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Newsletter

1st Edition | 2025

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Anvisa opens inquiry for inputs regarding regulatory sandbox on cosmetics, hygiene products, and perfumes

The Board of the National Health Surveillance Agency (Anvisa) has opened Directed Inquiry No. 4/2024 in order to receive inputs regarding the draft invitation notice for selecting interested parties to participate in the Pilot Project of the Experimental Regulatory Environment (Regulatory Sandbox) related to personal hygiene products, cosmetics, and perfumes.

The Regulatory Sandbox consists of an experimental regulatory model designed to provide a controlled environment aimed at enabling the development of new products and services and encouraging innovative regulatory solutions in light of new technologies. In this environment, new ideas can be tested without risks to public health.

Read more about the Regulatory Sandbox in previous editions of Bios from 2024 (7th ed. and 9th ed.).

The implementation of the experimental regulatory environment represents a milestone in the regulation of cosmetics, hygiene products, and perfumes in Brazil. By means of the directed inquiry, interested parties can submit inputs that will support Anvisa's next steps regarding the content of the invitation notice for the selection of those interested in participating in the project.

This is Anvisa's first Regulatory Sandbox and the first one in the health sector in Brazil. At the 24th Public Ordinary Meeting, Anvisa's Board highlighted the dynamism of the cosmetics sector, marked by rapid global transformations, new technologies, business models, and consumption forms, such as product personalization. In this regard, innovation is essential for Brazil to maintain its competitiveness in the global market.

The expectation for the launch of the invitation notice for receiving projects is in the first quarter of 2025. The submissions of inputs regarding the invitation calling notice before Anvisa may occur until January 31, 2025. The full draft is available on Anvisa's Website.

Public Inquiry on new RDC regarding sanitary sanctioning administrative processes within Anvisa will remain open until early February

Anvisa published on December 3, 2024 (and republished on December 13, 2024) Public Inquiry No. 1,297/2024, by means of which it intends to gather inputs from the regulated sector regarding the proposed Resolution of the Board (RDC in Portuguese) that lays out guidelines to be observed in Sanitary Sanctioning Administrative Processes (PAS in Portuguese) within the Agency. The full proposal is available on Anvisa's website.

According to the agency, the new RDC seeks to "provide transparency and legal certainty to the process" and is one of the measures being adopted by Anvisa to improve its inspection processes[1].

This is an initiative included in the 2024-2025 Regulatory Agenda, under Topic No. 1.4 - Definition of procedures for the judgment of Sanitary Administrative Processes (PAS). If approved, the new RDC will be applied complementarily, mainly to Laws No. 6,437/1977[2] and No. 9,784/1999[3] and to RDC Anvisa No. 266/2019[4].

The draft introduces innovations by proposing definitions of terms essential to inspection measures in sanitary surveillance and to the sanitary administrative process, providing greater legal certainty and directing the interpretation of the rules as a whole.

Please find below the main points brought by the proposed RDC:

- **Processes will be public, as a rule, after the decision of first instance (art. 26):**

  The proposal states: "After the decision of first instance is rendered, PAS will be public, except for data protected by legal acts or regulations." Currently, the records of sanitary administrative processes are inaccessible to those who do not have a direct interest in the case.

- **Concept of responsive inspection (art. 2, XI, and arts. 3 to 12):**

  There is a strong focus on responsive inspection, defined as "a regulatory approach based on criteria that guide the sanitary authority in the proportional and efficient selection of administrative measures, considering the health risk

1 Public Inquiry No. 1,297/2024. Available at Anvisa's Website.

2 It describes violations of federal sanitary legislation and establishes the respective sanctions.

3 It regulates the administrative process within the scope of the Federal Government.

4 It provides for the procedures related to filing administrative appeals against the decisions of the National Health Surveillance Agency.

associated with the violation, the compliance history of the regulated entity, and the need to prevent or mitigate risks to public health more quickly."

This stance relates to the notions of sanitary notification, consent decree (TCAC in Portuguese), and double inspection mentioned explicitly in the proposal, which carry a less punitive and more instructive bias for sanitary inspection, in line with the Agency's reliance notions and actions.

- **Express provision on penalties for violations and the possibility of reformatio in pejus (art. 24, par. 2):**

It is now proposed to make it clear, in a specific regulation, that "The limits of the fines established in Laws No. 6,437, of August 20, 1977, and No. 9,294, of July 15, 1996, will be applied per violation and not per sanitary administrative process" and that it will be possible to increase the sanction on appeal (reformatio in pejus).

These are positions already adopted by Anvisa and, specifically regarding the concept of reformatio in pejus, this is a prerogative already allowed by Law No. 9,784/1999 and recognized by the Federal Supreme Court as applicable to sanitary administrative processes.

- **Acts and protocols via SEI System (arts. 19, 28, and 77):**

There is a provision determining that acts in processes must be carried out electronically (SEI-Anvisa), including filing defenses, appeals, as well as reporting notices of violation and administrative orders.

- **Deadlines for defense and appeal (arts. 18 and 27):**

The deadlines for filing defenses and administrative appeals will also become clearer. The regulation provides for the same current deadline of 15 days to file defenses, as established in Law No. 6,437/1977. However, it diverges from the Law by establishing a deadline of 20 days for filing administrative appeals at the Court of Appeals.

This should put an end to the uncertainty regarding the deadline for filing appeals before Anvisa's General Management of Resources (GGREC in Portuguese), but Anvisa has already adopted the 20-day deadline provided for by RDC Anvisa No. 266/2019 (in theory, not applicable to sanctioning processes).

This should bring greater legal certainty regarding the deadlines considered by Anvisa, which, in practice, would be as follows:

Document	**Deadline** (counted from the notification to the respondent)
Defense	15 days
Appeal to GGREC	20 days
Appeal to Anvisa's Board (Dicol)	20 days

- **Criteria for applying penalties (arts. 24, 38, 51 and 52):**

  Definition of criteria involving factors such as the economic capacity of the notified party, their history, and any mitigating and aggravating circumstances, including establishing a table for the base fine amounts applicable based on the size of the notified entity and nature of the violation under analysis.

  By detailing such criteria, already provided for in Law No. 6,437/1977, the new regulation potentially promotes greater clarity and transparency regarding the aspects considered by the judging authority during the determination of the applicable penalties.

Anvisa will receive suggestions regarding the draft regulation until February 3, 2025.

Anvisa publishes clarifications related to the import of medical device components

On December 10, 2024, Anvisa shared new understandings concerning the procedures and documents required for storage in special warehouses and importers of medical device components.

The Agency clarified that, as a rule, importers of medical device parts, and of accessories already regulated within processes related to finished medical equipment or IVD (in vitro diagnostics), are exempt from the Authorization for Company Operation (AFE in Portuguese) for import activities, regardless of whether the intended use of the component is for manufacturing a national medical device or for replacing and repairing medical equipment in use.

However, this exemption does not extend to importers of accessories not regulated within previous processes, considered finished medical devices.

Regarding storage activities, Anvisa emphasized that special warehouses[5] are exempt from AFE to store products in customs facilities, according to RDC Anvisa No. 939/2024. "Other customs warehouses, which operate storing components, accessories subject to regulation, and medical devices, must fully comply with RDC 939/2024 concerning the mandatory AFE for storing medical devices."[6]

Anvisa announced that it will update its Import Manuals to include the specificities above and to encompass appropriate indications of import purpose, manufacturing stage, and other necessary information during the completion of the LI/LPCO - Medical Device form.

Individuals whose import processes were denied for reasons that are no longer applicable after Anvisa's updated understanding must initiate new import processes and attach the notification communicating Anvisa's understanding. Once the new processes are approved, it will be possible to petition for the release of goods involved in the previously denied processes.

5 The special warehouse customs regime allows the storage of parts, items, components, and replacement or maintenance materials, with suspension of payment of federal taxes, contribution to PIS/PASEP-Import, and COFINS-Import (art. 14 of Law No. 10,865/2004), for vehicles, machinery, equipment, devices, and instruments, whether foreign, nationalized or not, and national goods that have employed foreign parts, items, and components (art. 480 of the Customs Regulation), used in activities defined in art. 1 of MF Ordinance No. 284/2003 and in art. 2 of IN SRF No. 386/2004. Other information are available on Brazilian Federal Revenue's website.

6 Anvisa clarifies the import of components for medical device. Available on Anvisa's website.

Anvisa publishes four new Public Inquiries on herbal medicines

Between November 29, 2024, and December 5, 2024, Anvisa published Public Inquiries No. 1290, 1291, 1292, and 1293/2024, all aimed at gathering inputs from the regulated sector regarding regulatory proposals concerning herbal medicines. Below are the highlights of each inquiry.

- **Public Inquiry No. 1290/2024:** Resolution of the Board (RDC) on the registration of herbal medicines and the registration and notification of traditional herbal products:
  - Brings greater depth to definitions applicable to the matter, such as extracts and their subdivisions, plant preparation, etc. (art. 3).
  - It resumes and updates procedures specifically applicable to the regularization of herbal medicines and traditional herbal products revoked by the recent Anvisa RDC No. 948/2024, which updated sanitary requirements for the regularization of medicines for human use, referencing the new regulation (Chapter II).
  - For the registration of products, it will be necessary to present to Anvisa data on formulation development, including information on the compatibility of the active pharmaceutical ingredient (API) with excipients and the main physicochemical characteristics of the API that may influence the performance of the finished product, as well as documents detailing manufacturing, characterization, and controls with bibliographic references that support safety data for excipients used for the first time in a medicine or a new route of administration (art. 6, XI).
    - Products must undergo a benefit-risk assessment considering the requested conditions of use, in addition to the safety and effectiveness data presented (arts. 20 and 31).
  - Registered or notified herbal medicines must display a green band on their secondary packaging that includes, in uppercase letters, "HERBAL MEDICINE" or "TRADITIONAL HERBAL PRODUCT," as well as specific information in the package insert (arts. 48 and 57).
  - The regulation makes many references to related Normative Instructions (IN in Portuguese), subject to Public Inquiry as outlined below (some of which are annexed to Anvisa RDC No. 26/2014, which currently regulates the subject).
  - Procedures for adapting products to the proposed RDC upon publication are specified, similarly to those

established by Anvisa RDC No. 26/2014 (arts. 44 to 52).

- The RDC shall apply to medicines and products obtained from fungi, algae, and lichens until specific regulations are established for them (art. 2, par. 6).

- **Public Inquiry No. 1291/2024**: Normative Instruction with prohibitions and restrictions applicable to the composition of herbal medicines:
  - The current list of plant species that cannot be used in the composition of traditional herbal products has been fully reflected in the proposed Normative Instruction;
  - The proposal brings changes related to the restrictions to be followed in the registration and notification of herbal medicines and traditional herbal products.

- **Public Inquiry No. 1292/2024**: Normative Instruction with a list of selected pesticides for analysis in herbal medicines:
  - The current list brought by RDC Anvisa No. 26/2014 has been fully reflected in the proposed Normative Instruction.

- **Public Inquiry No. 1293/2024**: Normative Instruction with a list of plant species that can be registered through simplified registration as traditional herbal medicine:
  - The current list, brought by IN Anvisa No. 2/2014, includes numerous plant species eligible for simplified registration as herbal medicines and traditional herbal products, along with specifications and restrictions to be observed.
  - The proposed Normative Instruction includes only six plant species, all classified as traditional herbal products, and does not provide details about each (Annex, Table I).
  - According to the proposed RDC subject to Public Inquiry No. 1290/2024, simplified registration can also occur if the plant species has Community herbal monographs with well-established use prepared by the Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMA) (art. 15, II, "b" of the proposed RDC).
  - According to the proposal, "the monographs and the evaluation report of the respective monographs will be made available by Anvisa" (art. 2, par. 2).
  - According to Anvisa, "(...) monographs have been developed for all herbal active pharmaceutical ingredients (API) for which the requested data were found in the sanitary legislation to prove safety and efficacy for herbal medicines, or effectiveness for traditional herbal products. Additionally, new plant species for inclusion in simplified registration

were reviewed, and monographs were proposed for those that had APIs with proven safety and efficacy or effectiveness, which would be lemongrass (Cymbopogon citratus (D.C.) Stapf) and guava tree (Psidium guajava L.)";

- Furthermore, "Through the review conducted, it was verified that three currently present species do not meet the requirements to remain in the simplified registration, namely centella (Centella asiatica (L.) Urban), cat's claw (Uncaria tomentosa (Willd. Ex Schult.) DC.), and kava-kava (Piper methysticum G. Forst.)".

Public Inquiries No. 1290, 1291, 1292/2024 will close on March 5, 2025, and Inquiry No. 1293/2024 will close on March 11, 2025.

MAPA establishes e-Phyto for the certification of plant origin products

The e-Phyto Sanitary Certification System was created by the Ministry of Agriculture, Livestock and Food Supply (MAPA in Portuguese) through Ordinance No. 749/2024, aimed at modernizing and speeding up the exchange of certification between countries.

The system will allow the issuance of a phytosanitary certificate for plant products in a standardized model, attached to said Ordinance, for products classified with simplified requirements – that is, exempt from Additional Declaration on the Phytosanitary Certificate (required when phytosanitary requirements of the importing country are applicable) and from prior phytosanitary treatment.

These products, with the electronic certificate, may be exported from any Brazilian customs facility to countries that accept the electronic format.

Phytosanitary certificates for plant products, within MAPA, must be issued exclusively in digital format via e-Phyto starting January 13, 2025, except in cases when the digital service is unavailable.

The authenticity of digital certificates can be verified using the QR code and electronic signature present in each document.

ANPD and ANS sign cooperation agreement for information exchange and study development

On December 20, 2024, the Brazilian Data Protection Authority (ANPD in Portuguese) and the Brazilian Supplementary Health Agency (ANS in Portuguese) signed Cooperation Agreement No. 01/2024, which aims to "(...) carry out educational actions in the area of personal data protection, hold multilateral meetings, and produce documents, including reports and technical studies on topics of mutual interest."

The actions planned for the partnership include:

- promoting joint actions regarding personal data protection, including information exchange;
- developing guiding actions and conducting meetings aimed at identifying problems and best practices;
- proposing innovations and regulatory and procedural improvements on health-related topics (e.g., supplementary health, digital health, international transfer, interoperability, conservation, anonymization, sharing, and elimination of health data).

For this purpose, entities must join meetings in a virtual environment or in-person and gather teams on an electronic platform for planning and monitoring the tasks to be carried out. Additionally, ANS must "(...) provide data, reports, technical opinions, diagnostics, studies, or statistics that it has on the supplementary health sector" useful for fulfilling the Agreement.

The Agreement will last for three years, with the possibility of renewal for the same period. Once the Agreement ends, within 90 days, ANS and ANPD must produce a joint report on the execution of activities, detailing the actions undertaken and the objectives achieved.

As detailed in the Agreement, the sharing of information between ANPD and ANS "(...) regarding the applicability of the LGPD and the storage, use, and transfer of health data, can greatly contribute to the effective operation of both and to the technical and legal security of the regulated sector and of personal data subjects."

Bioinputs Law sanctioned

The Bioinputs Law (Law No. 15,070/2024) was published in December 2024. The regulation governs products, processes, and technologies of plant, animal, or microbial origin for use in agricultural and livestock products, in aquaculture or forestry systems, which impact animals, plants, microorganisms, soil, and derived substances that interact with the products and processes in question. The text was sanctioned without vetoes. Check our analysis in the 11th edition of Bios 2024.

The law must be regulated within 360 days. The regulated sector will have up to 12 months, after the regulatory framework is published, to adapt the labels of bioinputs already registered with MAPA and comply with the requirements to be specified, including concerning good practices.

Public Inquiry opened regarding sanitary risk management actions and reliance in CBPF and CBPD/A

Anvisa will receive inputs until March 3, 2025, to the proposed RDC on sanitary risk management and the monitoring of compliance of companies applied to the granting or renewal of the Good Manufacturing Practices Certificate (CBPF in Portuguese) and the Good Distribution and/or Storage Practices Certificate for establishments manufacturing active pharmaceutical ingredients (APIs), medicines, cannabis products for medical purposes, biological products, and health products.

The proposal, available on Anvisa's website, states that the granting or renewal of the above certificates can occur by means of **(i)** analysis of an equivalent inspection report, **(ii)** risk analysis, or **(iii)** conducting an inspection motivated by the conduction of risk analysis (art. 4).

The aforementioned risk analysis and continuous monitoring of compliance must consider, among other factors, (arts. 3 and 6):

- the class and classification of risk of the product; the complexity and criticality of the establishment;
- the compliance history and regularity of companies and products; line, stage of manufacturing, and pharmaceutical form to be certified;
- inspection reports or CBPF issued by Equivalent Foreign Regulatory Authority (AREE in Portuguese);
- inspection reports or CBPF issued by regulatory authorities or entities that are members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S);
- inspection reports issued by the health authority of a member country of the International Medical Device Regulators Forum (IMDRF);
- audit reports issued under the Medical Device Single Audit Program (MDSAP).

Anvisa will consider these factors in its decision, which may also be based on artificial intelligence models (art. 3, par. 3). For establishments located in Mercosur countries, risk management must be based on guidelines set forth by existing legislation within Mercosur (art. 11).

This is yet another initiative by Anvisa aimed at streamlining its processes, including by leveraging intelligence produced by other health surveillance entities and authorities – the reliance[7].

Anvisa's website contains a form for receive inputs.

7 Read more about reliance in the previous editions of Bios from 2024: Edition 6, Edition 5, Edition 4, Edition 2, Special Edition : 1 Year Since the End of ESPIN, Regulatory Trends in Health and Agriculture - Bulletin published on March 3, 2023

Anvisa internalizes GMC MERCOSUL Resolution No. 18/2023 and updates concepts of personal hygiene products, cosmetics, and perfumes degree 1 and degree 2

By means of Anvisa RDC No. 949/2024, Anvisa amended RDC No. 907/2024, which covers the definition, classification, technical requirements for labeling and packaging, microbiological control parameters, as well as the technical requirements and procedures for regulation personal hygiene products, cosmetics, and perfumes.

The amendment was due to the internalization of GMC MERCOSUL Resolution No. 18/2023. The highlights include an update of the concepts of degree 1 and degree 2 products.

Previously, these were differentiated based on the presence of basic properties (for which evidence was not initially required, and which did not require detailed information regarding their mode of use and restrictions on use) or on the presence of specific indications (whose characteristics require proof of safety and/or efficacy, as well as information and care, mode and restrictions of use).

The new RDC modified its definitions to encompass the degree of health surveillance necessary for each based on "(...) their area of application, target audience, specific formulation conditions, or health impact of the declared purposes of use": degree 1 products initially require a lower degree of health surveillance, and degree 2 products require a higher degree.

RDC Anvisa No. 949/2024 also updated the sample list of products belonging to degree 1 and degree 2 categories. For example, products such as nail whiteners, glue or adhesive for eyelashes, wigs or nails, air fresheners, etc., were expressly added to degree 1 category. Any applicable adjustments to products already regulated must be made by January 2, 2030.

The RDC clarified that products for pregnant women or children; for people with acne-prone or sensitive skin; for sensitive teeth, anticaries, antiplaque, antitartar, teeth whitening; for the hygiene of immobilized individuals; for intimate hygiene; antiperspirants, anti-stretch marks, skin whitener, among others, are mandatorily classified as degree 2.

Finally, the regulation introduced many new definitions to assist in interpreting and enforcing the regulation, such as for dermal adhesive, tanning activator or accelerator, mouthwash, etc.

Anvisa publishes regulation on electronic petitioning

The recent Anvisa RDC No. 947/2024 now addresses several permissions, obligations, and guidelines from the Agency regarding electronic petitioning in its systems and will revoke previous outdated acts regarding the topic, such as Anvisa RDC No. 208/2005, which allows the use of digital signatures in electronic petition procedures with Anvisa.

The regulation will come into effect on March 13, 2025 and establishes that protocols to Anvisa must be carried out exclusively electronically, except for specific exceptions. However, "The organizational unit responsible for analyzing the submitted request may require, at its discretion, until it loses the right to review the acts performed in the process, the presentation of the original paper document of the digitized document."

According to the act, "Guidelines on which system should be used for each type of petition will be available on the Agency's website." The petitioning systems are accessed by registering external users (representatives of the regulated sector, individuals or legal entities).

The new RDC does not cover, for example, the formal requirements for dossier compilation established by Anvisa RDC No. 25/2011, which addresses the physical, virtual, and postal protocol of documents and will be revoked once Anvisa RDC No. 947/2024 comes into effect.

Anvisa RDC No. 470/2021, which covers the procedures for receiving documents in electronic format – that is, in CD-ROM or DVD-ROM format, as well as the related Normative Instruction Anvisa No. 50/2019, which addresses petition matters requiring electronic protocol, will also be revoked.

Documents must still be filed in Portuguese, and the submission of documents in English and Spanish is allowed, with the caveat that Anvisa may request that translations of documents be submitted (as a rule, simple translations; sworn only as specified).

Furthermore, Anvisa RDC No. 947/2024 brings details about electronic signatures and about the availability of petitioning systems and guidelines on cases of unavailability.

New Anvisa RDC on the regulation of medicines came into effect on January 1, 2025

RDC Anvisa No. 948/2024, published on December 17, 2024, sets out the sanitary requirements for the regulation of human use medicines and is already in effect.

The regulation applies to medicines subject to sanitary registration, in which prior evaluation of the technical dossier is required, or to sanitary notification, in which prior evaluation of the technical dossier is waived. Therefore, the RDC does not apply to, for example, experimental medicines, cannabis products, compounded medication.

According to the new RDC, the sanitary regulation of medicines for human use is valid for 10 years and must observe the categorization and classification of products, as follows:

- Categorization will consider:
  - the method to obtain the Active Pharmaceutical Ingredient (API): synthetic, semisynthetic, biological, herbal, medicinal gas, or radiopharmaceutical;
  - the class of the medicine: new, innovative, similar, or traditional; and
  - the characteristics of the API and the medicine: generic, dynamized, specific, and advanced therapy.
- Classification will consider:
  - the ATC (Anatomical Therapeutic Chemical) system[8];
  - prescription restrictions;
  - use restrictions;
  - destination;
  - target population;
  - pharmaceutical form;
  - route of administration; and
  - complexity or health risk.

More than 50 definitions are established for the many regulated terms introduced by the act, which provides information on the necessary licenses for the regulation of medicines, such as Authorization for Company Operation (AFE in Portuguese), sanitary license, Good Manufacturing Practices Certificate (GMP Certificate), etc.

In addition, the RDC lists several other norms applicable to medicines that must also be fulfilled by the regulated sector.

Finally, the regulation lists the general documentary requirements applicable to the regulation of medicines for human use and the steps for the analysis of processes and granting of registration or regulation by Anvisa.

8 Anatomical Therapeutic Chemical (ATC) classification system of the World Health Organization (WHO) in which active pharmaceutical ingredients (APIs) are divided into different groups and subgroups in up to five levels according to their sites of action, therapeutic, pharmacological, and chemical properties.

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