization of a cleaning product company in Brazil.
Source: prepared by the authors.

The health surveillance inspection is conducted with a visit to the company to verify compliance with legal and technical regulations, such as Good Manufacturing Practices (GMP). This is a strong point in Brazilian regulations, as it identifies the conformity of the structure and organization of the establishment, checks the veracity of the data reported, and suggests guidance and correction measures (ANVISA, 2021). Obtaining the Certificate of Good Manufacturing Practices (CBPF) is not legally required, which is contradictory as compliance

with its requirements is necessary to approve the operating license. The possible obligation of the CBPF for the operation of companies would represent a positive step forward for ANVISA, considering the requirement for biannual inspections in establishments.

Companies that manufacture, import, and export cleaning products must request ANVISA for the Company Operating Authorization (AFE) by submitting the inspection report issued by the local body. AFE aims to ensure control of companies' compliance with technical requirements (ANVISA, 2014). The procedures for obtaining the operating license and the AFE could be unified in a single request, flowing between the local and national levels of the agency with greater efficiency.

Any enterprise or activity that uses environmental resources with polluting potential depends on prior environmental licensing (IBAMA, 2021). Thus, sanitizer producers need to follow requirements in the environmental area, such as licensing established by the National Environmental Policy, and safety, such as the provision of the Safety Data Sheet for Chemical Products (FISPQ), mandatory by Regulatory Standard 26.

A study of environmental impacts must be conducted to request an environmental license, describing measures to mitigate those negative and enhance those positive (IBAMA, 2021). The FISPQ is a safety requirement to communicate the dangers of chemicals to various interested parties and is part of environmental licensing. Although sanitary and environmental licensing procedures are separate, Brazilian legislation covers environmental and safety aspects similar to the US EPA and ECHA for cleaning products.

In the United States, company regulation occurs only within the scope of the US EPA for pesticides, in which the process is developed in six stages, as shown in Figure 2. The request is made through a letter with data from the company to register with the US EPA. The agency will issue an establishment identification number to register the products (USA, 2022d).

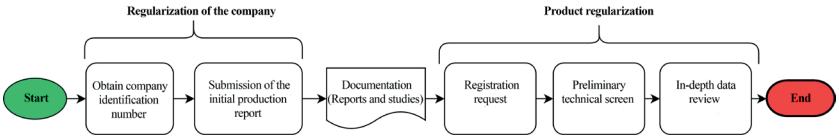

Figure 2. Flowchart of regularization of a cleaning product company in the United States.
Source: prepared by the authors.

After issuing the identification number, the company has 30 days to send the initial production report, with production and distribution projections for each product. This document must be updated annually, reporting discontinued production lines (USA, 2022d). The US EPA can control pesticide companies in the United States based on data such as annual production per product, obtaining a strategic view of the sector, and identifying whether the companies are in balance with the environment. In Brazil, this is verified by the environmental agency, using a different procedure than health surveillance. The regularization stage of European companies was not considered in this study, as this varies between member states.

The risk classification of the sanitizer determines its form of regulation; if it is risk 1 (low), they are notified (no supporting studies are required), and if it is risk 2 (high), they must be registered (stability and pH reports are required, label sketch and packaging design) (ANVISA, 2010). Product notifications do not require revalidation; registrations must be made every five years (BRASIL, 2013). The US EPA recommends a pre-registration meeting with agency staff to resolve any concerns before applying for pesticide registration (USA, 2022d). While the possibility of prior meetings would be of great value in Brazil, considering structural and personnel limitations, it would represent a challenge for implementation.

Pesticide registration documentation is divided into two blocks: administrative and study data. Mandatory administrative documents cover company, applicant, and product information. The study data block involves product chemical data, danger to non-target organisms, user exposure, product performance, and packaging safety. Notably, at the pre-registration meeting, the non-requirement of one of the studies mentioned above can be defined (USA, 2022d).

For cleaning products classified as hazardous substances, the CPSC does not carry out safety, efficacy, or quality assessment/approval before starting sales, as it has no regulatory function. This assesses the risks generated to the consumer by the products available on the market. Manufacturers must ensure the safety of their products, follow FHSA labeling requirements, and not incorporate prohibited substances into the composition. If a cleaning product on the market risks users' health and safety, the CPSA can take mitigating actions and apply the appropriate penalties.

The registration of chemicals in European Union member states is carried out within the scope of ECHA, as shown in Figure 3. The request is made through the registration dossier, consisting of the technical dossier and chemical safety report (ECHA, 2016).

Figure 3. Flowchart of regularization of a cleaning product in the European Union.
Source: prepared by the authors.

The mandatory information in the technical dossier varies according to the annual quantity produced, covering the identification of the manufacturer and the product, information on production, use, classification, and labeling, safe use guidelines, information on the properties of the substance, and exposure. The safety report is required when the production volume equals or exceeds 10 tons per year. These must contain a summary of risk management measures, identification of physicochemical properties, and assessment of hazards to human health, the environment, and exposure (ECHA, 2016).

In Brazil, the United States, and the European Union, the studies required to request registration are the manufacturer's responsibility. Myers *et al.* (2009) state that studies carried out in commercial laboratories for regulatory purposes, even following Good Laboratory Practices, do not guarantee reliability and scientific validity. For Boone *et al.* (2014), conflicts of interest between the laboratory and the company responsible for the cleaning products can compromise the research results.

Boone *et al.* (2014) argue that independent, non-profit laboratories should carry out the tests, but with the costs paid by manufacturers. In Brazil, such a measure could be implemented in local health surveillance bodies or public universities, as both cover the entire national territory. A blind analysis in a laboratory other than the place of origin of the request should be performed to reduce influences on study decisions. Another aspect is the incompleteness of studies conducted only in the laboratory, whose environmental conditions can be controlled, as occurred with the herbicide Atrazine in the United States. These authors believe that regulatory decisions need to combine laboratory and field studies, as the latter allows the identification of insights into the potential effects of a product on the environment.

The American (US EPA and CPSC) and European (ECHA) agencies do not consider the cumulative risk to the environment of regulated chemicals. Therefore, when analyzing each product only independently, the systemic view of how they affect the environment and its balance is lost. In Brazil, the environmental agency has the necessary basis for this assessment through environmental impact studies. In the case of the US EPA, this is done with annual production reports in

the United States. The American agency can direct its efforts toward field research, which allows it to identify the risks accumulated in the environment in which companies operate (VRYZAS *et al.*, 2020).

The European Union is at the forefront with the voluntary environmental label, the EU Ecolabel, defining environmental standards throughout the entire life cycle of products (EU, 2023). The US EPA has the Safer Choice label for chemicals, aiming to promote those more environmentally friendly considering their life cycle (USA, 2022e). The CPSC does not have an environmental labeling program, as it is outside its scope of action. The United States and the European Union have federal incentives for product evaluation through the regulatory agency. In Brazil, ANVISA does not have its own labeling program for cleaning products, representing an opportunity for improvement. However, creating a program of this magnitude involves alignment with other bodies, such as the Ministry of the Environment.

Given the above, the regularization of cleaning products and companies in Brazil is subject to improvement, such as increasing the requirement for studies, as Europe does; improving guidance for applicants, such as the US EPA pre-registration meeting; and making the CBPF mandatory, so that inspections occur periodically. Prior verification of documentation, carried out by the US EPA and ECHA, can reduce bureaucracy in the registration of sanitation workers. While the CPSC could define product regulations before launching on the market, it establishes voluntary standards created by the companies. This can generate pressure from large corporations and not affect all products in use by consumers.

Conclusion

The way each location handles the regularization of its products is the result of its historical processes. In Brazil, it came with the reorganization of the public health system. On the other hand, in the United States, it happened during the emergence of concerns about the environmental impacts caused by human beings. In Europe, such regulations were due to demands for common regulations among Member States.

Brazilian regulatory procedures are similar to international practices regarding the technical and scientific requirements of cleaning products and similar products. ANVISA monitors and shares experiences with other regulatory agencies around the world. The centralization of the topic of cleaning products in a single agency, the curation of regulations, the visit to the company to issue the

company's Operating Authorization, the different forms of communication to reach greater audience diversity, and the fixed term of the manager's mandate are certainly advantages of Brazilian regulation. On the other hand, the improvement points involve the translation of legislation, more significant study requirements, improved guidance for applicants, and reduced bureaucracy.

The Brazilian agency has an adequate structure to deal with its responsibilities in the national territory, as is the case with institutions in the United States and the European Union. This indicates a high level of management that facilitates Brazil's relations with other locations since standards are similar between different locations. Cleaning product regulation is fundamental to achieving sustainable development, as it aims to protect human health and the environment. These are chemicals that can have significant negative impacts if not used responsibly. Its regulation must be aligned with sustainable development goals, have popular participation, and focus on continuous improvement and being updated with technological and market changes. This can guarantee security for the entire society based on actions carried out by users and producers.

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How to cite this article (ABNT):
SILVA, E. A.; MOURA, I. E. M. O.; MOITA NETO, J. M. Cleaning products regulation in three world markets: the Brazilian case effectiveness. *Veredas do Direito*, Belo Horizonte, v. 20, e202543, 2023. Available from: http://www.domhelder.edu.br/revista/index.php/veredas/article/view/2543. Access on: Month. day, year.