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This is an informative newsletter produced by the **Life Sciences and Healthcare** practice of TozziniFreire Advogados.

INDEX

Click at the topic of your interest and browse through the content

Anvisa opens Public Inquiry to update Maximum Tolerated Limits of contaminants in food

The Board (Dicol) of the National Health Surveillance Agency (Anvisa) approved the opening of Public Inquiry No. 1,289/2024 regarding the update of the lists of Maximum Tolerated Limits (MTL) of contaminants in food.

The regulation of MTL in food is currently determined by Anvisa Board Resolution (RDC) No. 722/2022. These limits are currently set by Anvisa Normative Instruction (IN) No. 160/2022.

IN Anvisa No. 160/2022 contains the MTL for metals (arsenic, cadmium, lead, copper, chromium, mercury, and tin), mycotoxins (toxic secondary metabolites derived from certain fungi[1]), and other contaminants in food.

According to Dicol, the updates subject to the Public Inquiry aim to align the regulations with the recommendations in Codex Alimentarius, which is a compilation of standards, guidelines, and codes of conduct recognized internationally, which contribute to the safety and quality of food products[2].

Through the Public Inquiry, the public can submit inputs that will support Anvisa's technical analyses to modify, include, or exclude requirements regarding MTL for contaminants.

The changes under review and subject to the Public Inquiry are:

- The reduction of MTL for lead in cereal-based foods for child consumption (from 0.05 mg/kg to 0.02 mg/kg) and in transitional foods for infants and young children (from 0.15 mg/kg to 0.02 mg/kg);
- The increase of MTL for fumonisins (B1 + B2) in corn flour, corn cream, cornmeal, flakes, and canjica (Brazilian hominy porridge) (from 1,500 mcg/kg to 2,000 mcg/kg);
- The introduction of MTL for fumonisins (B1 + B2) in raw corn (4,000 mcg/kg);
- The introduction of MTL for hydrogen cyanide in cassava flour (10 mg/kg);
- The introduction of MTL for monochloropropane-1,2-diol (3-MCPD) in liquid seasonings containing acid-hydrolyzed vegetable proteins (0.40 mg/kg) – except for naturally fermented soy sauce; and
- The introduction of MTL for melamine in **(i)** general food products, except child formulas (2.5 mg/kg); **(ii)** formulas for infants, transitional formulas, and formulas for young children marketed in powder form (1.0 mg/kg); and **(iii)** formulas for

1 Federal University of Santa Maria. Available at: https://www.lamic.ufsm.br/site/pt/micotoxinas/o-que-sao-micotoxinas. Accessed on: November 8, 2024.

2 Food and Agriculture Organization of the United Nations. Available at: https://www.fao.org/fao-who-codexalimentarius/about-codex/en/#c453333. Accessed on: November 8, 2024.

infants, transitional formulas, and formulas for young children marketed in liquid form (0.20 mg/kg).

By approving the Public Inquiry with society's participation in submitting inputs, Dicol clarified that MTL for contaminants in harmonized food or food negotiated within Mercosur are not part of the proposal's scope.

Inputs for the Public Inquiry can be submitted from November 8, 2024, to December 23, 2024, using an electronic form available on Anvisa's website, where a full draft of the Normative Instruction under discussion is also available.

Anvisa approves Normative Instructions to establish warnings on displays and packaging of smoking products

On November 1, 2024, Anvisa published IN Anvisa No. 331/2024 and IN Anvisa No. 332/2024, which contain new health warnings and messages to be used on displays, showcases, and packaging of tobacco-derived smoking products.

As determined by Dicol, these norms seek to disseminate clear information to raise consumer awareness about the risks inherent in smoking product consumption.

The messages and warnings established by the normative instructions contain texts and visual elements aimed at discouraging tobacco use.

These measures are supported by Law No. 9,294/1996, which establishes that such products must contain warnings about the harm caused by consumption. This Law explicitly prohibits the advertising of smoking products within the Brazilian territory.

The messages and warnings regarding the harm caused by tobacco are periodically updated, and the most recent changes occurred over the past year, with the publication of IN Anvisa No. 271/2023 and IN Anvisa No. 272/2023.

The guidelines to be followed by companies regarding the layout, design, and content of the warnings are listed in the normative instructions, such as the minimum required percentage area of the graphic set for the warnings, the texts, and their respective formatting, among others.

The new normative instructions came into effect on November 1, 2024, and revoked the previous regulations addressing this matter.

Anvisa opens doors for veterinary prescription of cannabis products and for the regulation of these products by Mapa

Anvisa approved a measure allowing veterinarians to prescribe cannabis-based veterinary products, as well as enabling the Ministry of Agriculture and Livestock (Mapa) to regulate such products.

To this end, Anvisa published RDC Anvisa No. 963/2024 on November 7, 2024, to update SVS/MS Ordinance No. 344/1998, which contains provisions on the registration and dispensing of products subject to special control.

Cannabis products are a regulatory category created by Anvisa in 2019 through RDC Anvisa No. 327/2019. This allowed, at that time, the regulation of products for human use (under the regime of sanitary authorization) that had not yet met the necessary technical and regulatory requirements to be classified as medicines (regulated under the sanitary registration regime).

The current measure addresses a demand from the Federal Council of Veterinary Medicine (CFMV in Portuguese). Considering that, until then, there was no regulatory framework authorizing veterinarians to prescribe products, such professionals risked being penalized if they prescribed these products. In a statement, CFMV stated that "with the new regulation, professionals can safely and legally prescribe cannabis without the risk of penalties"[3].

With the new rules:

- Mapa, responsible for regulating veterinary products, has been able to regulate cannabis products for commercialization purposes in Brazil; and
- Qualified veterinarians will be able to prescribe cannabis medicines (registered with Anvisa), cannabis products (authorized by Anvisa), and animal-use-only products regulated by Mapa[4].

Since these are products subject to special control, veterinary prescriptions must occur through a special prescription to be retained by drugstores.

RDC Anvisa No. 936/2024 will come into effect on December 2, 2024.

3 Regional Council of Veterinary Medicine of the State of Paraíba. Available at: https://www.crmvpb.org.br/uso-da-cannabis-na-medicina-veterinaria-e-aprovado-pela-anvisa/. Accessed on: November 8, 2024.

4 National Health Surveillance Agency. Available at: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/produtos-a-base-de-cannabis-poderao-ser-regularizados-para-uso-em-animais. Accessed on: November 8, 2024.

Anvisa publishes list of companies authorized to manufacture/import custom medical devices

On October 29, 2024, Anvisa published a list of companies that received authorization to manufacture or import custom medical devices. The list of authorized companies is contained in Resolution RE Anvisa No. 3,971/2024 (link).

Custom medical devices are part of the category of personalized medical devices, whose regulation is currently provided by RDC Anvisa No. 925/2024. This regulation establishes guidelines related to the manufacturing, marketing, importing of such products, and exposure to their use.

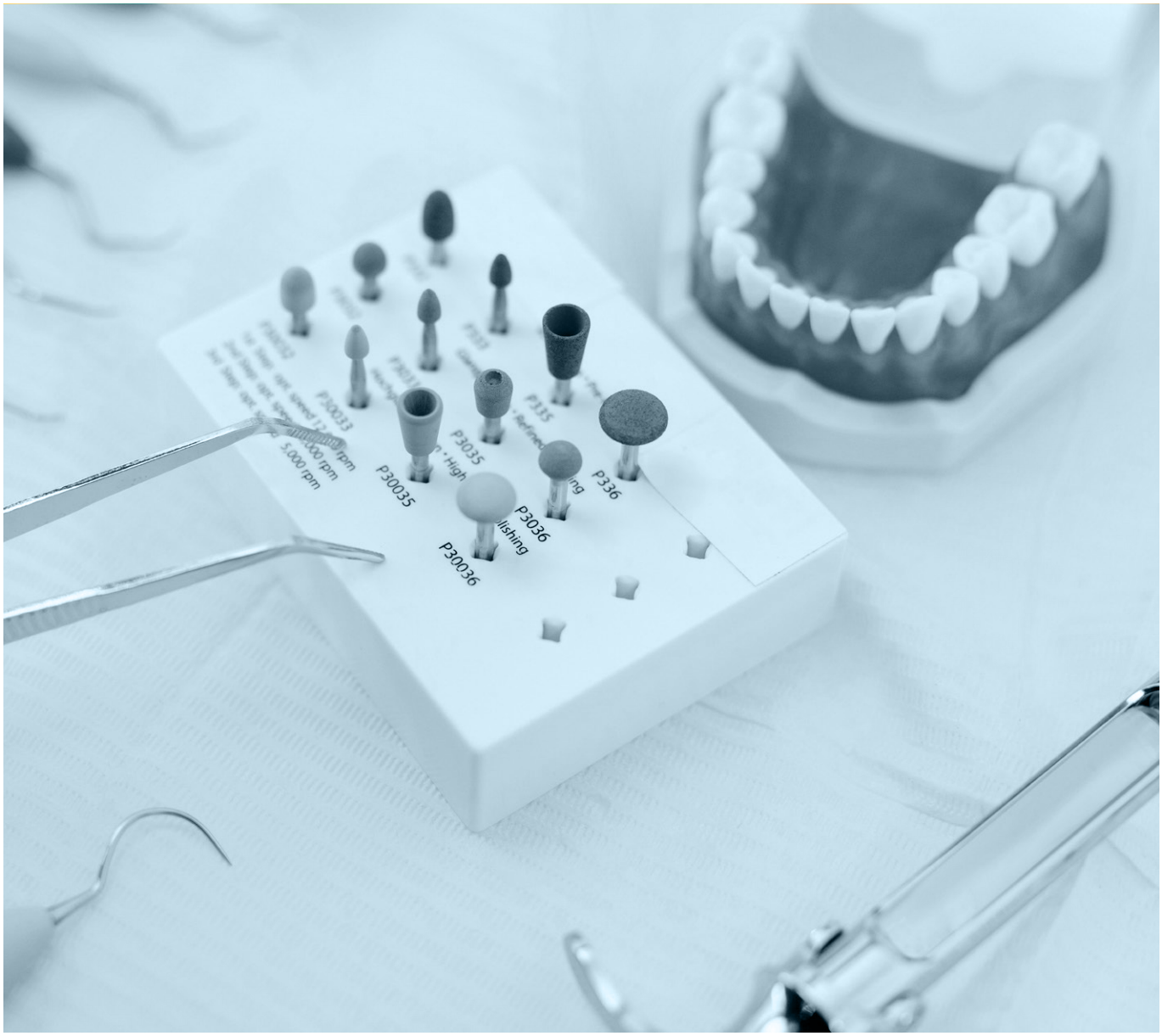
Personalized medical devices are devices intended for a particular individual and are divided into three categories according to RDC Anvisa No. 925/2024:

- **Custom medical devices:** Exclusively intended to meet the anatomical-physiological conditions of a specific individual. These are medical devices manufactured specifically according to the prescription of the health professional, who provides specific design characteristics. In this category, the responsibility for the device lies with the health professional, even though the design may be developed in conjunction with the manufacturer.
- **Patient-specific medical devices:** These are tailored to the patient's anatomy through sizing techniques based on references or anatomical characteristics verified in imaging tests. These are medical devices produced in batches through processes that can be validated and reproduced, and, unlike the previous category, the responsibility lies with the manufacturer, even if the development occurs in conjunction with the health professional.
- **Adaptable medical devices:** These are adapted, adjusted, assembled, or molded according to the specific anatomical-physiological characteristics of the patient before use, following the manufacturer's instructions on-site. Such medical devices are mass-produced.

Regarding regularization, patient-specific medical devices and adaptable medical devices must be registered with Anvisa. Thus, they are subject to the requirements inherent in their respective regime as provided for in RDC Anvisa No. 751/2024.

Custom medical devices, on the other hand, are exempt from registration. Sanitary control of such devices is made prior to making them available to the market, through manufacturing/import authorization and manufacturing/import notification. The procedures and requirements are detailed in RDC Anvisa No. 925/2024.

Resolution RE Anvisa No. 3,971/2024, along with the list of companies authorized to manufacture/import custom medical devices, came into effect on the date it was published.



Geceis announces substantial investment for production of inputs within SUS framework

The Executive Group of the Economic-Industrial Health Complex (Geceis in Portuguese) announced a record investment aimed at boosting Brazilian production of strategic inputs for the Unified Health System (SUS). The investment is part of the new Growth Acceleration Program (PAC) and totals R$ 4.2 billion.

Out of the 322 projects received by the Ministry of Health, 175 correspond to the Local Development and Innovation Program (PDIL) and 147 to the Productive Development Partnerships (PDP).

Both programs are part of the National Strategy for the Development of the Economic-Industrial Health Complex, aimed at strengthening the national industry for the production of inputs that are essential to foster universal access to health.

Detailed information about the PDP and PDIL programs can be found in our special edition of BIOS (link), published on August 6, 2024.

The approved proposals aim to strengthen the production of inputs that are essential to meet the main demands related to the health of the Brazilian population, as well as to reduce Brazil's dependence on imports.

The products include advanced therapies for SUS, vaccines, saline solutions, medicines for neglected diseases/populations, oncology products, immunosuppressants, monoclonal antibodies, radiopharmaceuticals, active pharmaceutical ingredients, medical devices, among others.

The investment is substantial and is expected to foster the national industry of such products. National production is expected to reach an average of 70% compared to the percentage of imported products. By 2027, investments are projected to total an estimated R$ 8.9 billion through the new PAC.

Numbers released by the Ministry of Health highlight the potential impacts of this measure. Currently, more than 90% of the raw materials used in Brazil to produce active pharmaceutical ingredients come from other countries. For medical devices, national production is capable of meeting 50% of the demand. For medicines and vaccines, the number is around 60%.

This and other information is available on the Ministry of Health's website (link).

Mapa and IFDC enter into partnership to stimulate innovation and sustainability in the fertilizer sector

At the end of October 2024, the Ministry of Agriculture and Livestock (Mapa) and the International Fertilizer Development Center (IFDC) signed a Memorandum of Understanding to foster innovation and sustainability in the fertilizer sector.

The partnership involves the Brazilian Agricultural Research Corporation (Embrapa), Mapa, Petrobras, and Brazilian universities. The aim is to explore technologies that increase the efficiency of fertilizers and promote sustainable agricultural practices. The cooperation is also expected to strengthen the Brazilian National Fertilizer Plan (PNF) by reducing dependence from other countries in the sector.

Founded in 1974, with operations in over 100 countries, IFDC is an international reference in solutions for food security and reduction of environmental impacts.

In a statement, Deputy Executive Secretary Cleber Soares said that "the partnership with IFDC is an essential step to strengthen innovation in fertilizers and boost Brazilian agriculture sustainably. This advancement reinforces our commitment to food security and reducing dependence from other countries, placing Brazil at the forefront of modern and sustainable agricultural practices."[5]

The meetings included discussions with fertilizer sector players from India, visits to IFDC facilities and laboratories, as well as discussions on possible measures to strengthen fertilizer efficiency.

Detailed information about the agreement can be obtained on Mapa's website (link).

5 Ministry of Agriculture and Livestock. Available at: https://www.gov.br/agricultura/pt-br/assuntos/noticias/mapa-e-embrapa-firmam-parceria-com-ifdc-nos-eua-para-fortalecer-inovacao-em-fertilizantes. Accessed on: November 8, 2024.

CMED extends deadline for adaptation to the new form for submitting complaints regarding the pharmaceutical market

The Executive Secretariat (SCMED) of the Chamber of Regulation of the Pharmaceutical Market (CMED) has extended the deadline for adapting to the new electronic form intended for submitting complaints about potential violations related to the pharmaceutical market.

Until now, citizens and interested parties have been able to report possible irregularities to the authorities via email or through Anvisa's official communication channels. With the deadline extension, the new tool will be the only official channel for submitting complaints starting on December 1, 2024.

According to SCMED, the new format for submitting complaints is part of CMED's measures to strengthen surveillance of the pharmaceutical market in Brazil.

In this regard, the tool aims to ensure greater transparency and strengthen the tracking, delivery, and receipt of documents, if compared to the previous communication methods used by interested parties.

SCMED also points out that the standardization in receiving responses resulting from the use of the form should also reduce the response time to citizens.

It is possible that this measure reflects potential stricter measures imposed by CMED to oversee the pharmaceutical market. It is also expected that the Chamber will soon provide a new electronic page listing administrative sanctioning processes.

The form for submitting complaints about possible irregularities in medicine trade is available on SCMED's website.

Partner responsible for the newsletter

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