

LAW No. 6,437, OF AUGUST 20TH, 1977.

Sets forth the violations to federal sanitary legislation, establishes their respective penalties, and makes other provisions.

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

TITLE I

VIOLATIONS AND PENALTIES

Article 1. Violations to federal sanitary legislation are hereby laid down, unless expressly established in special regulations.

Article 2. Notwithstanding the applicable penalties of civil and criminal nature, health violations shall be punished, alternately or cumulatively, as follows:

I - warning;

II - fine;

III - arrest of products;

IV - destruction of products;

V - interdiction of products;

VI - suspension of sales and/or of product manufacture;

VII - cancellation of product registration;

VIII - partial or total interdiction of establishments;

IX - prohibition of advertising; ([Phrasing established by Law no. 9,695, 1998](#))

X - cancellation of the company's operating permit; ([Phrasing established by Law no. 9,695, 1998](#))

XI - cancellation of the establishment's operating license; ([Phrasing established by Law no. 9,695, 1998](#))

XI-A - intervention in the establishment that receives public resources from any government sphere. ([Included by Law no. 9,695, 1998](#))

XII - imposition of corrected messages; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XIII - suspension of advertising and publicity. ([Included by Provisional Measure no. 2,190-34, 2001](#))

Paragraph 1. The penalty of fine shall consist in payment of the following values: ([Included by Provisional Measure no. 2,190-34, 2001](#))

I - for minor violations, from R\$ 2.000,00 to R\$ 75.000,00; [\(Included by provisional Measure no. 2,190-34, 2001\)](#)

II - for serious violations, from R\$ 75.000,00 to R\$ 200.000,00; [\(Included by provisional Measure no. 2,190-34, 2001\)](#)

III - for major violations, from R\$ 200.000,00 to R\$ 1.500.000,00. [\(Included by provisional Measure no. 2,190-34, 2001\)](#)

Paragraph 2. The fines herein addressed shall be applied in double amount in the case of recidivism. [\(Included by provisional Measure no. 2,190-34, 2001\)](#)

Paragraph 3. Notwithstanding the provisions of Articles 4 and 6 hereof, the competent health surveillance authority shall take into consideration the economic status of the offender when imposing fines. [\(Included by provisional Measure no. 2,190-34, 2001\)](#)

Article 3. The result of health violations is hereby imputable to whoever has given it cause or has concurred thereto.

Paragraph 1. Cause is hereby deemed as an action or omission without which the violation would not have been committed.

Paragraph 2. Causes that derives from force majeure or natural events or unforeseeable circumstances that may determine damages, deterioration or change in products or assets of public health's interest hereby preclude the imputation of violation.

Article 4. Health violations are hereby classified as follows:

I - minor, in which the offender may benefit from mitigating circumstances;

II - serious, in which an aggravating circumstance has been verified;

III - major, in which two or more aggravating circumstances have been verified.

Article 5. The intervention in establishments addressed in Subsection XI-A of Article 2 hereof shall not exceed 180 days, renewable for equal and successive periods, and shall be ordered by the Ministry of Health, which shall assign an intervenor, who shall be vested with management powers, being business partners, managers or directors that contractually or legally detain such powers discontinued. [\(Phrasing established by Law 9,695, 1998\)](#)

Paragraph 1. Intervention orders may be requested to be reviewed to the Ministry of Health, which shall review them within thirty days without any suspensory effect. [\(Phrasing established by Law no. 9,695, 1998\)](#)

Paragraph 2. Having the revision request not been reviewed within the aforementioned period of time, the intervention shall cease by operation of law due to the lapse of time. [\(Phrasing established by Law no. 9,695, 1998\)](#)

Paragraph 2-A. At the end of interventions, intervenors shall render accounts of the period of intervention. [\(Included by Law no. 9,695, 1998\)](#)

Article 6. When imposing penalties and assessing their severity, health surveillance authorities shall take the following into account:

I - mitigating and aggravating circumstances;

II - the severity of violations in view of their consequences to public health;

III - criminal record of the offender with regard to sanitary regulations.

Article 7. The following are mitigating circumstances:

I - the offender's act is not deemed essential to the course of events;

II - the sanitary legislation has been misunderstood, which is deemed excusable due to the offender's incapacity to admit the unlawfulness of the act;

III - the offender has spontaneously and immediately intended to repair or mitigate the consequences of his/her harmful act to public health;

IV - the offender has suffered possibly resistible coercion in order to commit the offense;

V - if primary offender and minor violation.

Article 8. The following are aggravating circumstances:

I - the offender is recidivist;

II - the offender has committed the offense to obtain pecuniary advantage from the consumption by the public of the product designed without complying with the sanitary legislation;

III - the offender has coerced another to the material execution of the act;

IV - the violation has had catastrophic consequences to public health;

V - after acknowledging the harmful act to public health, the offender has refrained him/herself from taking the appropriate actions to avoid it;

VI - the offender has acted with malice, even if eventual fraud or bad faith.

Sole Paragraph. The specific recidivism shall enable the imposition of the maximum penalty and the characterization of the violation as major.

Article 9. Should there be both aggravating and mitigating circumstances, penalty shall be imposed pursuant to whichever circumstances are predominant.

Article 10. The following are health violations:

I - to build, install, or open, in any part of the national territory, laboratories that manufacture medications, drugs, supplies, cosmetics, hygiene products, dietary products, medical devices, or any other establishment that manufactures food, additives to food, beverages, packaging, sanitizing products, and any other product that is of interest to public health, without any registration, license, and permit granted by the competent health surveillance body or without complying with the pertinent legal provisions.

penalty - warning, interdiction, cancellation of permits and licenses, and/or fine.

II - to build, install, or open hospitals or healthcare centers, medical offices in general, nursing homes, healthcare units, similar establishments or facilities that are intended for health promotion, protection and recovery, without any license granted by the competent health surveillance body or without complying with the pertinent legal and regulatory provisions:

penalty - warning, interdiction, cancellation of licenses, and/or fine.

III - to install or maintain open medical or dental offices, clinical research centers, hemodialysis clinics, blood banks, human milk banks, eye banks and establishments intended for similar activities, institutions of aesthetics, gymnastics, physiotherapy and of recovery, seaside resorts, hydromineral, thermal and climate resorts, nursing homes or others similar, centers that use devices and equipment that emit x-ray, radioactive substances, ionizing radiation and others, establishments, laboratories, offices or services of optics, of optical equipment or material, dental prostheses, equipment or materials for dental use, or that conduct commercial, industrial or philanthropic activities along with individuals that practice technical and healthcare professions or activities, without any license granted by the competent health surveillance body or without complying with the pertinent legal and regulatory provisions: ([Phrasing established by Law no. 9,695, 1998](#))

Penalty - warning, intervention of establishment, interdiction, cancellation of licenses and/or fine; ([Phrasing established by Law no 9.695, 1998](#))

IV - to extract, manufacture, transform, prepare, manipulate, purify, fractionate, package or repack, import, export, store, ship, transport, purchase, sell, provide, or use food, food products, medications, drugs, pharmaceutical supplies, dietary products, hygiene products, cosmetics, medical devices, packaging, sanitizing products, instruments or equipment that may be of interest to public or individual health, without any registration, license, or permit granted by the competent health surveillance body or without complying with the pertinent provisions of the sanitary legislation:

penalty - warning, arrest and destruction of products, interdiction, cancellation of product registration, and/or fine;

V - to advertise products subject to health surveillance, food, and others, without complying with the sanitary legislation:

penalty - warning, prohibition of advertising, suspension of sales, imposition of corrected messages, suspension of advertising and publicity, and fine. ([Phrasing established by Provisional Measure no. 2,190-34, 2001](#))

VI - to failure to notify diseases or zoonoses transmissible to humans, in accordance with the legal or regulatory provisions in force, when legally responsible for doing such:

penalty - warning and/or fine;

VII - to prevent or hinder the implementation of health surveillance measures with regard to transmissible diseases and to the sacrifice of domestic animals considered dangerous by health surveillance authorities:

penalty - warning and/or fine;

VIII - to hold back mandatory vaccine certificates, hinder, neglect, or oppose to the implementation of health surveillance measures that seek to prevent dissemination and transmission of diseases, and that intend to preserve and maintain health:

penalty - warning, interdiction, cancellation of licenses or permits, and/or fine;

IX - to oppose to the requirement for immunological proves or to its imposition by health surveillance authorities:

penalty - warning and/or fine;

X - to hinder or oppose to inspections performed by competent health surveillance authorities in the exercise of their powers:

Penalty - warning, intervention, interdiction, cancellation of licenses and/or fine; ([Phrasing established by Law no 9,695, 1998](#))

XI - to fill out prescriptions without complying with expressive determination of laws and regulatory norms or medical regulations:

penalty - warning, interdiction, cancellation of licenses, and/or fine;

XII - to provide, sell, or perform commercial activities regarding medications, drugs and medical devices whose sales and use depend on medical prescription, without meeting this requirement and without complying with legal and regulatory provisions:

penalty - warning, interdiction, cancellation of licenses, and/or fine;

XIII - to take or apply blood, perform surgeries of plasmapheresis, or develop other hemotherapeutic activities without complying with legal and regulatory provisions:

Penalty - warning, intervention, interdiction, cancellation of licenses and of product registration and/or fine; ([Phrasing established by Law no 9,695, 1998](#))

XIV - to export or use blood and its derivatives, placentas, organs, glands or hormones, as well as any substance or part of the human body, without complying with legal and regulatory provisions:

Penalty - warning, intervention, interdiction, cancellation of licenses and of product registration and/or fine; ([Phrasing established by Law no 9,695, 1998](#))

XV - to label food, food products, beverages, medications, drugs, pharmaceutical supplies, dietary products, hygiene products, cosmetics, perfumes, medical devices, sanitizing products, products for aesthetic correction, and any other product, without complying with legal and regulatory provisions:

penalty - warning, destruction of products, interdiction, and/or fine;

XVI - to change the manufacturing process of products subject to health surveillance control or to modify their basic components, name, and other elements object of their registration without the required authorization from the competent health surveillance body:

penalty - warning, interdiction, cancellation of licenses and permits, and/or fine;

XVII - to reuse packaging of sanitizing products, or others similar, and of products hazardous to health for the packaging of food, beverages, soft drinks, dietary products, medications, drugs, hygiene products, cosmetics, and perfumes:

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of product registration, and/or fine;

XVIII - to import, export, exhibit for sale or deliver for consumption products of interest to health that have past their expiration date, or to assign to them new dates after they have expired: ([Phrasing established by provisional Measure no. 2,190-34, 2001](#))

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of product registration and of operating licenses and permits, and/or fine;

XIX - to industrialize products of health surveillance interest without the assistance of a legally licensed technical manager:

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of product registration, and/or fine;

XX - to use, when preparing hormones, organs of sick, exhausted or skinny animals, or of animals that present signs of decompositions when manipulated:

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of product registration and of operating licenses and permits, and/or fine;

XXI - to commercialize biological, immunotherapeutic products and others that require special care as to their conservation, preparation, shipment or transportation, without observing the proper conditions required for their preservation:

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of product registration, and/or fine;

XXII - to have private companies apply raticides, whose action is manifested by gas or vapor, in galleries, manholes, basements, or locations with possible connections with residences or visited by people and animals:

penalty - warning, interdiction, cancellation of licenses or permits, and/or fine;

XXIII - to failure to comply with legal and regulatory provisions, measures, formalities, and other health surveillance requirements, if transportation companies, their agents and consignees, commanders or individuals directly responsible for ships, aircraft, railways, land vehicles, whether domestic or foreign:

penalty - warning, interdiction, and/or fine;

XXIV - to failure to observe the health surveillance requirements related to real estate, if owner or person who legally own the property:

penalty - warning, interdiction, and/or fine;

XXV - to practice healthcare professions or activities without the required legal license:

penalty - interdiction and/or fine;

XXVI - to perform activities related to the promotion, protection, and recovery of people's health without the required legal license:

penalty - interdiction and/or fine;

XXVII - to cremate or use cadavers without complying with the pertinent sanitary legislation:

penalty - warning, interdiction, and/or fine;

XXVIII - to defraud, forge, or adulterate food, beverages, medications, drugs, pharmaceutical supplies, medical devices, cosmetics, hygiene products, dietary products, sanitizing products, and any other product that may be of public health's interest:

penalty - warning, arrest, destruction and/or interdiction of products, suspension of sales and/or of product manufacture, cancellation of product registration, partial or total interdiction of establishment, cancellation of the company's operating permit and license, and/or fine; ([Phrasing established by Provisional Measure no. 2,190-34, 2001](#))

XXIX - to violate any other legal and regulatory provision intended for health protection:

penalty - warning, arrest, destruction and/or interdiction of products, suspension of sales and/or of product manufacture, cancellation of product registration, partial or total interdiction of establishment, cancellation of the company's operating permit and license, and/or fine; ([Phrasing established by Provisional Measure no. 2,190-34, 2001](#))

XXX - to exhibit or deliver for human consumption refined, milled, or granulated salt without the proper proportion of iodine established by the Ministry of Health: ([Phrasing established by Law no. 9,005, 1995](#))

penalty - warning, arrest and/or interdiction of products, suspension of sales and/or of product manufacture, cancellation of product registration, partial or total interdiction of establishment, cancellation of the company's operating permit and license, and/or fine; ([Phrasing established by Provisional Measure no. 2,190-34, 2001](#))

XXXI - to failure to comply with acts issued by competent health surveillance authorities that seek to enforce the pertinent legislation:

penalty - warning, arrest, destruction and/or interdiction of products, suspension of sales and/or of product manufacture, cancellation of product registration, partial or total interdiction of establishment, cancellation of the company's operating permit and license, prohibition of advertising, and/or fine; ([Phrasing established by Provisional Measure no. 2,190-34, 2001](#))

Sole Paragraph. Establishments part of the Public Administration or created thereby shall not depend on operating permits and licenses, being, nonetheless, subject to the requirements hereof as to adequate facilities, equipment, instruments, as well as to technical assistance and responsibilities.

XXXII - to failure to comply with legal and regulatory provisions, measures, formalities, and other health surveillance requirements, regardless of being physical person or legal entity that provides services of public health's interest in ships, aircraft, land vehicles, customs offices, airports, harbors, bus stations, frontiers, and support services centers for land vehicles: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, interdiction, cancellation of the company's operating permit and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXIII - to failure to comply with legal and regulatory provisions, measures, formalities, and other health surveillance requirements, if companies administrating customs offices, airports, harbors, bus stations, frontiers and support services centers for land vehicles: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, interdiction, cancellation of the company's operating permit and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXIV - to failure to comply with legal and regulatory provisions, measures, formalities, and other health surveillance requirements related to import or export of raw materials or products subject to health surveillance, regardless of being physical person or legal entity: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of the company's operating permit, cancellation of product registration, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXV - to failure to comply with legal and regulatory provisions, measures, formalities, and other health surveillance requirements related to establishments and to good manufacturing practices of raw materials and products subject to health surveillance: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of the company's operating permit, cancellation of product registration, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXVI - to change the establishment of storage of interdicted imported products without previous authorization of the competent health surveillance body: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of the company's operating permit, cancellation of product registration, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXVII - to commercialize interdicted imported products: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of the company's operating permit, cancellation of product registration, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXVIII - to failure to ensure maintenance of quality and identity patterns of interdicted imported products or of products waiting for visual inspection in establishments intended for storage and/or distribution of products subject to health surveillance: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, arrest of products, destruction of products, interdiction, cancellation of the company's operating permit, cancellation of product registration, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XXXIX - to discontinue, suspend or reduce, without just cause, the manufacture or distribution of boxed warning drugs of continuous and essential use to users' health, causing market shortage: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, total or partial interdiction of establishment, cancellation of product registration, cancellation of the company's operating permit and license, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XL - to failure to communicate the Ministry of Health's health surveillance bodies about the discontinuance, suspension or reduction of manufacture or distribution of the drugs addressed in Subsection XXXIX hereof: ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, total or partial interdiction of establishment, cancellation of product registration, cancellation of the company's operating permit and license, and/or fine; ([Included by Provisional Measure no. 2,190-34, 2001](#))

XLI - to failure to comply with legal and regulatory provisions, measures, formalities, and other health surveillance requirements, regardless of being physical person or legal entity that provides services of interest to public health in ships, aircraft, land vehicles, customs offices, airports, harbors, bus stations, frontiers, and support services center for land vehicles ([Included by Provisional Measure no. 2,190-34, 2001](#))

penalty - warning, total or partial interdiction of establishment, cancellation of product registration, cancellation of the company's operating permit and license, and/or fine. ([Included by Provisional Measure no. 2,190-34, 2001](#))

Article 11. Failure to observe or to comply with the sanitary legislation upon entrance and permanence of foreigners in the country shall hinder their disembarkation or permanence in national territory by the competent health surveillance authority.

TITLE II

PROCEEDINGS

Article 12. Sanitary violations shall be investigated through their own administrative proceedings, initiated upon the drawing up of the violation notice and conducted pursuant to the procedure and time frames herein established.

Article 13. Violation notices shall be drawn up by the health surveillance authority at the headquarters of the competent authority or at the location where the offense has been committed, and shall contain the following items:

I - name of the offender, his/her home and residence, as well as other elements required for his/her qualification and civil identification;

II - location, date and time of the drawing up of the document that attests the violation;

III - description of the offense and reference to the violated legal or regulatory provision;

IV - penalty to which the offender is subject and the respective legal provision that authorizes the imposition thereof;

V - offender's acknowledgement that he/she shall respond to the fact in administrative proceedings;

VI - signature of the offender or, in the case of absence or refusal, signature of two witnesses and of the reporting officer;

VII - time frame to appeal, if applicable.

Sole Paragraph. Should the offender have refused to sign the violation notice, this fact shall be referred therein.

Article 14. The penalties herein addressed shall be applied by the competent health surveillance authorities of the Ministry of Health, States, Federal District and Territories, pursuant to their respective duties established in the legislation or delegated thereto by agreements.

Article 15. The authority that determines the drawing up of the violation notice shall order, within the proceeding records, that the reporting officer proceeds with previous verification of factual matters.

Article 16. Public civil servants are liable for the statements in violation notices, being hereby subject to penalties for serious violations in cases of falsehood or omission with malice aforethought.

Article 17. Offenders shall be notified for the purpose of acknowledgment of violation notices as follows:

I - in person;

II - by mail;

III - by public notice, if in unknown or uncertain location.

Paragraph 1. Should the offender be notified in person and refuse to provide acknowledgment, this circumstance shall be clearly mentioned by the authority that made the notification.

Paragraph 2. The public notice addressed in Subsection III of this Article shall be published solely once on the official press, being this notification considered effective five days after the publication thereof.

Article 18. Despite the drawing up of the violation notice and should there be subsisting obligations to be complied, a public notice shall be published establishing a period of 30 days for the compliance thereof, according to the provision of Paragraph 2, Article 17.

Sole Paragraph. The period for complying with subsisting obligations may be shortened or extended in exceptional cases by well-grounded procedural orders in view of public interest.

Article 19. Failure to comply with obligations in the public notice addressed in Article 18 hereof shall result in forced compliance and in the imposition of daily fine, appraised according to the values corresponding to the violation classification, until the obligation thereof has been met, notwithstanding other penalties established in the legislation in force.

Article 20. Disrespect or contempt for the competent civil servant as to their legal obligations, as well as any hindrance against the supervision of compliance with laws and regulatory acts on health matters, shall subject the offender to the penalty of fine.

Article 21. Fines imposed in violation notices may have 20% discount if the offender makes the payment within 20 days, counted from the date of notification, implying tacit waiver of the right to defense or appeal.

Article 22. Offenders may file defense or rebuttal to violation notices within 15 days, counted from the date of notification.

Paragraph 1. Before judging the defense or rebuttal herein addressed, the judging authority shall hear the reporting officer, who shall have ten days to make a statement.

Paragraph 2. Regardless of the submission of defense or rebuttal, violation notices shall be judged by the head of the competent health surveillance body.

Article 23. In the case of a product or substance addressed in Article 10, Subsection IV, the investigation of the unlawful act shall be conducted by the arrest of samples for interdiction and fiscal analysis, if appropriate.

Paragraph 1. Arrest of samples for analysis, whether for fiscal or control purposes, shall not be imposed along with interdiction of products.

Paragraph 2. Traces of alteration or adulteration in the product caught in the act are hereby precluded from the provisions of the previous paragraph, in which cases interdiction shall be imposed as a preventive measure or a preliminary injunction.

Paragraph 3. Interdiction of products shall be mandatory when fraudulent actions that imply forgery or adulteration are evidenced in laboratory analysis or in examination of processes.

Paragraph 4. Interdiction of products and establishments, as a preventive measure, shall last for the amount of time necessary for the performance of tests, assessments, analyses or any other required measure, being hereby prohibited, regardless of the situation, to exceed 90 days, whereafter the product or establishment shall be automatically released.

Article 24. In the case of product interdiction addressed in Paragraph 2 of Article 23 hereof, the health surveillance authority shall draw up the respective order, whose first copy shall be given to the offender or to his/her legal representative, along with the violation notice, complying with the same requirements as to acknowledgement.

Article 25. Should interdiction be imposed as a result of the laboratory report, the competent health surveillance authority shall enclose the respective order to the proceeding records and shall draw up the interdiction notice, including, if appropriate, that of the establishment.

Article 26. Interdiction and arrest orders shall specify the nature, quantity, name and/or brand, type, origin and holder of the product, as well as the company's name and address.

Article 27. Arrest of products or substances shall consist in the collection of representative samples of the existing stock, which shall become inviolable to ensure authenticity and preservation characteristics and shall be divided in three parts: one shall be given to the holder or party responsible for the product in order to be used as counter-proof, and two shall be immediately sent to the official laboratory for indispensable analyses.

Paragraph 1. Should the quantity or nature not enable sample collection, the product or substance shall be sent to the official laboratory for fiscal analysis in the presence of the holder or company's legal representative and of a specialist indicated by the company.

Paragraph 2. In the case addressed in Paragraph 1 hereof, should the mentioned people be absent, two witnesses shall be summoned to observe the analysis.

Paragraph 3. A conclusive and detailed report of the fiscal analysis shall be drawn up and filed at the official laboratory; copies shall be enclosed to the proceeding records and provided to the manufacturer, as well as to the holder or party responsible for the product or substance.

Paragraph 4. Offenders, when disagreeing with the condemnatory result of the analysis, are entitled to request counter-proof, whether separate or along with the request for review of the appealed decision, by submitting the sample in their power and indicating their own specialist.

Paragraph 5. A certified minute shall be drawn up from the counter-proof report, being dated and signed by all participants; the original copy shall be enclosed to the proceeding records and shall contain all issues addressed by the specialists.

Paragraph 6. The counter-proof analysis shall not be carried out if there are traces of violation of the sample in power of the offender, in which case the condemnatory report shall prevail as definitive.

Paragraph 7. The same analytical method used in the condemnatory fiscal analysis shall be applied to the counter-proof analysis, unless otherwise agreed by the specialists to use another.

Paragraph 8. Difference in the results of the condemnatory fiscal analysis and of the counter-proof analysis shall lead to appeal to a higher authority within 10 days, which shall determine another fiscal analysis to be carried out in the second sample in power of the official laboratory.

Article 28. Having the violation not been proven by the fiscal or counter-proof analysis and having the product been considered safe for use, the competent authority shall draw up an order to release the product and archive the proceedings.

Article 29. In violations that do not depend on analyses or examinations, including those of contempt for the health surveillance authority, the investigation shall be conducted as summary proceedings and shall be considered closed if the offender does not appeal within 15 days.

Article 30. Offenders are hereby entitled to appeal against condemnatory decisions within the same period of time established for defense, including in the case of fine.

Sole Paragraph. Being the condemnatory decision upheld, the appeal may be filed, within 20 days after acknowledgment or publication, to a higher authority in the same government sphere under whose jurisdiction the proceedings had been initiated.

Article 31. Appeals may not be filed in the case of definitive condemnatory decision when the laboratory report is confirmed in the counter-proof analysis or in the case of fraud, forgery or adulteration.

Article 32. Appeals filed against non-definitive decisions shall have suspensory effect with regard to the payment of the pecuniary penalty, not prohibiting immediate imposition of compliance with the subsisting obligation according to Article 18 hereof.

Sole Paragraph. The appeal addressed in Paragraph 8 of Article 27 hereof shall be considered within 10 days.

Article 33. When the penalty of fine is imposed, the offender shall be notified to make the payment within 30 days, counted from the date of notification, being the money collected to the account of the National Health Fund or to the account of the financial bodies of States, Federal District or Territories, pursuant to the administrative jurisdiction under which the proceedings has been conducted.

Paragraph 1. Notifications shall be made by registered letter or by public notice published in the official press if the offender has not been located.

Paragraph 2. Failure to pay fines within the period of time herein established shall lead to their registration for judicial charges, pursuant to the pertinent legislation.

Article 34. Having the period of time set forth in the Sole Paragraph of Article 30 hereof passed and if the condemnatory decision has not been appealed or the counter-proof analysis has not been requested, the report of the condemnatory analysis shall be considered definitive and the proceedings, unless initiated by a federal health surveillance body, shall be transmitted in order to declare registration cancellation and determine product arrest and destruction in the entire national territory, notwithstanding other criminal penalties, when applicable.

Article 35. Destruction of products and cancellation of registrations, operating permits and establishment licenses shall solely be imposed after the publication of an unappealable decision in the official press.

Article 36. In the case of definitive condemnation of products whose modification, adulteration or forgery does not make them unsafe for use, the health surveillance authority may, when announcing the decision, direct their distribution to support service establishments, preferably official ones, whenever the re-use thereof is viable to health programs.

Article 37. Having the investigation ended due to the lapse of time to appeal without having submitted defense or because appeals have been judged, the health surveillance authority shall announce the final decision and consider the case closed after publication in the official press and adoption of the imposed measures.

Article 38. Violations to any legal or regulatory provision of sanitary order shall hereby lapse in five years.

Paragraph 1. The lapse term shall be interrupted by the notification or by any other act passed by the competent authority that aims to investigate the violation and, consequently, impose penalties.

Paragraph 2. The lapse term shall not be counted if there is any administrative proceedings with pending decisions.

Article 39. This Law shall come into force of the date of its publication.

Article 40. [Decree-law no. 785, of August 25th, 1969](#), and all provisions to the contrary are hereby revoked.

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

ERNESTO
Paulo de Almeida Machado

GEISEL