

Regulatory Aspects of Additives in Brazilian Gelatin Desserts

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Gelatin desserts are a standard part of many people's daily lives due to their practicality and affordable price. In this study, compliance with ANVISA regulatory standards related to the use of additives in the production of these desserts was analyzed. Eighteen products of various brands and flavors were collected and classified into standard and diet categories. Inconsistencies in the use of some additives were observed: lack of regulation for the additive's use in this type of dessert, incorrect classification, and labeling, and the absence of information about the additive's classification on the label (artificial, natural, or synthetic identical to natural). Therefore, based on the analysis of the obtained samples, we concluded that some brands of gelatin desserts still need to comply with the legislation regulating this product fully.

Keywords: Gelatin. Legislation. Additives.

Since ancient times, there have been records of recipes to obtain jelly or solidified broth from fish and meat by boiling fish heads, leftover meat, bones, and cattle hooves. Over time, this type of food gained popularity and became one of the primary protein sources for the poorest communities. Eventually, it began to be widely produced and sold as a food product known as gelatin [1].

Gelatin is a protein obtained through the partial hydrolysis of collagen from animal bones, skin, and cartilage. There are two main types of gelatin: type A, which is extracted using acids, and type B, which is extracted using alkaline means [2].

Gelatin is used in various food and non-food products, including crafts and artistic products. Before it reaches the familiar form, the raw material undergoes several processing steps in industries to extract collagen [1].

The first time powdered gelatin was intended for dessert production was in 1845, as evidenced by a US patent. Fifty years later, Jell-O popularized gelatin as a dessert worldwide [3].

The gelatins commonly sold in supermarkets for consumption are referred to as "gelatin desserts"

because, in addition to the main ingredient, gelatin itself, several other ingredients are added to create the final product consumed as a dessert. Some of the ingredients used in the production of this food are intended to enhance its characteristics; these ingredients are called additives. According to the Ministry of Health (2023):

"A food additive is defined as any ingredient intentionally added to food, without the purpose of nutrition, to modify the physical, chemical, biological, or sensory characteristics during manufacturing, processing, preparation, treatment, packaging, packaging, storage, transport, or handling of food."

They are present in practically all industrialized food products to improve their appearance and shelf life. In gelatin desserts, additives play a crucial role by adding flavor, stabilizing the texture, intensifying the color, and more, ultimately promoting a more attractive product for consumers.

Like other food products, the manufacture of gelatin is regulated by stringent federal legislation that undergoes regular review. Gelatin is classified as a meat product according to decree No. 9,013, dated March 29, 2017, which governs all aspects of its manufacturing [4]. Furthermore, Ordinance No. 384, issued on August 25, 2021, approves the Technical Regulations establishing the identity and quality standards for gelatin, hydrolyzed gelatin, and edible collagen [5]. In addition to traditional gelatin of animal origin, a vegan option is available in supermarkets called "vegan gelatin," a plant-

Received on 28 January 2024; revised 19 May 2024.

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J Bioeng. Tech. Health

2024;7(2):130-138

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based dessert made from seaweed agar. This type of food is categorized as a dessert or dessert powder in category 19 and subcategory 2 ("other desserts with or without gelatin, with or without starch, with or without gelling agents") according to the Brazilian food categorization system established by the National Health Surveillance Agency - Anvisa (Guide nº 43/2020 – version 1, p 26, 2020).

Regarding additives, they are regulated by Resolution - RDC No. 778, dated March 1, 2023, which outlines the functions and usage of food additives [6], and by Normative Instruction - IN No. 211, dated March 1, 2023 [7], which sets forth conditions and limits for the use of food additives. This study aims to analyze whether the use of food additives in gelatin desserts aligns with their intended functions and complies with the corresponding legislation regulating the production and marketing of such desserts.

Materials and Methods

Eighteen food products with various flavors were analyzed, covering almost all consumption possibilities within the dessert category, including ready-to-consume and preparation-required desserts. These products were classified into two categories: standard and diet (sugar-free). The analysis encompassed products from 12 brands falling under subcategories such as gelatin desserts or other desserts. Labeling information was gathered from retail supermarkets in Salvador, Bahia, and online sources.

The obtained results were compared with relevant legislation, including Normative Instruction - IN Nº 211, dated March 1, 2023, for desserts; RDC nº 725, 2022, and RDC Nº 722 for flavorings; and RDC nº 239, dated July 26, 2018, for sweeteners.

Results and Discussion

Out of the total products evaluated ($n = 18$), 7 fall under the standard classification, while 11 are categorized as diet desserts (Table 1). This indicates a notable increase in the production of diet gelatins,

reflecting companies' efforts to cater to a broader consumer base, including those unable or unwilling to consume sugar. This trend also extends to desserts incorporating natural additives such as coloring, flavoring, and sweeteners. Additionally, Table 1 shows that 14 gelatin products are of animal origin, while 4 are of vegetable origin, highlighting the diversity of options available in the Brazilian market.

It is evident that gelatin desserts dominate the market, a trend driven by consumer demand and production costs, which subsequently influence purchasing power.

Figure 1 shows all additives found on product labels with their respective technological functions. Figure 2 shows these same additives according to their technological function, but they are found by normative instruction No. 211 for the category of desserts.

Acidity Regulators

According to Normative Instruction (IN) No. 211, acidity regulators are characterized by altering or controlling the acidity or alkalinity of foods. Therefore, according to Table 2, it is possible to observe all the additives that appeared in some products and how often they were present. It was observed that all additives present are according to the normative instruction mentioned above and by their category for all products found.

Acidulants

According to Normative Instruction No. 211, acidulants are substances that increase acidity or give food an acidic flavor. Moreover, according to Table 3, which presents all the acidifiers used in these products and their frequency, only 2 additives comply with IN No. 211 corresponding to the food category in which they are used. However, the additive fumaric acid was not regulated for use in this type of food, even though, according to the International Food Additive Numbering System (INS), it is considered an acidulant [8].

Table 1. Information on the collected dessert products (n = 18).

| Flavor | Rating | Brand | Origin | Presentation |
|-------------------------|-----------|---------------|--------|--------------|
| Açaí with Banana | Standard | Dr. Oetker | Animal | Powder |
| Pineapple | Standard* | Dr. Oetker | Animal | Powder |
| Blackberry | Diet | Dr. Oetker | Animal | Powder |
| Pineapple, mint, ginger | Diet* | Dr. Oetker | Animal | Em pó |
| Cherry | Standard | Royal | Animal | Powder |
| Passion Fruit | Diet | Royal | Animal | Powder |
| Strawberry | Standard | Sol | Animal | Powder |
| Strawberry | Standard | Apti | Animal | Powder |
| Lemon | Diet | Apti | Animal | Powder |
| Tangerin | Diet | Linea | Animal | Powder |
| Raspberry | Diet | Lowçucar | Animal | Powder |
| Mango | Diet * | Lowçucar | Animal | Powder |
| Blueberry | Standard | Neilar | Animal | Powder |
| Lemon | Diet | Magro | Animal | Powder |
| Orange | Standard | Gelialgas | Vegan | Hydrated |
| Strawberry | Diet | Vegan | Vegan | Powder |
| Red Fruits | Diet | Dolce Vita | Vegan | Hydrated |
| Açaí with guarana | Diet | Vigor e Saúde | Vegan | Hydrated |

* Contains other additives even though they are the same type and brand.

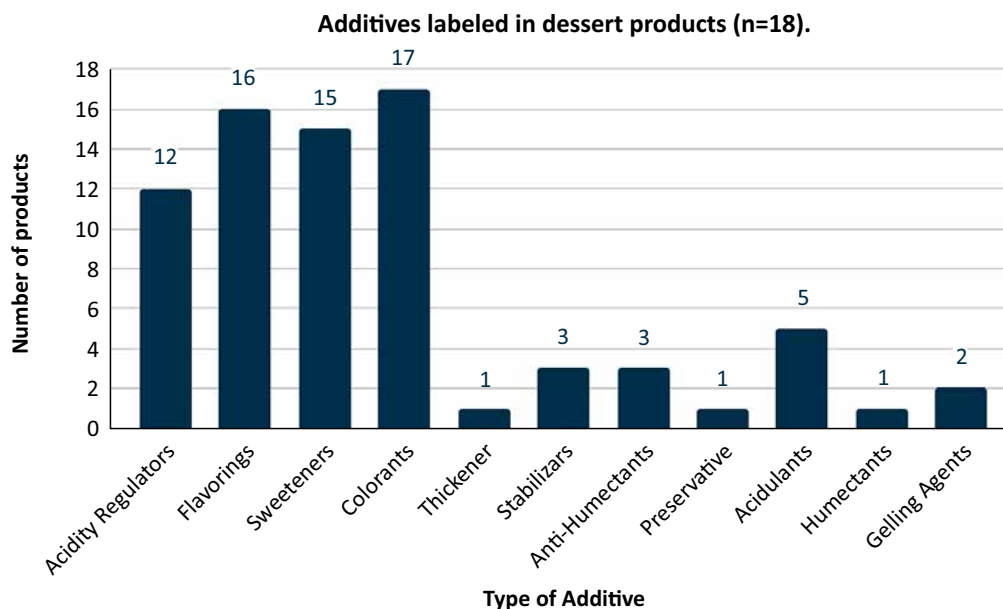
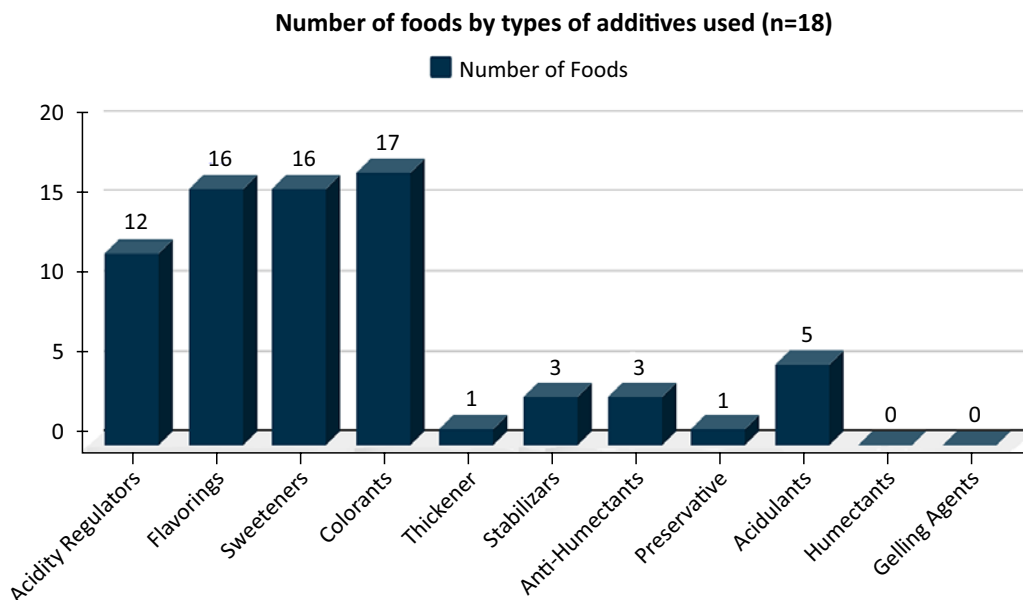
Figure 1. Frequency of types of additives found in products according to their labeling.

Figure 2. Frequency of types of additives found in products according to the analysis carried out.**Table 2.** Acidity regulating additives (n = 12).

| INS | Name | Frequency in products | Maximum limit (mg/kg ou mg/L) | Category of dessert that can be used |
|----------|------------------|-----------------------|-------------------------------|--------------------------------------|
| 297 | Fumaric acid | 10 | Quantum satis | 19.1 and 19.2 |
| 331(iii) | Sodium citrate | 11 | Quantum satis | 19.1 and 19.2 |
| 330 | Citric acid | 1 | Quantum satis | 19.1 and 19.2 |
| 296 | Malic acid (DL-) | 1 | Quantum satis | 19.1 and 19.2 |

Table 3. Acidifying additives (n = 5).

| INS | Name | Frequency in products | Maximum limit (mg/kg ou mg/L) | Category of dessert that can be used |
|-----|--------------|-----------------------|-------------------------------|--------------------------------------|
| 297 | Fumaric acid | 3 | - | - |
| 355 | Adipic acid | 1 | Quantum satis | 19.1 and 19.2 |
| 330 | Citric acid | 2 | Quantum satis | 19.1 and 19.2 |

Preservatives, Stabilizers, and Thickeners

Table 4 outlines three additives, each corresponding to its specific function. Notably, it does not include other additives in products with similar functions. As per Normative Instruction No. 211, the definitions of these functions are as follows:

- Preservative: Prevents or delays food alteration caused by microorganisms or enzymes.

- Stabilizer: Maintains a uniform dispersion of two or more immiscible substances in food.
- Thickener: Increases the viscosity of food.

All food additives in the table comply with IN No. 211 for desserts. Notably, potassium sorbate, categorized as a preservative, includes a note specifying its usage limit expressed in terms of sorbic acid, individually and in combination. Potassium sorbate and sodium carboxymethyl

cellulose are the sole ingredients used in products falling under category 19.2.1, corresponding to ready-to-eat desserts.

Antihumectants

As per Normative Instruction No. 211, antihumectants are additives characterized by their ability to reduce the hygroscopic properties (moisture absorption from the air) of foods and prevent individual particles from sticking together. Table 5 lists the two additives in some food products, specifically gelatin desserts, that exhibit antihumectant properties. Both additives comply with IN No. 211, with two reservations outlined:

Firstly, both additives are restricted to post-preparation desserts.

Secondly, for tricalcium phosphate, the limit specified in Table 5 applies to the ready-to-consume product.

Flavors

According to Normative Instruction No. 211, flavoring is a substance or mixture with aromatic or flavorful properties that can impart or enhance the

aroma or flavor of food. However, none of the analyzed products lists the additives used due to Article 12 of RDC No. 722 §3°. The declaration must indicate the technological function without specifying the individual additives for flavoring additives. This information is authorized by RDC No. 725, 2022. The resolution provides definitions for different types of flavorings found in products:

Artificial Flavoring: A chemical compound obtained by synthesis that has yet to be identified in products of animal, vegetable, or microbial origin, used either in its primary state or prepared for human consumption.

Flavoring Identical to Natural: A chemically defined substance obtained by synthesis, isolated from raw materials of animal, vegetable, or microbial origin, with a chemical structure identical to substances in natural raw materials.

Synthetic Flavoring: A chemically defined compound obtained by chemical processes, comprising flavoring identical to natural and artificial flavoring.

Table 4. Preservative, stabilizing, and thickening additives.

| Function | INS | Name | Frequency in products | Maximum limit (mg/kg ou mg/L) | Category of dessert that can be used |
|--------------|----------|--|-----------------------|-------------------------------|--------------------------------------|
| Preservative | 202 | Potassium Sorbate | 1 | 500 | 19.2 |
| Stabilizer | 331(iii) | Sodium citrate | 3 | Quantum satis | 19.2 |
| Thickener | 466 | Sodium carboxymethyl-cellulose (cellulose gum) | 1 | Quantum satis | 19.2 |

Table 5. Antihumectant additives (n = 3).

| INS | Name | Frequency in products | Maximum limit (mg/kg ou mg/L) | Category of dessert that can be used |
|--------|----------------------|-----------------------|-------------------------------|--------------------------------------|
| 341iii | Tricalcium Phosphate | 2 | 25,000 | 19.1 and 19.2 |
| 551 | Silicon Dioxide | 3 | Quantum satis | 19.1 and 19.2 |
| 330 | Citric acid | 2 | Quantum satis | 19.1 and 19.2 |

Flavors and Labeling

RDC No. 725, 2022, Article 10 §1 explains that for flavorings exclusively intended for industrial use, the declaration of ingredients and usage instructions can be alternatively made in commercial documents, except when there are restrictions on the limit of use for specific components in food. Figure 3 illustrates the types of flavorings found according to the label, where 3 are artificial, 5 are synthetic, identical to natural, and 8 have only the flavoring name on the packaging label. However, this last type of labeling does not comply with RDC No. 725, 2022, Article 6, IV, which requires the classification of natural or synthetic flavors based on the nature of their raw materials or production processes.

Despite the lack of classification on the label for these 8 flavorings, they provide information in small letters on the front packaging about the flavorings used. Figure 4 categorizes the products analyzed into 4 artificial flavorings and 12 synthetic identical to natural flavorings. Comparing images 3 and 4, it is evident that out of the 8 flavorings without classification, 1 is artificial, and 7 are identical to natural. This highlights the need for consumers to make a more significant effort to obtain information about the products they consume.

Gelificants

According to Normative Instruction No. 211, a gelling additive is a substance that provides texture through gel formation. Therefore, of the 4 vegan gelatins analyzed, only 3 products used algae extract or agar-agar as the main product to constitute the dessert. Furthermore, 2 products present agar-agar as a gelling additive (Table 6). According to Normative Instruction No. 211, it is not presented as a gelling additive in the dessert category 19.2, only as a thickener, stabilizer, and emulsifier.

Dyes

As per Normative Instruction No. 211, a dye is a substance that imparts, intensifies, or restores the

color of a food. Decree No. 55,871, dated March 26, 1965, provides definitions for different types of dyes found in products:

Natural Coloring: Harmless pigment or dye extracted from a vegetable or animal substance.

Artificial Coloring: Substance, an artificial coloring agent with a defined chemical composition, obtained through a synthetic process.

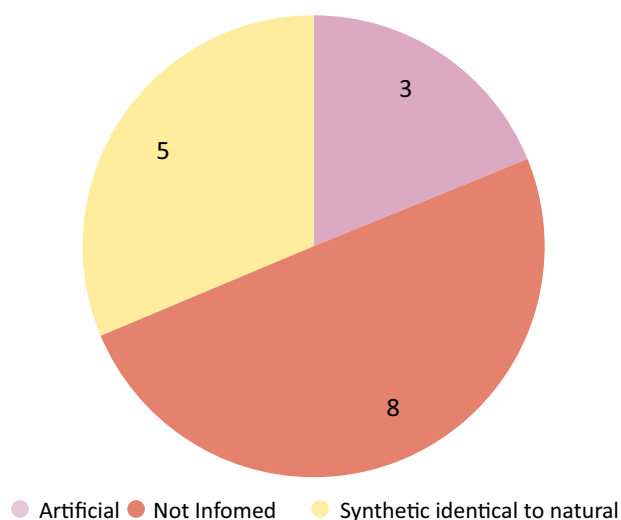
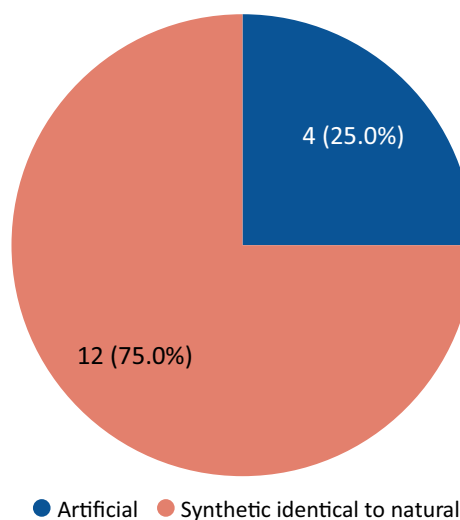
Table 7 outlines all the dyes used in these products and their frequency and type (natural or artificial). Only one dye, beetroot powder, appears to deviate from compliance with IN No. 211 for the corresponding food category. However, this discrepancy is due to the name under which it is presented, as it contains the additive betanin (also known as beet red), a water-soluble dye predominantly found in beetroot (*Beta vulgaris*). Betanin is categorized in the International Food Additive Numbering System (INS) as number 162 and aligns with IN No. 211 for categories 19.1 and 19.2, with its usage limit defined as quantum satis.

Sweeteners

According to Normative Instruction No. 211, a sweetener is a substance that imparts a sweet flavor to food, distinct from sugars. Table 8 displays all the additives found in some products and their frequency and type (natural or artificial). While IN-211 does not specify which sweeteners should be used in the dessert food category, all additives listed in Table 8 are recognized in the international numbering system for food additives as sweeteners and are permitted for use in foods by RDC No. 239, dated July 26, 2018.

However, RDC No. 239, dated July 26, 2018, stipulates that sweeteners can only be used to partially or wholly replace sugars in specific categories:

- Foods and beverages for weight control, by Ordinance SVS/MS No. 30, dated January 13, 1998.

Figure 3. Frequency of flavorings according to their classification on the label.**Figure 4.** Frequency of flavorings according to their classification on the packaging.**Table 6.** Gelling additives (n = 2).

| INS | Name | Quantity |
|-----|-----------|----------|
| 406 | Agar-agar | 2 |

Table 7. Coloring additives (n = 17).

| INS | Name | Quantity | Natural | Maximum limit (mg/kg ou mg/L) | Category of dessert that can be used |
|----------|------------------------------|----------|---------|-------------------------------|--------------------------------------|
| 100(i) | Turmeric | 2 | Yes | 150 | 19.1 and 19.2 |
| 160b | Urucum | 1 | Yes | 10 | 19.1 and 19.2 |
| 140i | Chlorophyll | 1 | Yes | Quantum satis | 19.1 and 19.2 |
| 160a(ii) | Beta-carotene | 1 | Yes | Quantum satis | 19.1 and 19.2 |
| - | Beetroot powder | 1 | Yes | | |
| 123 | Bordeaux S/Amaranto | 7 | No | 100 | 19.1 and 19.2 |
| 110 | Twilight Yellow FCF | 9 | No | 100 | 19.1 and 19.2 |
| 133 | Bright blue FCF | 5 | No | 150 | 19.1 and 19.2 |
| 129 | Red 40/ Allura Red AC | 2 | No | 150 | 19.1 and 19.2 |
| 102 | Tartrazine | 5 | No | 150 | 19.1 and 19.2 |
| 171 | Titanium Dioxide (Inorganic) | 1 | No | Quantum satis | 19.1 and 19.2 |
| 132 | Indigotine blue | 1 | No | Quantum satis | 19.1 and 19.2 |

Table 8. Sweetener Additives (n = 16).

| INS | Type | Quantity | Natural |
|---------|----------------------|----------|---------|
| 951 | Aspartame | 9 | No |
| 952(iv) | Sodium cyclamate | 4 | No |
| 950 | Acesulfame potassium | 11 | No |
| 954(iv) | Sodium saccharin | 4 | No |
| 955 | Sucralose | 4 | No |
| 960 | Steviol Glycosides | 2 | Yes |
| 967 | Xylitol 1 | 1 | Yes |

- Food for restricted sugars diets, as per items 4.1.1.1, 4.1.1.2, and 4.1.1.3 of SVS/MS Ordinance No. 29, dated January 13, 1998.
- Foods and drinks for diets with controlled sugar intake, according to item 4.2.4 of Ordinance SVS/MS No. 29, dated 1998.
- Formulas for enteral nutrition, by Resolution of the Collegiate Board of Directors - RDC No. 21, dated May 13, 2015.
- Foods and drinks with complementary nutritional information for attributes like "contains no sugar," "no added sugar," "low in sugar," or "reduced in sugar." This includes references to attributes like "low in energy value" or "reduced in energy value" when sugar is partially or entirely replaced, as per RDC No. 54.
- Supplements by Resolution of the Collegiate Board that regulates food supplements - RDC No. 243, dated July 26, 2018, which outlines the health requirements for food supplements.

Notably, 5 out of the 7 standard products with higher quantities of sugar as an ingredient utilize sweeteners, which contrasts with the resolution. However, products targeted for diet purposes remain compliant with the resolution.

Conclusion

The study highlights notable differences in the classification, function, and quantity of additives used in gelatin desserts across standard, diet, and vegan options. Vegan variants

typically feature fewer additives, with most being of natural origin. Diet variants lacking sucrose utilize sweeteners to impart sweetness. Analysis of the additives in gelatin desserts reveals inconsistencies in adherence to applicable legislation among brands. Some additives are not even explicitly regulated for this food category.

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