



Presidency of the Republic
Office of Civil Affairs
Sub Office for Legal Affairs

LAW Num. 6.437, OF AUGUST 20, 1977.

Defines violations of federal sanitary legislation,
establishes the respective sanctions, and
establishes other arrangements.

I, THE PRESIDENT OF THE REPUBLIC, hereby make known that the **NATIONAL CONGRESS** decrees and I sanction the following Law:

TITLE I

INFRACTIONS AND PENALTIES

Art . 1^o - Infractions of federal sanitary legislation, apart from those provided for expressly in special laws, are defined in this Law.

Art . 2^o - Without impairment to such civil or penal sanctions as may be applicable, sanitary violations shall be punished, alternatively or cumulatively, with the following penalties:

I - warning;

II - fine;

III - seizure of the product;

IV - rendering the product unviable;

V – banning of the product;

VI - suspension of sale and/or manufacture of the product;

VII - cancellation of product registration;

VIII - partial or total banning of the establishment;

~~IX – prohibition of advertising;~~

~~— X – cancellation of company's federal operating permit;~~

~~— XI – cancellation of the establishment's state operating license.~~

IX - prohibition of advertising; ([Text taken from Law Num. 9.695, of 1998](#))

X - cancellation of company's federal operating permit; ([Text taken from Law Num. 9.695, of 1998](#))

XI - cancellation of the establishment's state operating license; [\(Text taken from Law Num. 9.695, of 1998\)](#)

XI-A – Intervention in establishments that receive public funding from any source. [\(Included by Law Num. 9.695, of 1998\)](#)

§ 1º-A. The punishment of a fine consists of the payment of the following amounts: [\(Included by Law Num. 9.695, of 1998\)](#)

I - for minor violations, from R\$ 2,000,00 (two thousand reais) to R\$ 20,000,00 (twenty thousand reais); [\(Included by Law Num. 9.695, of 1998\)](#)

II - for serious violations, from R\$ 20,000,00 (twenty thousand reais) to R\$ 50,000,00 (fifty thousand reais); [\(Included by Law Num. 9.695, of 1998\)](#)

III – for extremely serious violations, from R\$ 50,000,00 (fifty thousand reais) to R\$ 200,000.00 (two hundred thousand reais). [\(Included by Law Num. 9.695, of 1998\)](#)

§ 1º-B. The fines set forth in this article are to be doubled in the case of repeat offenses. [\(Included by Law Num. 9.695, of 1998\)](#)

§ 1º-C. The amounts of the fines set forth in this Law are to be incremented by the coefficient for the adjustment of exchange rates referred to in the sole paragraph of Art. 2º of Law nº 6.205, of April 29, 1975. [\(Included by Law Num. 9.695, of 1998\)](#)

§ 1º-D. Without impairment to what is set forth in Arts. 4º and 6º of this Law, in the application of the penalty of the fine the competent sanitary authority shall take into consideration the economic capacity of the offender. [\(Included by Law Num. 9.695, of 1998\)](#)

XII - requirement of a corrective message; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XIII - suspension of advertising and publicity. [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

§ 1º The punishment of a fine consists in the payment of the following amounts: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

I - for minor violations, R\$ 2,000,00 (two thousand reais) to R\$ 75,000.00 (seventy-five thousand reais); [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

II - for serious violations, from R\$ 75,000.00 (seventy-five thousand reais) to R\$ 200,000.00 (two hundred thousand reais); [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

III - for extremely serious violations, from R\$ 200,000.00 (two hundred thousand reais) to R\$ 1,500,000.00 (million five hundred thousand reais). [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

§ 2º The fines set forth in this article are to be doubled in the case of repeat offenses. [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

§ 3º Without impairment to what is set forth in Arts. 4º and 6º of this Law, in the application of the penalty of the fine the competent sanitary authority shall take into consideration the economic capacity of the offender. [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

Art . 3º -The result of a sanitary violation is to be imputed to the caused it or contributed to it.

§ 1º - The cause is considered to be the action or failure to act without which the violation would not have occurred.

§ 2º - Excluded from such imputation of responsibility for the violation causes resulting from *force majeure* or arising from natural events or unforeseeable circumstances, that may come to cause damages, deterioration or alteration of products or goods relating to public health.

Art . 4º - Sanitary violations are classified as follows:

I - minor, those in which the offender is benefited by attenuating circumstances;

II - serious, those in which the existence of an aggravating circumstance has been ascertained;

III – extremely serious, those in which the existence of two or more aggravating circumstances has been ascertained.

~~Art . 5º - The punishment of a fine consists in the payment of the following amounts:~~

~~—— I – for minor violations, from Cr\$2,000,00 to Cr\$10.000,00;~~

~~—— II – for serious violations, from Cr\$10.000,00 to Cr\$20,000,00;~~

~~—— III – for extremely serious violations, from Cr\$20,000,00 to Cr\$80.000,00.~~

~~§ 1º - The amounts of the fines set forth in this Law are to be incremented by the coefficient for the adjustment of exchange rates referred to in the sole paragraph of Art. 2º of Law Num. 6.205, of April 29, 1975.~~

~~§ 2º - Without impairment to what is set forth in Articles 4º and 6º of this Law, in the application of the penalty of the fine the competent sanitary authority shall take into consideration the economic capacity of the offender.~~

~~Art. 5º The punishment of a fine consists in the collection of the amount in cash, which varies depending on the severity of the violation, according to the classification established in the foregoing article, which are subject to the following limits: [\(Text taken from Law Num. 7.967, of 1989\)](#).~~

~~—— I – for those in item I, between NCz\$ 500,00 and NCz\$ 2,500,00; [\(Text taken from Law Num. 7.967, of 1989\)](#)~~

~~—— II – for those in item II, between NCz\$ 2,500,00 and NCz\$ 5,000.00; and [\(Text taken from Law Num. 7.967, of 1989\)](#)~~

~~—— III – for those in item III, between NCz\$ 5,000.00 and NCz\$ 20,000,00. [\(Text taken from Law Num. 7.967, of 1989\)](#)~~

~~§ 1º Fines will be doubled for repeat offenses of the same violation, and increased by fifty percent for multiple offenses involving different violations. [\(Text taken from Law Num. 7.967, of 1989\)](#)~~

~~§ 2º Without impairment to what is set forth in Articles 4º and 6º of this Law, in the application of the fine, the sanitary authority shall take into consideration the economic capacity of the offender. [\(Text taken from Law Num. 7.967, of 1989\)](#)~~

~~§ 3º The amounts established in this article shall be adjusted on the basis of the daily variation of the National Treasury Bond (BTN) or such other rate as may come to replace it. [\(Included by Law Num. 7.967, of 1989\)](#)~~

Art. 5^o Intervention in the establishment, as provided for in sub-paragraph XI-A of Art. 2^o, shall be decreed by the Minister of Health, who shall appoint an mediator, who shall be invested with authority to manage, apart from the partners, managers or directors or contractually or statutorily authorized to conduct such functions, and his appointment shall not exceed one hundred and eighty days, which is subject to renewal for the same period of time. [\(Text taken from Law Num. 9.695, of 1998\)](#)

§ 1^o Upon the decreeing of an intervention the offender will have recourse to a motion for review, without a suspensive effect, addressed to the Minister of Health, who must assess it within a period of thirty days. [\(Text taken from Law Num. 9.695, of 1998\)](#)

§ 2^o If the motion for review is not examined within the period indicated in the foregoing paragraph, the intervention shall cease as a matter of common law through the simple expiration of the period. [\(Text taken from Law Num. 9.695, of 1998\)](#)

§ 2^o-A. At the end of the intervention, the mediator shall submit a rendering of accounts for the period that the intervention lasted. [\(Included by Law Num. 9.695, of 1998\)](#)

Art . 6^o - For the imposition of the punishment and its adjustment, the sanitary authority shall take into account:

- I – the attenuating and aggravating circumstances;
- II – the seriousness of the offense, keeping in mind its consequences for public health;
- III – the past history of the offender with regard to sanitary laws.

Art . 7^o - The following are attenuating circumstances:

- I – the action of the offender was not essential to the achievement of the result;
- II – failure to understand sanitary law, admitted as excusable, when the agent is plainly incapable of recognizing the illicit nature of the act;
- III – the offender, acting spontaneously of his own accord, immediately seeking to repair or mitigate the consequences of whatever act that is harmful to public health has been imputed to him;
- IV – if the offender has been subject to coercion, which he might have resisted, to commit the act;
- V – if it is the offender's first offense, and the violation committed is of a minor nature.

Art . 8^o - The following are aggravating circumstances:

- I – if it is a repeat offender;
- II – if the offender has committed the violation to obtain a financial advantage resulting from consumption by the public of a product prepared in violation of what is set forth in sanitary legislation;
- III – if the offender has coerced others in the material execution of the violation;

IV – if the violation has calamitous consequences for public health;

V – if, having knowledge of an act that is harmful to public health, the offender fails to take measures within his capacity endeavoring to prevent it;

VI – if the offender has acted out of malice, as well as possible fraud or bad faith;

Sole paragraph –Repeat offenses of the same crime render the offender susceptible to the maximum penalty and characterization of the violation as extremely serious.

Art . 9º - If there is a conflict of attenuating and aggravating circumstances the application of the punishment will be determined on the basis of which elements predominate.

Art . 10 – The following are sanitary violations:

I - to build, install or cause to operate, in any part of the national territory, laboratories for the production of medications, drugs, inputs, cosmetics, hygiene products, diet products, correlatives, or any other establishments that manufacture foodstuffs, additives for foodstuffs, beverages, packages, cleaning products and other products relating to public health, without registration, license or permits of the competent sanitary agency, or in violation of the relevant legal standards:

punishment - warning, ban, cancellation of permit and of license, and/or fine.

II - to build, install or cause to operate hospitals, first-aid units or facilities, clinics in general, rest homes, health services or units, establishments or similar organizations, engaged in the promotion, protection and recovery of health, without a license from the competent sanitary agency or in violation of the relevant legal and regulatory standards.

punishment - warning, ban, cancellation of license and/or fine.

~~III – to install medical dental consulting offices, or any paramedical activities, laboratories for analysis and clinical research, blood banks, human milk repositories, eye banks, and establishments for similar activities, institutes for beautification, gymnastics, physiotherapy and rehabilitation, hydromineral, thermal, climacteric health resorts, rest facilities and the like, offices or services using devices and equipment that generate x-rays, radioactive substances or ionizing radiation or other kinds of radiation, optical establishments, laboratories, production units and services, for optical devices and materials, dental prostheses, devices and materials for dental use, or conducting commercial, industrial or philanthropic activities with the participation of agents practicing technical or auxiliary related professions or occupations relating to health, without a license from the competent sanitary agency, or in violation of what is set forth in other relevant legal and regulatory standards:~~

~~— punishment – warning, ban, cancellation of license, and/or fine;~~

III – to install or maintain in operation medical, dental and clinical research consulting offices, hemodialysis clinics, blood banks, human milk repositories, eye banks, and establishments engaged in similar activities, institutes for beautification, gymnastics, physiotherapy and rehabilitation, hydromineral, thermal, climacteric health resorts, rest facilities and the like, offices or services using devices and equipment that generate x-rays, radioactive substances or ionizing radiation or other kinds of radiation, optical establishments, laboratories, production units and services, optical devices and materials, dental prostheses, devices or materials for dental use, or conducting commercial, industrial, philanthropic activities, with the participation of agents practicing technical or auxiliary professions or occupations related to health, without a license

from the competent sanitary agency, or in violation of what is set forth in other relevant legal and regulatory standards: [\(Text taken from Law Num. 9.695 of 1998\)](#)

Punishment - warning, intervention, ban, cancellation of license and/or fine; [\(Text taken from Law Num. 9.695 of 1998\)](#)

IV – to extract, produce, manufacture, transform, prepare, manipulate, purify, fractionate, package or repackage, import, export, store, dispatch, transport, purchase, sell, assign or use foodstuffs, nutritional products, medications, drugs, pharmaceutical inputs, diet products, hygiene products, cosmetics, correlatives, packages, cleaning products, utensils and devices relating to public or individual health, with registration, license or permits by the competent sanitary agency or in violation of what is set forth in the relevant sanitary legislation:

punishment - warning, seizure and rendering unviable, ban, cancellation of registration, and/or fine;

V – to engage in advertising of products subject to sanitary oversight, foodstuffs and other things, in violation of sanitary legislation:

~~punishment – warning, prohibition of advertising, suspension of sale and/or fine;~~

punishment - warning, prohibition of advertising, suspension of sale, requirement of a corrective message, suspension of advertising and publicity and fine. [\(Text taken from Provisional Measure Num. 2.190-34, of 2001\)](#)

VI – failure to report a disease or animal pathology that is transmissible to humans on the part of someone who has a legal opportunity to do so, according to what is determined by the legal or regulatory standards in force:

punishment - warning, and/or fine;

VII – to prevent or hinder the application of sanitary measures concerning contagious disease and the sacrifice of domestic animals considered dangerous by the sanitary authorities:

punishment - warning, and/or fine;

VIII – to withhold an attestation of a required vaccination, to fail to execute, hinder or obstruct the execution of sanitary measures aimed at the prevention of contagious diseases and their dissemination, the preservation and maintenance of health:

punishment - warning, ban, cancellation of license or permit, and/or fine;

IX – to obstruct the requirement for immunological tests or their execution by sanitary authorities:

punishment - warning, and/or fine;

X – to obstruct or hinder the enforcement actions of the competent sanitary authorities in the exercise of their duties:

~~punishment – warning, ban, cancellation of license and permit, and/or fine;~~

Punishment - warning, intervention, ban, cancellation of license and/or fine; ([Text taken from Law Num. 9.695 of 1998](#))

XI – to issue a prescription not in accordance with medical standards or with the explicit ruling of the law and regulatory standards:

punishment - warning, ban, cancellation of license, and/or fine;

XII – to provide, sell or engage in acts of commerce involving medications, drugs and correlatives whose sale and use require a medical prescription without observance of this requirement, and in violation of legal and regulatory standards:

punishment - warning, ban, cancellation of license, and/or fine;

XIII – to draw or make transfusions of blood, engage in operations of plasmapheresis, or engage in other hemotherapeutic activities in violation of legal and regulatory standards:

~~punishment - warning, ban, cancellation of license and registration, and/or fine;~~

Punishment - warning, intervention, ban, cancellation of license and registration and/or fine; ([Text taken from Law Num. 9.695 of 1998](#))

XIV – to export blood and its derivative products, placentas, organs, glands or hormones, as well as any substances or parts of the human body, or to use them in violation of legal and regulatory provisions:

~~punishment - warning, ban, cancellation of license and registration, and/or fine.~~

Punishment - warning, intervention, ban, cancellation of license and registration and/or fine; ([Text taken from Law Num. 9.695 of 1998](#))

XV – to label foodstuffs and nutritional products or beverages as well as medications, drugs, pharmaceutical inputs, diet products, hygiene products, cosmetics, perfumes, correlatives, cleaning products, beautification products or any others in violation of legal and regulatory standards:

punishment - warning, rendering unviable, ban, and/or fine;

XVI – to alter the manufacturing process of products subject to sanitary control, to modify their basic components, name, or other elements subject to registration, without the necessary authorization from the competent sanitary agency:

punishment - warning, ban, cancellation of registration of license and permit, and/or fine;

XVII – to re-use containers of cleaning products and the like as well as other products capable of being harmful to health, in the packaging of foodstuffs, beverages, soft drinks, diet products, medications, drugs, hygiene products, cosmetics and perfumes:

punishment - warning, seizure, rendering unviable, ban, cancellation of registration, and/or fine;

~~XVIII – to put up for sale or convey for consumption products relating to health whose period of validity has expired, or to insert on them new dates after the expiration of the period:~~

XVIII – to import or export, put up for sale or convey for consumption products relating to health whose period of validity has expired, or insert on them new dates after the period has expired; ([Text taken from Provisional Measure Num. 2.190-34, of 2001](#))

punishment - warning, seizure, rendering unviable, ban, cancellation of registration, of license and of permit, and/or fine.

XIX – to engage in industrial production of products of sanitary significance without the participation of a supervising technician who has been legally licensed:

punishment - warning, seizure, rendering unviable, ban, cancellation of registration, and/or fine;

XX – to use in the preparation of hormones, organs of sick, exhausted or emaciated animals, or that exhibit indications of decomposition when they are handled:

punishment - warning, seizure, rendering unviable, ban, cancellation of registration, of permit and of license, and/or fine;

XXI – to sell biological or immunotherapy products or others that require special conservation measures, preparation, shipping or transport, without observance of the conditions necessary for their preservation:

punishment - warning, seizure, rendering unviable, ban, cancellation of registration, and/or fine;

XXII - application, by private companies, of rat poisons whose effects are produced by gas or vapor, in galleries, sewers, basements, attics or places that can communicate with residences or places that are frequented by people and animals:

punishment - warning, ban, cancellation of license and of permit, and/or fine;

XXIII – failure to comply with legal and regulatory standards, measures, formal requirements and other sanitary requirements by transport companies, their agents and factors, commanders or individuals in charge of ships, aircraft, railways, land vehicles, both national and foreign:

punishment - warning, ban, and/or fine;

XXIV – failure to observe sanitary requirements concerning buildings, by their owners or by whomever may legally hold possession thereof:

punishment - warning, ban, and/or fine;

XXV – to engage in professions and occupations related to health without the necessary legal license:

punishment - ban and/or fine;

XXVI –to assign the performance of tasks relating to the promotion, protection and recovery of health to persons without the necessary legal license:

punishment - ban, and/or fine;

XXVII – to undertake the cremation of cadavers, or to make use of them in violation of the relevant sanitary standards:

punishment - warning, ban, and/or fine;

XXVIII – to falsify, adulterate or make fraudulent foodstuffs, including beverages, medications, drugs, pharmaceutical inputs, correlatives, cosmetics, hygiene products, diet products, cleaning products or any other products relating to public health:

~~punishment – warning, seizure, rendering unviable and/or banning of product; suspension of sale and/or manufacture of product, cancellation of product registration, partial or total banning of the establishment, cancellation of company's federal operating permit, cancellation of the establishment's state operating license;~~

punishment - warning, seizure, rendering unviable and/or banning of product, suspension of sale and/or manufacture of product, cancellation of product registration, partial or total banning of the establishment, cancellation of company's federal operating permit, cancellation of the establishment's state operating license and/or fine; ([Text taken from Provisional Measure Num. 2.190-34, of 2001](#))

XXIX – to engage in transgressions against other legal and regulatory standards intended for the protection of health:

~~punishment – warning, seizure, rendering unviable and/or banning of product; suspension of sale and/or manufacture of product, cancellation of product registration; partial or total banning of the establishment, cancellation of company's federal operating permit, cancellation of the establishment's state operating license, prohibition of advertising;~~

punishment - warning, seizure, rendering unviable and/or banning of product; suspension of sale and/or manufacture of product, cancellation of product registration; partial or total banning of the establishment, cancellation of company's federal operating permit, cancellation of the establishment's state operating license, prohibition of advertising and/or fine; ([Text taken from Provisional Measure Num. 2.190-34, of 2001](#))

~~XXX – to put up or convey for human consumption salt, whether refined or milled, that does not contained iodine in the proportion of ten milligrams of metalloid iodine per kilogram of product:~~

XXX – to put or convey for human consumption, refined, milled or granulated salt that does not contain iodine in the proportion established by the Ministry of Health. ([Text taken from Law Num. 9.005, of 1995](#))

~~punishment – warning, seizure and/or banning of product, suspension of sale and/or manufacture of product, cancellation of product registration, partial or total banning of the establishment, cancellation of company's federal operating permit, cancellation of the establishment's state operating license;~~

punishment - warning, seizure and/or banning of product, suspension of sale and/or manufacture of product, cancellation of product registration and partial or total banning of the

establishment, cancellation of company's federal operating permit, cancellation of the establishment's state operating license and/or fine; ([Text taken from Provisional Measure Num. 2.190-34, of 2001](#))

XXXI – failure to comply with rulings issued by the competent sanitary authorities concerning the application of the relevant legislation:

~~punishment - warning, seizure, rendering unviable and/or banning of product, suspension of sale and/or manufacture of product, cancellation of product registration, partial or total banning of the establishment; cancellation of the company's state operating license, prohibition of advertising.~~

punishment - warning, seizure, rendering unviable and/or banning of product, suspension of sale and/or manufacture of product, cancellation of product registration; partial or total banning of the establishment; cancellation of company's federal operating permit, cancellation of the establishment's state operating license, prohibition of advertising and/or fine; ([Text taken from Provisional Measure Num. 2.190-34, of 2001](#))

Sole paragraph - Establishments that are members of the Government or are established by it are not required to have an operating license, although they are subject to the requirements concerning the appropriate facilities, equipment and devices, and technical responsibility and service.

XXXII – failure to comply with legal and regulatory standards, measures, formal requirements, or other sanitary requirements, by natural or juridical persons, who provide services relating to public health on ships, aircraft, land vehicles, customs terminals, airport or port terminals, border stations and crossings and facilities for servicing land vehicles: ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

punishment - warning, ban, cancellation of federal operating permit and/or fine; ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

XXXIII - failure to comply with legal and regulatory standards, measures, formal requirements, or other sanitary requirements, by companies administering customs terminals, airport or port terminals, border stations and crossing and facilities for servicing land vehicles: ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

punishment - warning, ban, cancellation of federal operating permit and/or fine; ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

XXXIV - failure to comply with legal and regulatory standards, measures, formal requirements, or other sanitary requirements relating to the import or export, by natural or juridical persons, of raw materials or products subject to sanitary oversight: ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

punishment - warning, seizure, rendering unviable, ban, cancellation of federal operating permit, cancellation of product registration and/or fine; ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

XXXV - failure to comply with legal and regulatory standards, measures, formal requirements, or other sanitary requirements concerning establishments and good manufacturing practices of raw materials and products subject to sanitary oversight: ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

punishment - warning, seizure, rendering unviable, ban, cancellation of federal operating permit, cancellation of product registration and/or fine; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XXXVI – undertaking to change the warehouse establishment for an imported product subject to a ban, without authorization from the competent sanitary agency: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

punishment - warning, seizure, rendering unviable, ban, cancellation of federal operating permit, cancellation of product registration and/or fine; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XXXVII – undertaking to sell an imported product subject to a ban: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

punishment - warning, seizure, rendering unviable, ban, cancellation of federal operating permit, cancellation of product registration and/or fine; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XXXVIII – failure to ensure in establishments intended for the storage and/or distribution of products subject to sanitary oversight, maintenance of the standards of sameness and quality of imported products subject to a ban or awaiting physical inspection: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

punishment - warning, seizure, rendering unviable, ban, cancellation of federal operating permit, cancellation of product registration and/or fine; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XXXIX – interrupting, suspending or reducing without just cause the production or distribution of red label low-risk prescription medications that are for continuous use or essential to the health of an individual, or of black label high-risk prescription medications, bringing about a market shortage: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

punishment - warning, total or partial banning of the establishment, cancellation of product registration, cancellation of company's federal operating permit, cancellation of the establishment's state operating license and/or fine; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XL – failure to communicate to the agency of sanitary oversight of the Ministry of Health the interruption, suspension or reduction of the manufacture or distribution of the medications referred to in sub-paragraph XXXIX: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

punishment - warning, total or partial banning of the establishment, cancellation of product registration, cancellation of company's federal operating permit, cancellation of the establishment's state operating license and/or fine; [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

XLI - failure to comply with legal and regulatory standards, measures, formal requirements, or other sanitary requirements, by natural or juridical persons, who provide services relating to public health on ships, aircraft, land vehicles, customs terminals, airport or port terminals, border stations and crossings and facilities for servicing land vehicles: [\(Included by Provisional Measure Num. 2.190-34, of 2001\)](#)

punishment - warning, total or partial banning of the establishment, cancellation of product registration, cancellation of company's federal operating permit, cancellation of the establishment's state operating license and/or fine. ([Included by Provisional Measure Num. 2.190-34, of 2001](#))

Art . 11 – Failure to observe or disobedience of sanitary standards for the entry and placement of foreigners in the Country shall entail prevention of the alien's departure or his being kept within the national territory by the competent sanitary authority.

TITLE II

PROCEEDINGS

Art . 12 – Sanitary violations will be investigated in their own administrative proceeding, initiated with the drawing up of a citation, in keeping with the practices and schedules established in this Law.

Art . 13 – The citation shall be drawn up at the main office of the competent department or at the place where the violation was detected by the sanitary authority who ascertained such violation, and it should contain:

I – the name of the offender, his address and residence, as well as other necessary elements necessary for his classification and civil identification;

II – the place, date and time of the drawing up of the citation where the violation was detected;

III – a description of the violation and mention of the legal or regulatory provision that has been violated;

IV – the penalty to which the offender is subject and the respective legal precept that authorizes its imposition;

V – recognition on the part of the party receiving the citation that he will answer for the offense in an administrative proceeding;

VI – signature of the party receiving the citation or, in its absence or refusal, the signature of two witnesses and the person issuing the citation;

VII – the deadline for the filing of an appeal, when applicable.

Sole paragraph – If the offender refuses to sign the citation, mention is to be made therein of such refusal.

Art . 14 – The penalties set forth in this Law shall be applied by the competent sanitary authorities of the Ministry of Health, the States, the Federal District and the Territories, in accordance with such authority as shall have been conferred upon them by the respective legislation or by delegation of competency on the basis of agreements.

Art . 15 – The official who decides that a citation is to be issued shall order the party issuing the citation, via a written order, to undertake prior verification of the substance of the offense.

Art . 16 – Officials are responsible for the statements they make in the citations, and are liable for punishment in the event of grave error, in cases of falsity or willful omission.

Art . 17 – The offender shall be made aware of the citation in one of the following manners:

I – in person;

II – by mail or courier;

III – by published notice, if his whereabouts are uncertain or unknown.

§ 1º - If the offender is served with notification in person and refuses to acknowledge receipt, this circumstance must be expressly mentioned by the official who served the notification.

§ 2º - The published notice mentioned in sub-paragraph III of this article shall be published only once, in the official bulletin, and notification will be considered to have been given five days after publication.

Art . 18 – When, notwithstanding the issuance of the citation, the offender continues to have obligations to fulfill, a published notice will be issued setting a deadline of thirty days for compliance, pursuant to what is set forth in § 2º of Art. 17.

Sole paragraph – The deadline for fulfillment of the outstanding obligation can be reduced or increased in exceptional cases for reasons of the public interest, through an order explaining the grounds for such adjustment.

Art . 19 – Disobedience of the ruling contained in the published notice noted in Art. 18 of this Law, shall entail, in addition to enforced compliance, the imposition of a daily fine, determined on the basis of the amounts corresponding to the classification of the offense, until the obligation has been completely fulfilled, without impairment to other penalties set forth in the legislation in force.

Art . 20 – Disrespect or contempt for a duly authorized official, as well as any preventive action against any attempt at enforcement of law or regulatory rulings concerning health, shall subject the offender to the penalty of a fine.

Art . 21 – Fines imposed by a citation may be subject to a twenty per cent reduction if the offender makes payment within a period of twenty days, counting from the date on which he was notified, which implies a tacit waiver of defense or appeal.

Art . 22 – The offender may offer a defense or challenge the citation within a period of fifteen days counting from his notification.

§ 1º - Prior to a hearing on the defense or challenge referred to in this article, the presiding authority must first hear the official who issued the citation, who will have ten days to present his position in this regard.

§ 2º - Whether or not a defense or challenge is presented, the citation will be adjudicated by the director of the competent agency of sanitary oversight.

Art . 23 – The investigation of illegality when dealing with the products or substances referred to in Art. 10, sub-paragraph IV, is to be carried out through the seizure of samples for the performance of a forensic analysis, and a ban, if applicable.

§ 1º - The seizure of samples for purposes of analysis, whether as a spot check or for forensic analysis, shall not be accompanied by the banning of the product.

§ 2º - Exceptions to what is set forth in the foregoing paragraph are to be made in cases in which indications of product alteration or adulteration are discovered, in which case the ban shall have a preventive character or that of an injunction.

§ 3º - The banning of a product shall be mandatory when laboratory analyses or process examinations prove fraudulent actions have taken place involving falsification or adulteration.

§ 4º - The banning of a product and the establishment of an injunction to institute such ban, shall last as long as necessary for the conduct of tests, exams, analysis or other measures that may be required, which cannot under any circumstances exceed a period of ninety days, at the end of which time the product or establishment shall be automatically liberated.

Art . 24 – In the event of the banning of a product, as provided for in § 2º of Art. 23, the sanitary authority shall issue the respective order, whose first copy shall be delivered together with the citation, to the offender or his legal representative, observing the same requirements as apply to delivery of the citation with regard to the acknowledgment of the recipient.

Art . 25 – If the intervention is executed on the basis of a laboratory report, the competent sanitary authority shall make due note of the respective procedural order and shall draw up the order for a ban, up to and including a ban of the establishment, if so indicated.

Art . 26 – The order for seizure and banning shall specify the nature, quantity, name and/or brand, type, origin, name and address of the company and of the holder of the product.

Art . 27 – The seizure of the product or substance shall involve the taking of a representative sample from the existing stock, which, divided into three parts, shall remain untouchable, in order to ensure the characteristics of its state of conservation and authenticity, and one part shall be delivered to the holder or responsible party, to serve as a counterproof, and the two remaining portions are to be sent immediately to the official laboratory for the performance of the essential analyses.

§ 1º - If the available quantity or character of the item in question does not allow for the taking of samples, the product or substances are to be sent to the official laboratory, for performance of a forensic analysis, in the presence of its holder or of the legal representative of the company and the expert appointed by the company.

§ 2º - In the event of the situation foreseen in § 1º of this article, if the people mentioned therein are not present, two witnesses will be summoned to be present at the analysis.

§ 3º - An exhaustive and comprehensive report of the analysis for enforcement purposes will be drawn up, which will be kept on file at the official laboratory, with copies extracted, one for the proceeding, and the others to be delivered to the holder or person responsible for the product or substance and one to the manufacturing company.

§ 4º - If the offender is in disagreement with a finding against him based on the analysis, he may separately or together with the motion for review of the decision that is being appealed, request expert evaluation of the counterpart, submitting the sample held by him, and appointing his own expert.

§ 5º - A detailed document will be drawn up from the expert evaluation of the counterpart, dated and signed by all participants, whose first copy shall form part of the record of the proceedings, and shall contain all of the issues raised by the experts.

§ 6º - The expert evaluation of the counterpart sample shall not be performed if there are indications of a violation of the sample in the possession of the offender and in such a case, the lab report supporting the guilty verdict shall prevail as the definitive opinion.

§ 7º - The same method used in the forensic analysis supporting a guilty verdict is to be applied in the expert evaluation of the counterpart, unless there should be agreement among the experts concerning the adoption of a different method.

§ 8º - A discrepancy between the results of the forensic analysis supporting a guilty verdict and the expert evaluation of the counterpart sample shall entail referral to a higher authority within a period of ten days, which shall perform a new expert evaluation, to be carried out on the second sample in the possession of the official laboratory.

Art . 28 – If the violation which is being investigated is not proven after the forensic analysis, or the expert evaluation of the counterpart, and the product is considered suitable for consumption, the competent authority shall issue an order releasing the product and calling for the conclusion of the proceeding.

Art . 29 – For offenses which do not require analyses or expert evaluations, including those for contempt of the sanitary authority, the proceeding shall be conducted with utmost dispatch, and will be considered concluded if the offender does not file an appeal within the period of fifteen days.

Art . 30 – The offender shall be able to appeal verdicts of guilty within a period of time equal to that allowed for the defense, even when the matter at issue is a fine.

Sole paragraph – If the guilty verdict is upheld, it will be possible to submit an appeal to a higher authority within the governmental sphere under whose jurisdiction the proceeding has been instigated, within a period of twenty days of its disclosure or publication.

Art . 31 – In the event of a definitive conviction concerning the product based on a laboratory report confirmed by the expert evaluation of the counterpart, or in cases of fraud, falsification or adulteration, there will be no possibility of filing an appeal.

Art . 32 – Appeals filed against decisions that are not definitive shall only have a suspensive effect with regard to payment of the monetary fine, and will not deter the mandatory requirement of immediate fulfillment of any outstanding obligation pursuant to what is set forth in Art. 18.

Sole paragraph – The appeal provided for in § 8º of Art. 27 shall be ruled upon within a period of ten days.

Art . 33 – When the punishment of a fine is applied, the offender shall be instructed to make payment within a period of thirty days, counting from the date of the notification, payable to the National Fund for Health, or the treasury departments of the States, the Federal District or the dos Territories, depending on the administrative jurisdiction in which the proceeding takes place.

§ 1º - If the offender cannot be located, notification is to be given via registered mail, or through a published notice appearing in the official bulletin, if the offender is not found.

§ 2º - If the fine is not paid within the period fixed in this article, this shall entail its being registered for legal collection action, pursuant to the relevant legislation.

Art . 34 - With the lapse of the period mentioned in the sole paragraph of Art. 30, if the guilty verdict is not appealed, or an expert evaluation of the counterpart sample is not requested, the lab report supporting the verdict is to be considered definitive and the proceeding, as long as it has not been instigated by the federal agency of sanitary oversight, is to be forwarded to enact the cancellation of registration and an order for the seizure and rendering unviable of the product throughout the national territory, independently of other applicable penalties, if such there be.

Art . 35 - Rendering products unviable and the cancellation of registration, of the company's federal operating permit and the establishment's state operating license shall only occur after the publication, in the official bulletin, of a decision that is not subject to appeal.

Art . 36 – In the event of a definitive adverse ruling for a product whose alteration, adulteration or falsification does not entail making it unsuitable for use or consumption, the sanitary authority can, in issuing its decision, order that it be distributed to welfare establishments, preferably government-run, when such use proves viable for health programs.

Art . 37 – When the conduct of the proceeding has been completed, once the deadlines for appeal have lapsed without the presentation of a defense, or the examination of appeals, the sanitary authority shall issue a final ruling considering the proceeding concluded after the publication of such ruling in the official bulletin and the adoption of the measures imposed.

Art . 38 – Violations of legal and regulatory provisions of a sanitary nature have a statute of limitations of five years.

§ 1º - The period for the statute of limitations is interrupted by notification or another enactment of the competent authority, that calls for the investigation of the issue and the consequent imposition of a penalty.

§ 2º - The period for the statute of limitations does not being to elapse as long as there is an administrative proceeding in progress for which a decision is pending.

Art . 39 – This Law shall take effect on the date of its publication.

Art . 40 - [Decree-law Num. 785, of August 25, 1969](#), and other provisions at variance with this are hereby rescinded.

Brasília, August 20, 1977; 156th year of Independence and 89th year of the Republic.

ERNESTO GEISEL
Paulo de Almeida Machado

This text does not replace what is published in the D.O.U. of August 24, 1977