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Regulation of the Ministry of Agriculture and Livestock (MAPA) Self-Control Law is Published

On August 1, 2024, Decree No. 12,126/2024 was published to regulate self-control programs in the sector governed by farming and cattle raising defense.

The decree also regulates the Compliance Incentive Program in Farming and Cattle Raising Defense for sectors of animal-origin products, edible and non-edible, and products intended for animal feeding. Furthermore, the Decree contains provisions regarding inspection and oversight procedures based on risk.

Self-control consists of a program to promote compliance of the regulated sector's production processes with regulatory requirements. Such requirements aim to ensure the quality and safety of products from sector agents who, through self-control, conduct internal monitoring procedures.

In this regard, the regulation of the Self-Control Law seeks to optimize actions to monitor the quality of products to be placed on the market.

According to the new regulation, self-control programs conducted by private sector agents must meet a series of mandatory requirements listed in the paragraphs of Article 4.

In this regard, the programs must (i) contain systematized and auditable records of the entire production process; (ii) address the withdrawal of batches in case of identification of non-conformities in the agricultural product that pose potential risks to consumer, animal, or plant health; (iii) describe self-correction procedures; as well as (iv) apply good practices throughout the production chain.

MAPA is also expected to establish specific regulations regarding the self-control of each production sector, as well as the procedures and frequency for official verification considering risk assessments, as provided for in Article 5 of Decree No. 12,126/2024.

Agreement between Brazil and Chile Expected to Facilitate Trade in Cosmetics between those Countries

Brazil and Chile have concluded negotiations for an agreement aimed at promoting trade in cosmetics products. Negotiations between the countries had been happening for over three years.

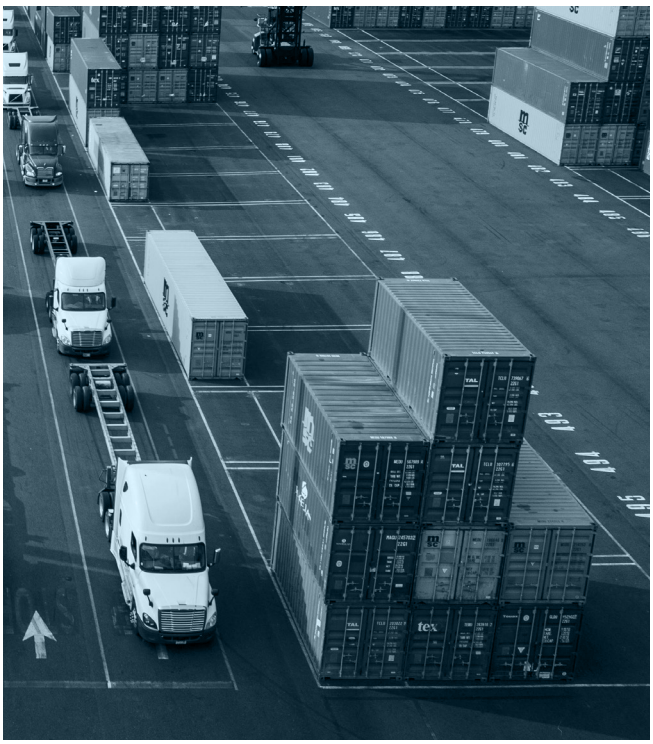
The agreement aims to encourage regulatory convergence between the countries, and its objectives include reducing technical barriers to trade between the involved countries, making regulations simple and clear, ensuring product safety, among others[1].

From a regulatory aspect, the commitments made by the countries under the agreement involve the definition of cosmetics, the reduction of prior sanitary requirements, the establishment of harmonization of rules related to labeling and good manufacturing practices, etc.[2].

The agreement will be an important initiative for the Brazilian cosmetics market. According to the Ministry of Development, Industry, Commerce, and Services (MDIC), approximately 80% of Brazilian exports of cosmetics, hygiene products, and perfumes are intended for Latin America, and in this market, Chile is the second largest destination, representing 16% of exports[3].

International cooperation involving products subject to sanitary regulation has intensified in recent years. In this regard, Anvisa (Brazilian Health Surveillance Agency) has increasingly adopted regulatory reliance practices to facilitate the regularization of products in Brazil.

Although negotiations between Brazil and Chile have been concluded, the agreement has not been officially signed yet.



1 Available at https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-e-chile-fecham-acordo-de-facilitacao-de-comercio-para-setor-de-cosmeticos. Accessed on August 6, 2024.

2 Ibidem.

3 Available at https://www.gov.br/mdic/pt-br/assuntos/noticias/2024/agosto/acordo-facilita-comercio-de-cosmeticos-entre-brasil-e-chile. Accessed on August 6, 2024.

Establishment of Regulatory Sandbox at Anvisa

On August 12, 2024, Anvisa opened Public Inquiry No. 9/2024 to gather public contributions on the Partial Report of the Regulatory Impact Analysis (AIR in Portuguese) to establish the Regulatory Sandbox model (or Experimental Regulatory Environment).

The public inquiry aims to support the AIR study so that the implementation of the Regulatory Sandbox model effectively meets society demands. Contributions can be made until 10/11/2024.

The Regulatory Sandbox is a mechanism in which companies can test innovative products and services in a controlled and safe manner before they are made available in the market.

The public inquiry proposes that the process be supervised and allow for the temporary suspension of existing rules, within an experimental environment, which, in theory, would prevent the testing or regulation of innovations.

With this, Anvisa seeks to offer a safe and effective regulatory approach for innovative products and services in situations in which the existence of current rules makes their testing and regulation impossible.

The creation of experimental regulatory environments is provided for in Ancillary Law No. 182/2021, and such mechanisms are already used in Brazil (e.g., MAPA).

Contributions can be submitted through Public Inquiry form No. 9/2024 (link).

National System for Prescription Control (SNCR) Comes into Effect

On July 18, 2024, SNCR came into effect. It was established by Anvisa through RDC Anvisa No. 873/2024, published in May 2024.

The new system enables the electronic and automated management of prescription notifications, and its operation is now available to local health authorities throughout the Brazilian territory.

In line with Law No. 13,732/2018, SNCR centralizes the special control of prescriptions for controlled substances. By virtue of the aforementioned Law, prescriptions for medications, including those subject to special control, are valid throughout the country.

So far, the use of the platform by authorities is optional, but will become mandatory from January 1, 2025.

Read more about SNCR in the 6th edition of our Life Sciences & Healthcare Newsletter 2024 (link).

STF Confirms Exclusive Jurisdiction of the Government in Health Plans and Insurance Matters – Direct Action for the Declaration of Unconstitutionality (ADI) No. 7552

On August 9, 2024, the Federal Supreme Court (STF) ruled the unconstitutionality of State Law AL No. 8,880/2023, which required health plans to cover tests prescribed by nutritionists, within the scope of ADI No. 7552.

As stated in the opinion of the judge-rapporteur, Luiz Fux, the unconstitutional norm refers to a matter to be ruled under the Government's exclusive jurisdiction. This issue had already been decided by STF in ADI No. 7376, the judge-rapporteur of which was Gilmar Mendes, reaching the same conclusion regarding the unconstitutionality of a similar legislation from the State of Rio Grande do Norte.

According to Article 22, I and VII, of the Federal Constitution, it falls exclusively under the Government's jurisdiction to legislate on civil rights and insurance policies, among other matters. Furthermore, ANS has the authority to establish coverage parameters in healthcare, as provided for in Article 4, V, of Law No. 9,961/2000, among other responsibilities.

In this regard, any rule and/or obligation related to health plans can only be established under Federal Law.

This decision applies individually to the analyzed case but may eventually be used, alongside ADI No. 7376, as a leading case for the judgment of similar lawsuits.

Ministry of Health Establishes Public Health Emergency Operations Center for MPOX (COE MPOX)

On August 15,2024, the Ministry of Health established the Public Health Emergency Operations Center through Ordinance No. 5,192/2024 for the coordinated management of actions to be adopted in Brazil regarding the MPOX disease.

The Ministry of Health's ordinance responds to the World Health Organization (WHO)'s decision, which declared a new public health emergency of international concern (PHEIC) for the international response to MPOX.

The declaration of PHEIC occurs in situations in which there is a risk to international public health due to the spread of the disease. Therefore, a coordinated international response is required, as stipulated by the International Health Regulations, incorporated nationally by means of Decree No. 10,212/2020.

By means of the ordinance, the Ministry fulfills Brazil's international obligations as a member of the WHO, in accordance with the International Health Regulations. It is an important step, but only the first one. At this moment, it is not enough to be concerned about MPOX; there is a need to address the issue: that is, the establishment of the Operations Center by the Ministry of Health is not a mere formality, but an important work to be done —with readiness, coordination with state and municipal authorities, international cooperation, and the intelligent use of epidemiological surveillance tools.

Please see the comment from partner Marco Torronteguy in an article published on Roncarati Publisher website (link).

Partner responsible for the newsletter:

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