DECREE NUMBER 90-97

THE CONGRESS OF THE REPUBLIC OF GUATEMALA

WHEREAS:

The Political Constitution of the Republic organizes the State to protect individuals and the family to achieve the supreme goal of achieving the common good and assigns it the duties of guaranteeing life, safety and comprehensive personal development to the inhabitants of the Republic,

WHEREAS:

The Political Constitution of the Republic itself recognizes that the enjoyment of health is a basic human right without discrimination and obliges the State to ensure it by taking actions for prevention, promotion, recovery and rehabilitation through its institutions in order to bring inhabitants the most complete physical, mental and social wellbeing and also recognizing that the health of the nation's inhabitants is a public good,

WHEREAS:

The achievement of such praiseworthy goals makes necessary the structuring of coherent State policies on health that guarantee the participation of all Guatemalans in the search for health, based on strategies of decentralization and deconcentration of programs and services and on social participation promoted based on the principles of equity, solidarity and subsidization,

WHEREAS:

Institutions charged with ensuring the health and wellbeing of Guatemalans and services and benefits require an effective modernization and coordination of their infrastructure, personnel, policies, programs and services in order to achieve the universality of coverage of services,

WHEREAS:

To achieve the Constitutional mandates State policies must be prepared that in the area of health allow the long-term modernization and restructuring of the health sector,

THEREFORE:

With the authority vested in him by Article 171 a) of the Political Constitution of Guatemala,

HEREBY DECREES:

The following:

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HEALTH CODE BOOK I

GENERAL PROVISIONS

SOLE TITLE

CHAPTER I

BASIC PRINCIPLES

ARTICLE 1. THE RIGHT TO HEALTH. All inhabitants of the Republic are entitled to the prevention, promotion, recovery and rehabilitation of their health without discrimination.

ARTICLE 2. DEFINITION. Health is a social product resulting from the interaction between the country's level of development, the people's living conditions and social participation, individually and collectively, in order for the inhabitants of the country to achieve the most complete physical, mental and social wellbeing.

ARTICLE 3. CITIZENS' RESPONSIBILITY. All inhabitants of the Republic are required to ensure, improve and preserve personal, family and community health and healthy conditions of the environment in which they live and carry on their activities.

ARTICLE 4. (Amended by Article 1 of Decree 53-2003 by the Congress of the Republic) **OBLIGATION OF THE STATE.** In compliance with its obligation to ensure the health of the inhabitants and maintain principles of equity, solidarity and subsidization, the State shall develop actions for the promotion, prevention, recovery and rehabilitation of health and pertinent complementarities through the Ministry of Public Health and Social Welfare and in coordination with State institutions, decentralized and autonomous bodies and organized and private communities, in order to secure for Guatemalans the most complete physical, metal and social wellbeing.

With this aim the State will oversee through the Ministry of Public Health and other public institutions, because the provision of health services to all the Guatemalan people is guaranteed to be free.

ARTICLE (Amended by Article 2 of Decree 53-93 by the Congress of the Republic) **COMMUNITY PARTICIPATION.** The State will guarantee communities' right of participation in health programs and services concerning planning, organization, control and social funding.

ARTICLE 6. INFORMATION ON HEALTH AND SERVICES. Concerning their health, all inhabitants are entitled to respect for their person, human dignity and privacy, professional secrecy and to be informed in understandable terms about risks related to loss of health and sickness and the services to which they are entitled.

ARTICLE 7. LAW OF GENERAL OBSERVANCE. This Code is a law of general observance, notwithstanding the application of special rules of social welfare. In the event of questions about the application of health laws, laws on social welfare and others of equal rank, the criterion applying to the rule which is most beneficial to people's health in general is the one that must prevail. Similarly, for purposes of their interpretation, that of their regulations and remaining provisions issued for the promotion, prevention, recovery and rehabilitation of people's health, the social interest shall basically prevail.

CHAPTER II

HEALTH SECTOR

ARTICLE 8. HEALTH SECTOR DEFINITION. Health sector is understood to be the collection of bodies and public, centralized and decentralized, autonomous, semi-autonomous institutions, municipalities, private institutions, and non-governmental and community organizations whose competency or purpose is the administration of health actions, including those dedicated to research, learning, education and training of human resources on health and education on health at the community level. For purposes of this law, henceforth it shall be called the "Sector".

ARTICLE 9. DUTIES AND RESPONSIBILITIES OF THE SECTOR. Institutions making up the Sector have the following duties and responsibilities:

a) The Ministry of Public Health and Social Welfare, which henceforth and for purposes of this Code shall be called the "Ministry of Health", is charged with guiding the Health Sector. This guidance is understood as the leading, regulation, oversight, coordination and assessment of health activities and institutions nationally. The Ministry of Health will also have the function of formulating, organizing and directing execution of policies, plans, programs and projects for the delivery of health services to the public. To fulfill the above duties, the Ministry of Health will have the broadest powers to perform all the actions and to dictate all the measures which, according to the laws, regulations and other provisions of the service, are incumbent when exercising of its duty.

b) The Guatemalan Institute of Social Welfare, as regards the health actions it undertakes within the country's social welfare system, according to its own laws and regulations. In coordination with the Ministry of Health with regard to health, it shall carry out health prevention and recovery programs, including mother-child care and prevention and accident care.

c) In accord with their powers, in coordination with the other Sector institutions, municipalities will participate in the partial or total administration of providing health programs and services in their respective jurisdictions.

d) Universities and other human resource training institutions will promote research on health matters and the educations and training of human resources on the professional and technical levels in coordination with State Bodies and Sector institutions.

e) Private entities, non-governmental organizations, community organizations and cooperative agencies will, according to their goals, participate in a coordinated manner with other Sector institutions on the solution to health problems through the execution of programs and the provision of services, environmental improvements and comprehensive community development, according to the policies, regulations and rules the Ministry of Health may establish for such a purpose.

f) Professional health-related societies as regards the regulation of professional performance.

ARTICLE 10. SECTOR COORDINATION. In order to fulfill its coordination duties, the Ministry of Health will carry out the following actions:

a) Ministry of Health-Guatemalan Institute of Social Welfare coordination. The Ministry of Health and the Guatemalan Institute of Social Welfare will coordinate their plans, programs on promotion, prevention, recovery and rehabilitation of health, and the utilization of their
human, physical and team resources in order to achieve the expansion of health services coverage, be efficient, effective and to prevent the duplication of services, infrastructure and expenses.

b) Intra- and Intersector Coordination. To fulfill the duty of coordination within the sector and with other sectors, the Ministry of Health will sign agreements and conventions with national, local and international bodies.

ARTICLE 11. PROGRAMMING AND ADMINISTRATION OF HEALTH SERVICES. The organization and administration of programs and services for promotion, prevention, recovery and rehabilitation of health included in this Code will be deconcentrated and decentralized according to the needs of the public and the process of administrative sector modernization. Sector institutions for the administration and provision of services will establish areas of influence to care for population groups, preferably coinciding with the territorial areas of the departments [geographic regions] and municipalities of the Republic.

CHAPTER III

NATIONAL HEALTH COUNCIL

ARTICLE 12. CREATION OF THE COUNCIL. The National Health Council is hereby created as a Sector advisory body attached to the Ministry of Health.

ARTICLE 13. ITS DUTIES Duties of the National Health Council will be the following:

a) Promote coordinating mechanisms among the institutions making up the Sector in order to ensure proper efficiency and effectiveness in the health activities they themselves undertake.

b) Give advice to the Ministry of Health on formulating and assessing policies and strategies and in the development of national sector and institutional health plans.

c) Other duties the Ministry of Health may assign it.

ARTICLE 14. ITS MAKEUP The Council will be made up of a regular representative and an alternate from the following entities:

a) Ministry of Health;

b) Guatemalan Institute of Social Welfare – IGSS;

c) National Association of Municipalities – ANAM;

d) Associations from development institutions that provide health services to the public;

e) Commercial, Industrial and Financial Services Coordinator – CACIF;

f) Assembly of Professional Societies Presidents;

g) University of San Carlos of Guatemala;

h) Private universities in the country;

i) Ministry of Education;

j) Any other institution that in the judgment of the Ministry may be a part of the Council temporarily.

The level and type of representation must be established in the regulation for the Health Council's functioning and will act *ad-honorem*.

ARTICLE 15. ITS ORGANIZATION The Council will be presided by the Minister of Health, and in his absence, by the Vice Minister, who will be appointed by the former. A regulation will rule the organization and specific functioning of the Council.

CHAPTER IV
ORGANIZATION AND DUTIES OF THE MINISTRY OF HEALTH

ARTICLE 16. BASES FOR MINISTRY ORGANIZATION. Organization of the Ministry of Health will be based on the Law of the Executive Branch and will be framed within the strategies of decentralization, deconcentration and social participation. A regulation will define the specific duties of each level and the corresponding organizational structure. It must fulfill the following purposes:

a) Give guidance to the sector in order to maintain the principles of solidarity, equity and subsidization in health activities aimed at the public;

b) Favor the public's access to public health services which must be provided with efficiency, effectiveness and good quality.

ARTICLE 17. DUTIES OF THE MINISTRY OF HEALTH. Duties of the Ministry of Health will be the following:

a) Give guidance on the development of national health activities;

b) Formulate national health policies;

c) Coordinate health activities that each of its offices and other sector institutions will carry out;

d) Regulate, monitor, supervise and assess the programs and services developed by its executing units as decentralized entities.

e) Ensure compliance with international health treaties and conventions;

f) Issue all the measures that according to the laws, regulations and other provisions of the service are incumbent for the exercise of its duties and care for the protection of inhabitants' health;

g) Develop activities for the promotion, prevention, recovery and rehabilitation of health and pertinent complementarities in order to secure satisfaction of the public's health needs;

h) Propitiate and strengthen community participation in the partial or total administration of health activities;

i) Coordinate the technical and financial cooperation that international bodies and nations provide the country based on domestic sector policies and plans;

Coordinate the actions and areas of non-governmental organizations regarding health in order to promote complementarities of activities and prevent duplication of efforts;

k) Prepare the regulations required for correct application of this law, review them and constantly readjust them.

ARTICLE 18. COMPREHENSIVE HEALTH CARE MODEL. The Ministry of Health must define a health care model that promotes the participation of other sector and organized community institutions, that prioritizes the activities of health promotion and prevention, guaranteeing comprehensive health care at the system's different care levels and steps of complexity while keeping in mind the national, multi-ethnic, multicultural and multilingual contexts.

ARTICLE 19. ORGANIZATIONAL LEVELS. Organization of the Ministry of Health will comprise the following levels and organizational duties:

a) Central Level responsible for:

I) Management and leadership of health activities.

II) Formulation and assessment of strategic health policies, plans and programs.

III) Normatization, oversight and control of health and supervision of health provision services.

b) Executive Level will be responsible for provision of health services based on care levels according to the degree of complexity of the services and resolution capacity.

ARTICLE 20. ADMINISTRATION OF HEALTH SERVICES. In order to carry out its technical, administrative, financial and human resources duties more efficiently and effectively, the Ministry will establish administrative and technical manager positions at each level requiring this, bearing in mind the different university and technical professions needed for Ministry management.

CHAPTER V SECTOR FINANCING

ARTICLE 21. ASSIGNMENT OF RESOURCES. The State will assign the resources necessary for public financing of health services provision in order to care for the general public and, prioritarily and obligatorily, for the ones most delayed in their social and economic development.

ARTICLE 22. SPECIFIC EARNINGS. Funds from the provision of services of any kind by public health care services, together with bequests and donations made to them, will be set up as private funds that may be designated towards the financing of offered services.

ARTICLE 23. OTHER FINANCING:

b) Municipalities and local, national or international organizations may designate financial resources for the provision of health services aimed at the public under their jurisdiction.
b) Non-governmental organizations, depending on their policies and programs and within the regulations of this Code, may finance the provision of health services that are coordinated with the Ministry of Health.

ARTICLE 24. MOBILIZATION OF RESOURCES. For the purpose of coordinating health services provision, the Ministry of Health may sign conventions and contracts with institutions that make up the Sector and other institutions linked to it. Public institutions in the Sector may also sign agreements to provide services among themselves and with private entities through conventions or other legal instruments. This documents will be executed under the conditions and requirements established through the regulatory route.

CHAPTER VI
EDUCATION AND TRAINING OF HUMAN RESOURCES IN HEALTH

ARTICLE 25. PRIORITY OF HUMAN RESOURCES. The Ministry of Health and other sector entities will prioritize human resources as the key factor in modernizing the Sector and implementing the comprehensive healthcare model.

ARTICLE 26. FORMULATION OF POLICIES AND STRATEGIES. The Ministry of Health will be responsible for formulating Sector policies on aspects of human resources and must implement the policies corresponding to the institution.

ARTICLE 27. FORMULATION OF PLANS AND PROGRAMS. The Ministry of Health will participate jointly with universities and other training institutions for human resources in formulating plans and programs for the education, training and management of human resources in health, based on established care models and the public epidemiological profile.

ARTICLE 28. DETECTION OF NEEDS. The Ministry of Health, in coordination with remaining institutions making up the Sector, will structure an information system capable of permanently detecting the needs of public healthcare institutions concerning human resources in health education and training.

ARTICLE 29. RESPONSIBILITIES FOR EDUCATION. Universities, the Ministry of Health, the Ministry of Education and other Sector institutions are responsible for educating professionals and technical and ancillary health and related sciences personnel according to the rules and academic requirements established for each educational level in the system.

ARTICLE 30. TRAINING OF HUMAN RESOURCES. The Ministry of Health, together with the rest of Sector institutions, are responsible for guiding and ensuring the update of staff on aspects tied to the provision of services through different adult education modalities related to improving performance and the development of institutions and human resources in health.

ARTICLE 31. TEACHING/SERVICE INTEGRATION. Undergraduate and postgraduate educational institutions on human resources in health will promote the linking of incoming college students to the health services as one of the basic strategies in their educational process, for which purposes the proper inter-institutional agreements will be ratified, approved and implemented.

ARTICLE 32. APPLICATION OF PRINCIPLES. The Ministry of Health and other Sector institutions will guarantee the management of human resources in health through the application of proper administrative, ethical and technical principles, depending on the implementation of the Comprehensive Healthcare Model and development of human resources by the Ministry of Health and the Sector.

ARTICLE 33. WORKING RELATIONSHIPS BY THE MINISTRY AND ITS STAFF. Working relationships among the Ministry of Health and its workers will be governed by the basic principles in the Political Constitution of the Republic of Guatemala, the Law of Civil Service, international conventions ratified by Guatemala and other laws and regulations on the matter along with the provisions of this Code.

CHAPTER VII HEALTH RESEARCH

ARTICLE 34: PROMOTION OF RESEARCH. The Ministry of Health will promote and push for the development of health research policies and technological development with the participation of the institutions making up the Sector.

ARTICLE 35: RESEARCH POLICIES. Institutions making up the Sector, in coordination with other institutions the State has created for such purposes, will formulate national health research policies.

ARTICLE 36: RESEARCH CAPACITY. The State will strengthen the capacity of institutions making up the Sector in research and technological development, promoting the development of research centers, improving the existing infrastructure, facilitating the management, administration and execution of projects and educating and training human resources.

BOOK II HEALTH ACTIONS

TITLE I
PROMOTION AND PREVENTION ACTIONS

CHAPTER I DEFINITION OF ACTIONS

ARTICLE 37. DEFINITION. For the purposes of this Code, the following shall be considered:

a) Health Promotion Actions are those actions aimed at promoting the normal physical, mental and social development of the individual, the family and the community, along with the preservation of healthy environments, which will be carried out by the State, Sector institutions and the community itself.

b) Health Prevention Actions are those actions carried out by the Sector and other sectors aimed at the control and eradication of sicknesses that affect the country's population.

ARTICLE 38. ACTIONS. Promotion and prevention actions will be designed to interrupt the epidemiological chain of nationwide sickness and to protect, diagnose and give early treatment to the susceptible population.

a) Health promotion actions will be aimed at maintaining and improving the health standard through the adoption of healthy lifestyles with an emphasis on personal care, physical exercise, proper food and nutrition, the preservation of healthy environments and avoiding the use of health damaging substances. In coordination with Sector institutions, the Ministry of Health must establish the necessary mechanisms so that society as a whole, individuals, families and communities will actively participate.
b) Health prevention actions will include the establishment of epidemiological oversight systems, immunizations, early case detection and treatment, health education and other measures appropriate for achieving control of endemic, emerging and recurring diseases, especially non-emerging ones with the potential to cause epidemic outbreaks.

c) Regarding the environment, promotion and prevention actions will seek access to the population with an emphasis on the ones most delayed, services for potable water, proper waste elimination and disposal, proper solid waste disposal, food hygiene, and the reduction of environmental pollution.

CHAPTER II HEALTHY LIFESTYLES

ARTICLE 39. EDUCATION PROGRAMS. Health promotion education and information programs must be designed for easy and proper understanding. For ethnic groups they must be done in their proper language and by valuing, respecting and taking into consideration their beliefs, customs and practices.

ARTICLE 40. MENTAL HEALTH. Within their areas of competency, the Ministry of Health and other Sector institutions will supervise the promotion, prevention, recovery and rehabilitation of mental health for individuals, family and society through the community and institutional network, within the primary healthcare framework, and favoring focuses on ambulatory care.

ARTICLE 41. FAMILY HEALTH. Through the Ministry of Health and other Sector institutions the State will undertake actions meant to promote women's and children's health with a comprehensive focus and to improve the physical and social family environment, together with applying measures for prevention and care of the family group at various stages of growth and development, including aspects of reproductive health.

ARTICLE 42. THE ELDERLY. The Ministry of Health, in coordination with the Guatemalan Institute of Social Welfare and other institutions with similar programs, must undertake programs within their areas of competency for comprehensive care of the elderly in all care programs based on the principle of respect and their full integrations into social development.

ARTICLE 43. FOOD AND NUTRITIONAL SAFETY. The Ministry of Health, in coordination with Sector institutions, other ministries, the organized community and international agencies, will promote actions guaranteeing the availability, production, consumption and biological use of foods intended to achieve safety of the Guatemalan people's food and nutrition.

ARTICLE 44. OCCUPATIONAL HEALTH. The State, through the Guatemalan Institute of Social Welfare, the Ministry of Labor and Social Welfare and other Sector institutions, within the areas of their competency and with the collaboration of public and private companies, will undertake actions meant to secure safe and healthy environments in the workplace, prevent occupational illnesses, and care for the specific needs of workers and workplace accidents.

ARTICLE 45. ORAL HEALTH. The State through the Ministry of Health and in coordination with other Sector institutions will undertake actions for the promotion, prevention and recovery of oral health.

ARTICLE 46. ACCIDENT PREVENTION. The Ministry of Health, in coordination with the Guatemalan Institute of Social Welfare, the Ministry of Labor and Social Welfare and municipalities, will carry out activities aimed at the investigation, prevention and control of accidents. It will also issue technical rules for the prevention of accidents and promote coordination among the public and private sectors for that purpose, within the area of its competency and notwithstanding the powers of other sectors.

ARTICLE 47.- DAMAGING HEALTH SUBSTANCES. Programs will be promoted to report on the risks of using substances that damage health, especially those that are addictive.

ARTICLE 48. SUBSTANCES BANNED BY LAW. Programs will be promoted to eradicate the use of substances that damage health whose use, production and marketing are considered in this Code and other laws to be banned, especially drugs in any of their forms and clandestine alcoholic beverages of any kind.

ARTICLE 49. (Amended by Article 1 of Decree 50-2000 by the Congress of the Republic). **ADVERTISING AND HARMFUL CONSUMPTION.**

a) All advertising related to tobacco, alcoholic beverages, wines, beers and fermented beverages done through the written, graphic, radio, television, electric or electronic media and mobile units must have authorization from the Ministry of Public Health and Social Welfare before being broadcast in such communications media.

b) Manufacturers, importers and advertisers of cigarettes and other tobacco products are obliged to show in their advertising spaces and place on the packaging or wrapper and on the product pack itself one of the following warnings in alternating fashion:

- SMOKING TOBACCO CAUSES CANCER.
- USE OF THIS PRODUCT CAUSES CARDIOVASCULAR DISEASE.
-
- USE OF THIS PRODUCT CAUSES CANCER OF THE MOUTH AND PHARYNX.
- SMOKING TOBACCO CAUSES ABORTIONS AND FETAL MALFORMATIONS IN PREGNANT WOMEN.
- USE OF THIS PRODUCT CAUSES LUNG CANCER.

When dealing with the product pack, warning captions must be visible, written in the Spanish language, with at least 12-POINT UPPER CASE ARIAL BLACK FONT, be clearly legible and fill 25% of the lower portion of the front panel of its package design or pack. The manufacturer must assign one of the warnings referenced in this section to FIFTY PERCENT OF EACH MONTH'S PRODUCTION until one hundred percent of it is completed and include all the warning legends, and so forth. Similarly, all packs must show in clear and visible lettering the following warning on their side: USE OF THIS PRODUCT CAUSES SERIOUS HEALTH DAMAGE.

All tobacco advertising by written, graphic, radio, television, electric or electronic media and mobile units must include the warning legends to which this section refers at the beginning and end of the advertisement in a rotating fashion and in the same issued monthly percentage of transmission shown. Furthermore, for televised, electric or electronic media, while it is being advertised, the advertisement must have the inserted banner showing the warnings listed in section b).

c) For televised, electric or electronic media, manufacturers, importers and advertisers of alcoholic beverages, wines, beers and fermented drinks must show in their advertising spaces that "EXCESS CONSUMPTION OF THIS PRODUCT IS DAMAGING TO THE USER'S HEALTH".
The above warning must be included at the beginning and end of the advertisement. All packaging and labeling of domestic or imported products containing alcoholic beverages, wines, beers and fermented beverages must contain the legend: "EXCESS CONSUMPTION OF THIS PRODUCT IS DAMAGING TO THE USER'S HEALTH". The above warning must be included at the beginning and end of the advertisement. All packaging and labeling of domestic or imported products containing alcoholic beverages, wines, beers and fermented beverages must contain the legend: "EXCESS CONSUMPTION OF THIS PRODUCT IS DAMAGING TO THE USER'S HEALTH". The legend must be written in Spanish and in at least 12-POINT UPPER CASE ARIAL BLACK FONT, clearly legible, occupy 25% of the front panel of the label, container and packing and must also show the ingredients' contents.

d) General advertising must not contain messages considered harmful to individual or group health, and there will be no promotion on users' moderation and self-control on the use of cigarettes or tobacco in any of its forms, alcoholic beverages, wines, beers or fermented drinks.

e) All advertising about tobacco, alcoholic beverages, wines, beers and fermented drinks through the written, graphic, radio, television, electric or electronic media and mobile units in any of its forms must include the warning THE USE OF THIS PRODUCT CAUSES SERIOUS HEALTH DAMAGE. Also, tobacco advertising must include the warnings shown in subsection b) of this article.

a) No advertising through radio, television, electric or electronic media and mobile units, the transmission of advertising about tobacco, alcoholic beverages, wines, beers and fermented beverages will be done during children's programming hours.

f) Advertising about tobacco, alcoholic beverages, wines, beers and fermented beverages must refer to the product by how it is presented or to its container, but in no case may it show or suggest its use directly through human models, animated drawings, sports athletes or public personalities for such purpose.

g) No propaganda or advertising that promotes the use of cigarettes or tobacco products, alcoholic beverages, wines, beers and fermented beverages may be placed less than 500 meters from the entrances and exits of preschool, preprimary, primary, middle and university educational institutions, facilities or sports complexes, hospital care institutions or recreation centers.

h) It is forbidden to make free or promotional distributions of cigarettes in packs or loose, alcoholic beverages, wines, beers or fermented beverages, or also of goods and services bearing the name or registered brand name of tobacco products, alcoholic beverages, wines, beers and fermented beverages anywhere in the country.

i) It is forbidden to sell cigarettes in individual form or fewer than 20 cigarettes per pack by any of the domestic or imported brands.

j) Any product distributed in violation of any of the above precepts, and any advertising that does not adhere to this law will be withdrawn or suspended immediately by provisions of the Ministry of Public Health and Social Welfare, and such actions will be at cost and the responsibility of the offender.

ARTICLE 50. BAN ON SALE AND USE TO MINORS UNDER THE AGE OF 18. The sale of alcoholic beverages and tobacco in any of their forms is forbidden to minors under the age of 18, as well as their use in any establishment or on the public street.

ARTICLE 51. (Amended by Article 2 of Decree 50-2000 by the Congress of the Republic).
PLACES FOR USE OF TOBACCO AND ITS DERIVATIVES.

a) Smoking is banned on the premises of State offices, their decentralized or autonomous entities and State companies, in buildings housing preschool, preprimary, primary and middle education centers and in university classrooms, urban and suburban group transportation units, taxis, medical care centers, public and private hospitals, movie theaters, enclosed places where public performances are held, theaters, airports, gas stations, places dispensing gas or other combustibles or flammable products, and in general, all those enclosed places where public services are offered, unless the owners of theaters, cinemas and public performance venues have premises adapted for smokers that are duly ventilated so as not affect non-smokers.

b) Establishments that dispense food must prepare places for smokers and non-smokers. Smoking areas must constitute no more than twenty-five percent of the total establishment area open to the public, and they must have proper ventilation so as not to affect the non-smoking areas.

CHAPTER III THE PREVENTION OF ILLNESSES

SECTION I

HEALTH OVERSIGHT

ARTICLE 52. OVERSIGHT. The Ministry of Health, in coordination with other Sector institutions and with the active participation of organized communities must promote and undertake actions meant to prevent the spread and the control and eradication of communicable diseases throughout the country, exercise technical oversight in compliance with the matter and issue the proper provisions according to established regulations.

ARTICLE 53. NATIONAL HEALTH INFORMATION SYSTEM. Health information system is understood as the collection of statistical data and reports on the health situation and its trends, productivity, coverage and costs of health services and the quantification and qualification of the different human, technological and financial resources of the institutions making up the Sector. The Ministry of Health and National Institute of Statistics will regulate its organization and operation according to their field of action.

ARTICLE 54. NOTIFICATION. Public and private health institutions, establishments and staff, plus authorities and the general community are required to immediately notify the Ministry of Health office in their jurisdiction about the appearance of environmental, behavioral or job risk factors, along with avoidable, communicable, non-communicable diseases, accidents and illnesses related to veterinary public health. Sicknesses that must be reported will be established in the regulation and the management of the individual or group case. Failure to comply with this provision will be sanctioned according to the provisions of the book of sanctions in this Code.

ARTICLE 55. ACCESS TO SERVICES. Public and private Sector establishments must provide the sick who are carriers of communicable diseases and their contacts access to etiological diagnosis and healthcare under conditions that respect their personal integrity and case confidentiality, notwithstanding the provisions of Article 54.
ARTICLE 56. OBSERVANCE. The sick who carry communicable diseases and their contacts are obliged to observe the provisions issued by the Ministry of Health to prevent the spread of and to promote the control or elimination of communicable diseases.

ARTICLE 57. BENCHMARK DIAGNOSIS. The Ministry of Health must establish the benchmark diagnosis system as a support for the health oversight system in order to collaborate on the research and control of communicable and non-communicable diseases that affect or put social groups at risk.

ARTICLE 58. RULES AND PROCEDURES. In the event of an epidemic or socio-environmental risk, the Ministry of Health, together with other Sector institutions and other involved sectors, must issue the rules and procedures necessary to protect the public.

ARTICLE 59. INSTITUTIONAL COOPERATION. In the event of an epidemic or socio-environmental risk, health sector institutions and those from other sectors and the community are obliged to cooperate on applying and observing the rules, laws and procedures that are established, according to need.

ARTICLE 60. ACTIONS FOR INTERNATIONAL PROTECTION. The Ministry of Health in coordination with health authorities from other countries, international bodies and other sectors will carry out international protective actions against disease and must be governed by the International Regulations from the World Health Organization, the Pan American Health Code and bilateral and multilateral agreements.

SECTION II

DISEASE CONTROL

ARTICLE 61. DISEASES PREVENTIBLE THROUGH VACCINATION. Given the importance of potential epidemics, their transcendence and the availability of technology for their control and eradication, the Ministry of Health will support with the necessary resources immunization programs, which with the participation of other Sector institutions, the community and civil society, will carry out the actions for control and eradication of such diseases and also by strengthening their epidemiological oversight system. The administration of safe and effective vaccines will be free in all sector public establishments.

ARTICLE 62. SEXUALLY TRANSMITTED DISEASES AND ACQUIRED IMMUNODEFICIENCY SYNDROME. The Ministry of Health is responsible for formulating, evaluating and supervising actions aimed at the control of sexually transmitted diseases. Given the magnitude, transcendence and other epidemiological characteristics of sexually transmitted diseases (STD) and Acquired Immunodeficiency Syndrome (HIV/AIDS), the Ministry of Health will support the specific development of programs for education, detection, prevention and control of STD's and HIV/AIDS with the participation of various sectors.

ARTICLE 63. VETERINARY HEALTH. The Ministries of Health and Agriculture, Livestock and Food will establish and coordinate a program to oversee, promote and care for veterinary public health for the prevention and control of diseases that affect human health and animals. These include, among others:

a) Steps to protect the public against animals that pose risks to health;

b) Animal immunization programs to prevent zoonotic diseases with the participation of the public and private sectors;
c) Procedures to control the importation and temporary, accidental or fraudulent introduction of products and vectors of any nature and type that are capable of posing a risk to health;

d) Promote the research of communicable diseases to humans, especially those transmitted through domestic animals.

ARTICLE 64. RABIES. The Ministry of Health in coordination with the Ministry of Agriculture, Livestock and Food and municipalities will be responsible for administering programs for the prevention of human and canine rabies and guaranteeing the availability of vaccines and care for persons at risk of developing this disease.

ARTICLE 65. DISEASES COMMUNICABLE THROUGH VECTORS. The Ministry of Health, in coordination with other Sector institutions that undertake actions in this area, will administer programs that promote community participation for protection of the environment and elimination of reservoirs that facilitate the proliferation of vectors which participate in transmitting these diseases. The Ministry of Health will be in charge of authorization and periodic control of companies dedicated to the elimination of plagues and vectors.

ARTICLE 66. SPECIFIC NUTRITIONAL DEFICIENCIES AND DENTAL CARIES. The Ministry of Health, in coordination with other Sector institutions and the private initiative, will undertake programs for the enrichment of foods with nutrients to prevent specific nutritional deficiencies and dental caries. ^

ARTICLE 67. EMERGING AND RE-EMERGING DISEASES AND OTHERS. The Ministry of Health, in coordination with other Sector institutions, must:

a) Promote and undertake appropriate actions to prevent the appearance and to control the spread of emerging or re-emerging communicable or non-communicable diseases that tend to become a threat to public health.

b) Formulate, evaluate and supervise appropriate actions for the prevention and control of diseases caused by microbes, chemical substances or natural toxins transmitted through food and water.

c) Formulate, evaluate and supervise appropriate actions for the prevention and control of acute and chronic poisoning from pesticides and chemical substances.

CHAPTER IV

HEALTH AND ENVIRONMENT

SECTION I

ENVIRONMENTAL QUALITY

ARTICLE 68. HEALTHY ENVIRONMENTS. The Ministry of Health, in collaboration with the National Environmental Commission, the municipalities and the organized community, will promote a healthy environment that favors the full development of individuals, families and communities.

ARTICLE 69. EXPOSURE LIMITS AND ENVIRONMENTAL QUALITY. The Ministry of Health and the National Environmental Commission will establish permissible exposure and environmental quality limits for environmental contaminants, whether they are chemical, physical or biological in nature. When the contaminants are of a radioactive nature, the Ministry of Health, in coordination with the Ministry of Energy and Mines, will establish permissible exposure and environmental quality limits. The regulation will also make a determination with respect to work periods for personnel who labor at sites exposed to these contaminants.

ARTICLE 70. OVERSIGHT OF ENVIRONMENTAL QUALITY. The Ministry of Health, the National Environmental Commission, the municipalities and the organized community will establish a system to oversee environmental quality based on permissible exposure limits.

ARTICLE 71.- THE RIGHT TO INFORMATION. The Ministry of Health, the National Environmental Commission and the municipalities must collect and disclose appropriate information to the public on the health risks associated with direct or indirect exposure to contamination agents that exceed established exposure and environmental quality limits.

ARTICLE 72. PROGRAMS FOR THE PREVENTION AND CONTROL OF ENVIRONMENTAL RISKS. The
The Ministry of Health, the National Environmental Commission, the municipalities and the organized community with all other appropriate public or private authorities will promote the development of personal care and the reduction of health risk programs tied to environmental imbalances or caused by chemical, physical or biological contaminants. The Ministry of Health will oversee compliance with the international accords ratified by Guatemala that ban the use of substances that harm the environment and humans, as a result.

ARTICLE 73. IMPORTATION OF WASTE. It is forbidden to import waste that is toxic, radioactive and/or hard to degrade.

ARTICLE 74. ENVIRONMENT AND HEALTH IMPACT ASSESSMENT. The Ministry of Health, the National Environmental Commission and the municipalities will establish the criteria to perform environmental impact assessment

studies aimed at determining the prevention and mitigation measures needed to reduce potential health risks from imbalances in the environmental quality as a result of performing jobs or processes for industrial, urban, agricultural, livestock, tourist, forest or fishing development.

ARTICLE 75. DANGEROUS SUBSTANCES AND MATERIALS. The Ministry of Health and the National Environmental Commission, in coordination with other authorities from the public and private sector, will establish the criteria, rules and standards for the production, importation, trafficking, distribution, storage and sale of substances and materials dangerous to health, the environment and individual and collective wellbeing.

ARTICLE 76. DISASTERS AND PUBLIC CALAMITIES. The Ministry of Health, jointly with other Sector institutions and other sectors, will participate in formulating policies, strategies, plans, programs and projects aimed at preventing and mitigating the impact of disasters and public calamities.

ARTICLE 77. SECTOR RESPONSIBILITY IN CASES OF DISASTER. The Ministry of Health, institutions that make up the Sector and the community will participate in all actions of prevention, care and rehabilitation in cases of disaster and in aspects of direct care both of people and the environment.

SECTION II POTABLE WATER

ARTICLE 78. ACCESS AND UNIVERSAL COVERAGE. The State, through the Ministry of Health, in coordination with the Institute of Municipal Promotion and other Sector institutions, will promote a policy of priority and public need that guarantees the public's access and universal coverage to potable water services, with emphasis on management by the communities themselves to guarantee sustainable handling of the resource.

ARTICLE 79.- OBLIGATORY NATURE OF THE MUNICIPALITIES. Municipalities are obliged to supply potable water to the communities located within their territorial jurisdiction pursuant to the provisions of the Municipal Code and population needs in the context of State policies on this matter and consigned in this law.

ARTICLE 80. PROTECTION OF WATER SOURCES. The State, through the Ministry of Health, in coordination with Sector institutions, will oversee the protection, preservation, exploitation and rational use of potable water sources. The country's municipalities are obliged as principal providers of potable water service to protect and preserve water sources and to support and collaborate with Sector policies to achieve universal coverage in their territorial jurisdiction in terms of quantity and quality of the service.

ARTICLE 81. PUBLIC UTILITY STATEMENT. The State, through the Ministry of Health, Sector institutions and others, will guarantee that the rivers, lakes, ponds, streams, river heads and other natural sources of water may, based on technical ruling, be declared of public use and interest for the supply of potable water on behalf of urban and rural populations according to the specific law. The aqueduct right of way will be regulated based on the Civil Code and other laws on the matter.

ARTICLE 82. PROMOTION OF THE BUILDING OF SERVICES. The Ministry of Health, in coordination with municipalities and the organized community, congruent with the provisions of Articles 78 and 79 of this law, will promote the construction of works designed to constantly provide and supply potable water to urban and rural populations.

ARTICLE 83. FURNISHING OF WATER AT WORK CENTERS. Agroindustrial or companies of any other sort will guarantee their workers access to water services that meet the requirements for human consumption.

ARTICL 84. FELLING OF TREES. The felling of trees is absolutely forbidden on the banks of rivers, streams, lakes, ponds and water sources up to 25 meters from their shores. Transgression of this provision will be punished pursuant to the provisions of this Code.

ARTICLE 85. NON-GOVERNMENTAL ORGANIZATIONS/NGO'S. The Ministry of Health, municipalities and the organized community will establish the priorities which non-governmental organizations must heed in order to supply potable water services.

ARTICLE 86. RULES. The Ministry of Health will establish the rules linked to the administration, construction and maintenance of potable water services for human consumption, overseeing in coordination with the municipalities and organized community the quality of the service and all water supplies for human use, whether public or private.

ARTICLE 87. WATER PURIFICATION. Municipalities and other public or private institutions in charge of managing and supplying potable water have the obligation to purify it based on methods established by the Ministry of Health. The Ministry must offer technical assistance to municipalities in a way that is efficient for their compliance. Transgression of this provision will entail sanctions that will be established in this law, notwithstanding the criminal sanctions which may be incurred.

ARTICLE 88. CERTIFICATE OF QUALITY. All water supply projects, prior to being placed into service, must have a certificate expedited by the Ministry of Health on which it is recorded that it is suitable for human consumption. If the certificate is not issued in the time established in the respective regulation, it will be understood as extended, with the official or employee who did not issue the opinion in the stipulated time bearing the responsibility for any harm.

ARTICLE 89. CONNECTION OF SERVICES. Owners or possessors of property and water supplies located in the urban radius endowed with central potable water networks must connect such services according to municipal regulations. It is the municipalities' responsibility to control obedience with this provision.

ARTICLE 90. POLLUTED WATER. It is forbidden to use polluted water to grow vegetables that are food for human consumption. In the respective regulation the means of control will be established.

ARTICLE 91. SUSPENSION OF SERVICE. Populations having potable water service are banned from suspending this service except in cases of *force majeure* that the health authorities will determine in coordination with the municipalities, such as: delinquency or questionable alteration by the user.

SECTION III
ELIMINATION AND DISPOSAL OF WASTE AND WASTE WATER

ARTICLE 92. FURNISHING OF SERVICES. Municipalities, industries, businesses, farming and livestock management and tourist entities and other types of public and private establishments must grant or promote the installation of proper systems for the healthy elimination of waste, waste water and sewage and the maintenance of such systems, according to this law and respective regulations.

ARTICLE 93. ACCESS AND COVERAGE. The Ministry of Health, along with Sector institutions, municipalities and the organized community, will promote universal coverage of the public to services for final waste disposal and the transporting and treatment of waste water. It will also promote health education activities for their correct use.

ARTICLE 94. SANITATION RULES. The Ministry of Health with other Sector institutions will, within their area of competence, establish sanitation rules to regulate works construction for the elimination and disposal of waste and waste water and jointly with the municipalities establish the authorization, supervision and control of such works.

ARTICLE 95. WASTE DISPOSAL. Unsanitary disposal of waste in public places, communal lands and vacant lots is prohibited. Contravention of this provision will be sanctioned by the respective authority, according to the Municipal Code, municipal regulations and this Code.

ARTICLE 96, CONSTRUCTION OF TREATMENT WORKS. Municipalities or users of the affected basins or sub-basins are responsible for building the works for the treatment of black and wastewaters to prevent the contamination of other water sources: rivers, lakes, and water heads. The Ministry of Health must provide technical assistance on aspects linked to their construction, functioning and maintenance.

ARTICLE 97. DISCHARGE OF WASTE WATER. It is forbidden to discharge contaminants of industrial or agroindustrial origin and to use untreated waste water without a prior favorable ruling from the Ministry of Health, National Environmental Commission (CONAMA), and authorization from the Municipal Council in the municipal jurisdiction or jurisdictions affected. Such a ruling must be issued within a period not to exceed the one established in the

respective regulation. It is likewise forbidden to discharge untreated waste water into rivers, lakes, streams and ponds or bodies of water, whether these are on the surface or underground.

ARTICLE 98. AUTHORIZATION FOR LICENSES. To extend general construction licenses or for the construction, repair and/or modification of public or private works designed for the elimination or disposal of waste or waste water, municipalities must previously obtain the favorable ruling from the Ministry of Health, which must be issued within the time periods indicated in the specific regulation. Should it not be produced, it will be considered as favorable, and the municipality will issue the respective authorization, notwithstanding that the Ministry of Health unit that did not prepare the ruling in the stipulated time period will be held liable.

ARTICLE 99. CONNECTION. In populations where there is a sanitary sewage system, property owners are obliged to connect their sanitary facilities to it, except in exceptional cases determined by the corresponding regulation. In populations where there is no sanitary sewage system, the use of private waste disposal systems will be allowed, so long as they meet the rules established by the Ministry of Health in order not to compromise ground water or contaminate bodies of water.

ARTICLE 100. PRIVATE SYSTEMS. Construction of private sewage disposal systems must be designed and built by adhering to provisions established by the Ministry of Health on the matter so as not to compromise ground water or contaminate bodies of water.

ARTICLE 101. AUTHORIZATIONS. The use of hot springs and the construction, installation and operation of public pools and baths will require the favorable technical ruling from the Ministry of Health prior to municipal approval and which must issued in the time periods stipulated in the specific regulation. If this is not forthcoming, it will be deemed favorable, notwithstanding that the Ministry of Health unit that did not issue the ruling in the respective time period will be held liable. These works also remain subject to the corresponding sanitary controls, pursuant to the provisions of the respective regulation.

SECTION IV

SOLID WASTE

ARTICLE 102. RESPONSIBILITY OF THE MUNICIPALITIES. It is up to the municipalities to provide cleanup and collection, treatment and disposal services for solid waste, according to the specific laws and in compliance with the applicable health rules. Municipalities may use places for disposal of solid waste or construction of the respective sanitary landfills, after a ruling from the Ministry of Health and the National Environmental Commission, which must be prepared within the non-extendable period of two months from solicitation. Should it not be produced, it will be considered as favorably issued, notwithstanding that the official or employee who did not issue the ruling in the stipulated time period will be held liable

ARTICLE 103. SOLID WASTE DISPOSAL. Discarding or accumulating solid waste of any kind in unauthorized places, around inhabited areas and in places that can do harm to people's health, the ornamentation or the landscape, using improper methods for its transportation and storage or proceeding to use, treat and make final disposal of it without the corresponding municipal authorization, is forbidden. Compliance with established health measures must be borne in mind to prevent environmental contamination, specifically those from effluents from legal or clandestine trash dumps.

ARTICLE 104. INADEQUATE PLACES. If the Ministry of Health confirms that there are places where solid waste is being deposited without meeting the requirements of this law, they must be transferred to other places that do comply with the health requirements, based on a program that by common agreement the respective municipalities and the Ministry of Health will establish.

ARTICLE 105. OPEN SITES AND SPACES. Owners or holders of plots of land, sites or open spaces in urban and rural areas must fence them in and keep them free of solid waste, undergrowth and standing water. Municipal authorities, in coordination with the health authorities, are responsible for enforcing this provision.

ARTICLE 106. HOSPITAL WASTE. Public and private hospitals which by their nature use or discard organic materials or substances that are toxic, radioactive or capable of disseminating pathogenic elements, and the waste produced in normal activities of such an establishment may only store and eliminate those wastes in the places and in the manner stipulated by the rules prepared by the Ministry of Health. Hospitals are required to install incinerators for managing and final disposal of waste, whose specifications and rules will be established in the respective regulation.

ARTICLE 107. SOLID WASTE FROM INDUSTRY AND COMMERCE. For the storage, transport, recycling and disposal of residue and solid waste and dangerous industrial waste, industrial or commercial companies must have proper systems according to the nature of their operations, especially when the danger and volume of waste does not allow the use of the usual service for the disposal of general waste. The Ministry of Health and corresponding municipality will rule on the basis of the specific regulation on this matter.

ARTICL 108. SOLID WASTE FROM FARMING AND LIVESTOCK MANAGEMENT COMPANIES. Solid waste from farming and livestock activities must be collected, transported, deposited and eliminated according to the rules and regulations that are established in order not to create sources of environmental pollution, so long as its reprocessing and/or recycling is not possible for use in other duly authorized activities.

SECTION V

URBANIZATION AND HOUSING

ARTICLE 109. PRIOR APPROVAL. The Ministry of Health, in coordination with the National Environmental Commission and the corresponding municipal corporation, must approve the requests for the formation of new urbanizations, an extension to the area of existing ones and installations of places for recreation or public gathering according to urban and sanitary regulations and rules within the time period established in the respective regulations.

ARTICLE 110. MODIFICATIONS OR REPAIRS. The Municipality, in coordination with the Ministry of Health, may order modifications or repairs to housing, buildings or deficient construction that pose a risk to life and health, pursuant to the provisions of the respective regulation. The construction of housing and urbanization is forbidden in areas declared to be high risk.

ARTICL 111. STABLES AND SHEDS. The permanent installation of stables for horses, cattle and pigs and of sheds for raising poultry is forbidden in urban areas. Municipalities and the National Environmental Commission (CONAMA) will ensure obedience with this provision, whose transgression will be sanctioned according to the provisions of this Code. Such institutions may authorize their installation for specific temporary activities after a request by the interested party or parties.

SECTION VI

CEMETERIES

ARTICLE 112. RESPONSIBILITIES OF THE MINISTRY OF HEALTH. The Ministry of Health, in coordination with municipalities and the National Environmental Commission, is in charge of establishing rules for the construction, operation, expansion or closure of cemeteries in the country.

ARTICLE 113. RESPONSIBILITY OF THE MUNICIPALITIES. The construction and administration of the Republic's cemeteries will belong to the municipalities, a function that may be conceded to private entities. Municipalities may also authorize the construction and installation of new cemeteries and their expansion and closure after a ruling from the Ministry of Health and the National Environmental Commission.

SECTION VII

CADAVERS

ARTICLE 114. HANDLING OF CADAVERS. Cadavers must be buried or cremated within twenty-four hours from the death, except in the following cases:

a) The cadaver has been embalmed, in which case the regulation and/or international rules will govern.

b) When there is need to do a subsequent judicial investigation;

c) When there are special and justifiable circumstances in the judgment of the health authorities and by order of a competent judge;

d) Burial or cremation of the body will be immediate when the cause of death is a sickness that poses a high risk to the public and in cases determined by the respective regulation.

ARTICLE 115. RECORDING THE DEATH. Burials and incinerations may only be done at duly authorized cemeteries. These must present proof to the administrator or person in charge of the cemetery of having recorded the death at the responsible institution according to the regulation in advance. In the case of cremation, it may authorize the relatives to dispose of the ashes as the family decides.

ARTICLE 116. EXHUMATION OF CADAVERS. The exhumation of cadavers before when they must remain obligatorily buried may only be done with express authorization from the Ministry of Health, according to regulations or by judicial order according to law.

ARTICLE 117. TRANSFER OF CADAVERS. The transfer of cadavers or human remains may only be done with prior authorization given by the health authority from the place and after having met the requirements determined by the regulation.

ARTICLE 118. INTERNATIONAL TRANSFER OF CADAVERS. The international transfer of cadavers will be authorized only with prior permission from the health authority from the countries involved and within international norms. Permission will be granted once it is verified that all regulatory demands have been met regarding preservation of the cadaver and safety conditions of the coffin and its packing, aside from other legal regulatory demands related to identification of the persons and the causes of death.

ARTICLE 119. ENTRY OF CADAVERS INTO THE COUNTRY. The person who wishes to bring the cadaver of a person who died abroad into Republic territory for burial or cremation must comply with international transfer norms for cadavers and be accompanied by the death certificate.

ARTICLE 120. USE OF CADAVERS, ORGANS AND TISSUE. Cadavers, their organs and tissue may be used for therapeutic, educational and scientific purposes pursuant to the provisions of the specific law on the disposal of organs and tissue. Its transgression will be sanctioned in this law.

SECTION VIII
ESTABLISHMENTS AND TEMPORARY PLACES OPEN TO THE PUBLIC

ARTICLE 121. HEALTH AUTHORIZATION. The installation and operation of public or private establishments deigned for public care and service may only be allowed after health authorization from the Ministry of Health. For fixed establishments authorization will be granted through a health license. The Ministry will carry out supervisory and control actions notwithstanding those that the municipalities must perform. The specific regulation will set out the requirements for conceding the above authorization and the time period for its issuance.

ARTICLE 122. HEALTH LICENSE. Fiscal offices may only issue or renew patents to the establishments referenced in the above article after presenting the health license issued by the Ministry of Health.

ARTICLE 123. INSPECTIONS. For health control purposes, the owners or administrators of establishments open to the public are required to allow duly identified officials to do inspections at any hour of their operations according to the provisions of the respective regulation.

CHAPTER V
FOOD, ESTABLISHMENTS AND FOOD VENDORS

SECTION I
HEALTH PROTECTION CONCERNING FOOD

ARTICLE 124. DEFINITION. A food is any natural, artificial, simple or compound, processed or unprocessed product that is ingested for the purpose of nourishment or improving nutrition and those ingested by habit or for pleasure, even when not for nutritional purposes.

ARTICLE 125. OTHER INGESTED PRODUCTS. For the purposes of regulation for this Code and its regulations, the following are included in this article:

a) Substances added as additives to food or beverages;

b) Food for infants and children under two years of age;

c) Food for the elderly;

d) Food for special regimens;

e) Non-alcoholic beverages;

f) Alcoholic beverages;

g) Water and ice for human consumption.

ARTICLE 126. (Amended by Article 3 of Decree 50-2000 by the Congress of the Republic). **ALCOHOLIC BEVERAGES.** All beverages containing more than 0.5% alcohol by volume will be deemed as alcoholic beverages and remain subject to evaluation for compliance and to health control, pursuant to the provisions of this chapter and respective regulation.

It is absolutely prohibited to use alcoholic beverages, wines, beers and fermented beverages in public parking lots and parking lots exclusive to establishments that sell food and/or liquors, as well as in the public street.

The use of parking lots exclusively belonging to those establishments that sell foods and/or liquors will give rise to applying them a fine of FIFTEEN THOUSAND QUETZALS (Q. 15,000.00). Reoccurrence will cause the imposed fine to be doubled the first time, and if the law continues to be broken, procedures will be taken according to Article 219, subsections c) and e) of the Health Code.

ARTICLE 127. OTHER DEFINITIONS. For the purposes of this Code and its regulations, the following is understood:

a) Unprocessed natural food: One that has experienced no modifications of physical, chemical or biological origin, except the ones indicated for health reasons or due to the separation of inedible parts. The definition includes fresh and frozen meats, fish and fresh and frozen shellfish.

b) Natural processed food: Any food product prepared based on a natural food that has been subjected to a proper technological process for its preservation and later consumption.

c) Artificial food: One that has been prepared for the purpose of imitating a natural food into which substances have been added that do not exist in the natural food, aside from the water or any natural or processed vehicle.

d) Enriched, fortified or balanced food: Any to which nutrients have been added for the purpose of strengthening its nutritional value pursuant to the stipulations of respective rules.

e) Food for special regimens: One that has been prepared with the goal of satisfying special nutritional regimens, whether for metabolic, esthetic or physiological reasons, and all those ingested as a nutritional supplement.

f) Altered food: One which through the action of natural or artificial causes such as humidity, temperature, air, light, time or enzyme action or other causes, has suffered substantial changes in its normal characteristics and deterioration or damage to its composition.

g) Contaminated food: One that contains physical, chemical, radiochemical, microbiological or biological contaminants in concentrations greater than those acceptable according to prevailing standards and regulations.

h) Adulterated food: All those that intentionally have been partially or totally deprived of useful elements or product characteristics, whether they have been replaced by others that are inert or foreign to the food or else when they

contain an excess of water or filler material, as shown by the prevailing regulations and specific norms. A food is also adulterated when substances have been added to reduce the alterations of nutritional or organoleptic physical characteristics belonging to the food or substances banned for their toxicity have been added.

i) Falsified food: One to which fake qualities have been attributed in order to simulate the appearance of a legitimate product without being so, or that does not come from legally authorized manufacturers.

j) Irradiated food: Any food that has been subjected to treatment with ionizing radiation, this being understood as gamma rays, X-rays or corpuscular radiation capable of producing ions directly or indirectly.

ARTICLE 128. THE PUBLIC'S RIGHT. All inhabitants are entitled to consume harmless foods and foods of acceptable quality. Therefore, the Ministry of Health and other Sector institutions will, within their area of competency, guarantee this through actions of prevention and promotion.

ARTICLE 129. FORMULATION OF POLICIES AND PROGRAMS. The Ministry of Health, in coordination with other Sector institutions, will be in charge of formulating the policies and strategies regarding food protection and harmlessness. In this context the National Food Control Program is created with the participation of the Ministries responsible for the control of food, the municipalities, the private sector and other organizations that represent consumers, by creating mechanisms that ensure inter-institutional coordination.

ARTICLE 130. AREA OF RESPONSIBILITIES. The Ministry of Health and other institutions shall, in a coordinated manner, undertake the following duties:

a) The Ministry of Health is in charge of prevention and control in the phases of processing, distributing, transporting and marketing all kinds of processed foods, domestic or imported, including the granting of the health license for opening of the establishments, health certification or health record concerning products and the evaluation of compliance with same by ensuring good manufacturing processes. It is also responsible for granting the health license and health control for sellers of unprocessed foods.

b) The Ministry of Agriculture, Livestock and Food is responsible for prevention and control in the phases of production, transformation, storage, transportation, importation and exportation of unprocessed natural foods.

c) The Ministry of Economy is responsible for control in the field of meteorology and industrial property.

d) The municipalities are responsible for prevention and authorization of establishments related to the management and dispensing of foods in municipal flea markets according to the norms established by the Ministry of Agriculture, Livestock and Food, marketing, fairs and sales of food in the public street.

e) To the Ministry of Health, in coordination with the Ministry of Energy and Mines through its specific department, fall the control and certification of radioactivity levels in foods and the evaluation of the effects of radioactivity and the aptness for consumption of such foods. A specific regulation will govern the matter.

ARTICLE 131. BENCHMARK HEALTH REGISTRY. Before marketing a food product with a commercial name, it must have authorization from the Ministry of Health and obtain its benchmark health registration or health certificate at this Ministry. The benchmark health registration will allow it to guarantee the food's harmlessness and quality and will constitute the basic standard that will serve for periodic control of the product in the market. Requirements for the benchmark health registration will be based on risk criteria established in the respective regulation.

ARTICLE 132. ASSESSMENT OF COMPLIANCE. Any food product with a commercial name designed for sale must be assessed according to the rules and regulations for harmlessness and quality by the Ministry of Health. Once this requirement is met and the requirements established in the respective regulation are fulfilled, the health certification will be extended. The time period for its issuance will be as established in the regulation.

ARTICLE 133. RESPONSIBILITY.

a) Producers or distributors of food for human consumption or the person who they certify to the health authorities will be responsible for compliance with the rules and/or health regulations that regulate its quality and harmlessness.

b) Distributors or vendors of foods for human consumption or the person that they verify to the health authorities will be responsible for the sale of foods with a commercial name that does not have a health registration or health certification or whose date of sale has expired or is found to be notably deteriorated.

c) Owners and representatives of establishments dispensing prepared foods, such as restaurants, cafeterias, diners and others, will be responsible for meeting the health standards that regulate the quality and harmlessness of foods.

In the event of non-compliance with this provision, the owner or his representative will be subject to the sanctions established in this Code.

ARTICLE 134. INTERNATIONAL AGREEMENTS. International agreements and treaties signed by the government of Guatemala on foods will guarantee the harmlessness and quality of imported and domestic products. A reciprocal treaty will also be guaranteed for Guatemalan products through procedures reconciled and approved by the Ministry of Health.

ARTICLE 135. LABELING. The contents, composition and specific health indications of the product consigned on the label must be written in Spanish and must also meet the health requirements established by the Ministry of Health in a specific regulation, notwithstanding other prevailing standards and regulations.

ARTICLE 136. ADVERTISING. Advertising and labeling that attributes therapeutic properties to foods or that leads to error or deceit by the public concerning the nature, ingredients, qualities, properties or origin of same is forbidden. A specific regulation will govern this matter.

ARTICLE 137. MATERIALS FOR CONTAINERS AND PACKAGING. The only use of materials allowed for the preparation of containers and packages will be those compatible with food and that do not cause alterations due to interaction with them.

ARTICLE 138. APPLICATION OF THE CODEX ALIMENTARIUS. Absent domestic standards for specific cases, or if these are insufficient or out of date, those of the Codex Alimentarius and other internationally recognized standards will also be applied, and where applicable, the provision issued by the higher authorities on the food health matter.

SECTION II
ESTABLISHMENTS FOR DISPENSING OF FOODS

ARTICLE 139. DEFINITION. For the purposes of this Code and its regulations, establishment or dispensing of foods is understood as any place or premises, permanent or temporary, fixed or mobile, designed for the fabrication, transformation, commercialization, distribution or marketing of foods.

ARTICLE 140. HEALTH LICENSE. Any individual or legal entity, public or private, who intends to install a food establishment must obtain a health license granted by the
Ministry of Health according to the health standards and regulations and in the period fixed therein. Exempted from this provision are establishments whose area of responsibility falls under the Ministry of Agriculture, Livestock and Food and municipalities, as contained in Article 130, subsections b) and d) of this law. The health license will be valid for five (5) years with the establishment subject to control during that period. In the event of non-compliance with the corresponding health laws or regulations, it will become obligee to the sanction contained in this Code.

ARTICLE 141. NOTIFICATION OF MODIFICATIONS. When a modification is to be made to establishments or dispensaries that had been already authorized pursuant to the provisions of Article 140 of this Code, the interested party must request a new authorization from the Ministry of Health in which the changes made are included.

ARTICLE 142. PERSONAL HEALTH. Responsible persons from the establishments and food dispensaries must constantly verify the good health condition of their staff, jointly and severally being responsible with the work team. A specific regulation will govern the matter.

ARTICLE 143. PERSONNEL STANDARDS. Staff will have the duty of observing the health rules and regulations and meeting the technical specifications for food establishments. Owners and their supervisory staff must promote and ensure compliance with the health laws and their regulations. ^

ARTICLE 144. INSPECTIONS. Owners, administrators, those in charge or responsible for establishments or food dispensaries will allow the competent health authority who is duly identified to enter at any hour of operations to perform the necessary inspections according to the provisions of the respective regulation. Provisions of this article will also be applied to the temporary storage and transport of foods.

ARTICLE 145. INSPECTIONS OF MARKETS AND STREET SALES. The Ministry of Health, in coordination with the municipalities, will exercise constant health oversight and control of food establishments in municipal indoor markets, fairs and street food sales, in order to ensure that they operate with the rules and health regulations that ensure their harmlessness, pursuant to the provisions of the respective regulation. If processed foods are dispensed with a commercial name, they must comply with prevailing regulations about health registration or health certification.

SECTION III

DONATED FOODS

ARTICLE 146. DONATION OF FOODS. The Ministry of Health and other institutions linked to this field must formulate donation policies in the framework of food safety established by the country.

ARTICLE 147. CRITERIA FOR ACCEPTANCE. Products will be accepted in keeping with the customs of the country and policies established on food assistance and which the respective regulation includes.

ARTICL 148. QUALITY AND HARMLESSNESS. Foods subject to donation must have a preservation period that allows for their distribution and use in good condition. The authorities in charge must establish agile mechanisms of distribution to maintain the harmlessness and quality of the foods. A specific regulation will govern this matter.

ARTICLE 149. GUARANTEE. The Ministry of Health will be responsible for authorizing the acceptance and distribution of the donation, verifying the harmlessness and quality of the foods. The authorities in charge must establish agile mechanisms of distribution to maintain the harmlessness and quality of the foods.

TITLE II
ACTIONS OF HEALTH RECOVERY AND REHABILITATION

CHAPTER I

DEFINITION OF ACTIONS

ARTICLE 150. DEFINITION. For purposes of this Code, the following shall be considered:

a) Health recovery: The group of general medical, dental and specialized services provided to the individual, family and society for the purpose of reestablishing health.

b) Health rehabilitation: The group of actions intended to reestablish people's capabilities in order to perform normal activities and to be able to actively participate with their community.

CHAPTER II
ORGANIZATION AND UNDERTAKING OF SERVICES FOR HEALTH RECOVERY

ARTICLE 151. HEALTH INFRASTRUCTURE POLICY. The Ministry of Health, in coordination with other Sector institutions, will formulate a policy that regulates the growth and development of the health infrastructure to guarantee optimal utilization of health resources by the State, thus avoiding unnecessary duplication of resources and efforts.

ARTICLE 152. LEVELS OF CARE. The Ministry of Health, in coordination with the Guatemalan Institute of Social Welfare, private institutions and other non-governmental and community organizations, will organize their services based on care levels, these understood as a group of different technologies appropriate for the education of specific groups on health problems of different complexities, in order to guarantee access and coverage to all inhabitants demanding care from the established health services network.

ARTICLE 153. REFERRAL AND COUNTER-REFERRAL SYSTEM. To guarantee public access to different health establishments, the Ministry of Health will create and standardize a referral and counter-referral network for patient care according to established care levels.

ARTICLE 154. NATIONAL BENCHMARK HOSPITALS. Third-tier [high complexity] domestic hospitals from both the Ministry of Health and the Guatemalan Institute of Social Welfare must become domestic benchmark hospitals to treat only highly specialized cases which by their nature require highly complex technology. General patient care that they currently cover must gradually be deconcentrated to regional and local peripheral hospitals.

ARTICLE 155. HIGH SPECIALITY CONCENTRATION. For the treatment of highly specialized cases, the Ministry of Health and other institutions making up the Sector, must propose and bring to practice performance models and services in order to increase their coverage and reduce costs.

ARTICLE 156. SHARED USE HEALTH ESTABLISHMENTS. Within the framework of the policy for development of the established health infrastructure, the Ministry of Health and Guatemalan Institute of Social Welfare and other Sector institutions must bring to practice a plan for the shared use of their health establishments, based on the health model defined by the Ministry of Health and according to care level.

ARTICLE 157. HEALTH CARE ESTABLISHMENTS. The Ministry of Health is responsible for authorizing and supervising the operation of public and private healthcare establishments depending on the rules that are established.

ARTICLE 158. BIOETHICS COMMITTEE. All hospitals, whether public or private, must have a Bioethics Committee, which will help the patient, family and treating physician within the legal framework to make the most correct decisions.

ARTICLE 159. AUTHORIZATION FOR CONSTRUCTION AND CHANGES. The installation, construction, expansion, modification and transfer of public and private healthcare establishments, no matter what type, will be authorized by the Ministry of Public Health according to the corresponding regulation.

ARTICLE 160. ACCREDITATION OF QUALITY. Every public or private health service must have the certificate of quality accreditation which will be extended by the Ministry of Health.

ARTICLE 161. ALTERNATE SYSTEMS. The State through the Sector will incorporate, regulate and strengthen alternate systems, such as homeopathy, natural medicine, traditional medicine, therapeutic measures and others for healthcare by establishing mechanisms for their authorization, assessment and control.

CHAPTER III
PHARMACEUTICALS AND OTHER RELATED PRODUCTS

SECTION I

PRODUCTS

ARTICLE 162. PHARMACEUTICALS AND OTHER RELATED PRODUCTS. The provisions in this field are aimed at health regulation and health oversight of the production, importation, exportation and marketing of these products. Also to the evaluation of compliance, health registration and inscription of products included in this chapter and the different establishments that produce and market them.

ARTICLE 163. NATURE OF THE PRODUCTS. For the purposes of this Code and its regulations, the following products are understood as included::

a) Medications or pharmaceutical products;

b) Cosmetics, personal hygiene products and products for the home;

c) Stupefactants, psychotropics and their precursors;

d) Phyto- and zootherapeutic products and similar;

e) Pesticides for domestic use;

f) Healing materials;

g) Laboratory reagents for diagnostic use;

h) Dental materials, products and equipment.

ARTICLE 164. DEFINITIONS. For purposes of the application of this Code, the products included in Article 163 of this chapter are defined as follows:

a) Medication or pharmaceutical product: Any simple or compound, natural or synthetic substance or mixture of them designed for persons and having the property of preventing, diagnosing, treating, alleviating or curing sicknesses or symptoms associated with them.

b) Cosmetics, personal hygiene products and products for the home:

Cosmetic: Anything prepared that is designed to be externally applied to the human body for purposes of embellishment, modification of its physical appearance or preservation of normal physiochemical conditions of the skin and its attachments (hair and nails).

Personal hygiene products: All products used for people's hygiene within which are dentifrices, mouthwashes, deodorants, antiperspirants, shaving products and aftershaves, talcum powders, condoms, tampons, disposable diapers, solid and liquid beauty soaps, toothpastes, mouthwash solutions and aerosols.

Home hygiene products: All those products used in home hygiene, including soaps and detergents, environmental deodorants, antiseptics and disinfectants for water and cleaning products for furniture, floors and kitchen appliances.

c) Stupefactants and psychotropics: Substances that affect organic and psychic health, that can create addiction and that are considered as such internationally. The term stupefactant may be applied to substances that belong to different pharmacological categories (analgesics, narcotics, central nervous system stimulants, hallucinogenics and others)…

a) Chemical precursors: Substances that may be used in the manufacture of stupefactants and psychotropics or of substances with similar effects that include their molecular structure into the final product so that they become fundamental for such processes.

d) Phyto- and zootherapeutic products and similar: Any preparation based on plants, algae, mushrooms, or tissue of animal origin having a defined pharmaceutical form attributed therapeutic purposes and whose use is safe.

e) Pesticides for domestic use: « Any substance designed to be applied in the environment of homes, public and private buildings and facilities, industries, private gardens, transportation vehicles, on persons and domestic animals and in public health programs, with the purpose of fighting organisms capable of causing harm to people's health, to flora or objects or transmitting sicknesses to human beings.

f) Healing material: All products used in the medical and dental practice to effect cures, within which can be mentioned: Cotton, gauze, tapes, surgical medical adhesive tapes, suture thread, and all those others included in the respective regulation.

g) Laboratory reagents for diagnostic use: Enzymatic, natural or synthetic chemical substances used for qualitative and quantitative dosing of biological samples and means of cultivation used with diagnostic purposes in vitro;

h) Dental materials, products and equipment: Products designed for use in people and that have the property of preventing, diagnosing, treating, alleviating or curing oral diseases.

ARTICLE 165. OVERSIGHT. The Ministry of Health will maintain control and oversight over the action of these products, according to the inhabitants' health risk, pursuant to the provisions of the respective regulation.

ARTICLE 166.- THE RIGHT TO INFORMATION. All advertising and promotion of propaganda made about products included in this chapter must be governed by ethical criteria, must give the user trustworthy, exact, balanced and up-to-date information so that he can apply its criteria and make the choice most in accord with his interests.

ARTICLE 167. BENCHMARK HEALTH REGISTRATION. The collection of specifications for the product to be registered that will serve as a standard to control it when it is being marketed. The registration will last for five years, so long as it maintains the characteristics of the master sample and meets the standards for quality and safety. Otherwise, sanctions that this code establishes will be applied. The registration must be made under the responsibility of a university professional from the concern, according to the provisions of the corresponding regulation.

ARTICLE 168. INSCRIPTION. The process by which a product is inscribed with the responsible institution designated by the Ministry of Health, stating the company and the responsible professional for the record. The regulation will establish the requirements necessary for such a purpose and the analysis to be done, according to risk criteria.

ARTICLE 169. BENCHMARK HEALTH REGISTRATION AND REQUIRED INSCRIPTION.
All products in this chapter must, prior to their marketing and pursuant to the provisions of the respective regulation, have:

a) Obligatory registration at the Ministry of Health:

Phyto- and zootherapeutic products and similar;

Healing material and others;

Cosmetics, personal hygiene products and products for the home;

Dental materials, products and equipment;

Laboratory reagents for diagnostic use;

b) Benchmark health registration:

Medication or pharmaceutical product;

Stupefactants and psychotropics;

Pesticides for domestic use.

ARTICLE 170. QUALITY RESPONSIBILITY. For the products in this chapter, manufacturers and importers will be directly responsible for their safety and quality. If the products do not comply with such characteristics and cause damage to health and the environment, those responsible will be sanctioned according to the specifications of this law.

ARTICLE 171. HEALTH CERTIFICATION. The Ministry of Health will establish safe and agile mechanisms to oversee and control the quality and safety of products included in this title, and to fulfill this requirement it will extend the corresponding document in the shortest time possible, according to the period fixed in the respective regulation.

SECTION II
PHARMACEUTICAL PRODUCTS OR MEDICATIONS

ARTICLE 172. NATIONAL MEDICATIONS PROGRAM. The Ministry of Health will establish a national medications program that will allow implementation of the medications policies, including their selection, quality, supply, production, marketing and domestic use, promoting social participation with the primary purpose being public access to quality medications. It will also designate the offices charged with these duties.

ARTICLE 173. RATIONAL USE OF MEDICATIONS. The Ministry of Health will regulate the supply, prescription, promotion and proper use of medications according to the healthcare levels and steps of complexity established in the healthcare model.

ARTICLE 174. ASSESSMENT OF COMPLIANCE. All medications on the market may be subjected to evaluation that guarantees their quality, effectiveness and safety levels, according to the master established in the benchmark health registration. The corresponding regulation establishes the procedures to be applied.

ARTICLE 175. INTERNATIONAL AGREEMENTS. International agreements or treaties signed by Guatemala on medications will include aspects of their legislation, strengthening, safety, quality and efficacy and a reciprocal treaty for Guatemalan products and imported products, through procedures reconciled and approved by the Ministry of Health.

ARTICLE 176. PRODUCTION AND DISTRIBUTION. Entities that produce and distribute medications must guarantee that they are prepared according to good manufacturing, laboratory and storage practices and likewise, those established in the respective regulation.

ARTICLE 177. BENEFITS. It is forbidden to change prescriptions prescribed by health professionals in exchange for economic or material benefit to the owners or employees of the establishment. The sanctions handed down for this failure will be applied both to the one who receives the benefit and the one who grants it, according to the book of sanctions in this Code.

SECTION III
STUPEFACTANTS AND THEIR PRECURSORS

ARTICLE 178. THERAPEUTIC GOALS. Any act related to stupefactants, psychotropics and their precursors may only be taken with therapeutic or industrial purposes after authorization from the Ministry of Health, in coordination with other institutions, according to their competency. Control will be exercised according to the Political Constitution and other laws of the Republic, this Code and other regulations and resolutions issued by the Ministry of Health and with the norms established in international treaties, conventions and agreements ratified by Guatemala.

ARTICLE 179. OVERSIGHT. The Ministry of Health is in charge of overseeing the production, fabrication and importation, marketing and distribution of stupefactants, psychotropics and their precursors according to domestic legislation and prevailing international treaties.

ARTICLE 180. CROPS. The cultivation and harvest of the poppy (Papaver somniferum), coca (Erythroxilon coca), hemp and marijuana (Cannabis indica and Cannabis sativa), poppy [amapola] and others that the law determines is prohibited and subject to destruction by the competent authority. Also forbidden is the trafficking and use of seeds and phytogenetic material with the germination capacity of the aforementioned plants, their resins and oils.

ARTICLE 181. CONSUMPTION FOR THERAPEUTIC PURPOSES. Personal use of stupefactants and psychotropics will be permitted only when done for therapeutic purposes and under prescription and medical oversight. Their prescription must be subjected to the corresponding regulations. Their prescription will be restricted to the professional who is legally authorized for the purpose.

SECTION IV
PHARMACEUTICAL ESTABLISHMENTS AND SIMILAR

ARTICLE 182. DEFINITION. Pharmaceutical establishments are production and control laboratories for pharmaceutical products and similar, drug stores, distributors, pharmacies, dental warehouses and sales of medicines. Its classification and definition will be detailed in the respective regulation according to the type of operation being performed.

ARTICLE 183. AUTHORIZATION. All establishments to which the above article refers require the health license issued by the Ministry of Health through the corresponding office for their setup and operation, which will be extended in the fixed time period and according to the rules established by the regulation. The health license will be valid for five (5)

years with the establishment subject to control during that period. In the event of non-compliance with the corresponding health laws or regulations, it will be obligee to the sanction this Code establishes.

ARTICLE 184. TECHNICAL DIRECTION FOR ESTABLISHMENTS. Pharmaceutical establishments will be under the technical direction of a university profession from the concern, exceptions being those included in the respective regulation. This professional must ensure the mechanisms for supervision of the establishments under his charge, and he will respond jointly with the owner, representative or manufacturer for the identity, purity and good condition of products that are fabricated, transformed, prepared, imported, exported, analyzed, stored, distributed or dispensed, according to the nature of the establishment.

ARTICLE 185. RESPONSIBILITY. Any of the people to whom the above article refers will be responsible when they become involved in the commission of events sanctioned by criminal, civil or administrative laws.

SECTION V

DONATED MEDICATIONS

ARTICLE 186. DONATION OF MEDICATIONS. The Ministry of Health will formulate the policies, standards and procedures for the donation of medicines, which must include the unsatisfied needs of the public in this area, standards of quality and effective communication among donors and the country's health authorities.

ARTICLD 187. CRITERIA FOR SELECTION. All donations of medications must be based on expressed needs and be commensurate with the country's disease rate. Donated medications or their generic equivalents must be approved in the donor country and in the receiving one for clinical use.

ARTICLE 188. QUALITY CRITERIA. All donated medicines must come from a trustworthy source and adapt to national standards, or lacking these, to internationally recognized quality standards. Donations must be medically first class.

CHAPTER IV
ACTIONS OF HEALTH REHABILITATION

ARTICLE 189. ESTABLISHMENT OF CENTERS. The Ministry of Health, in conjunction with other institutions making up the Sector, will promote the establishment of physical, psychological, social and occupational rehabilitation centers and services, as well as disability prevention programs.

ARTICLE 190. COORDINATION OF ACTIONS. The Ministry of Health through its competent bodies will procure on its own or through coordinated actions with other institutions the physical and mental rehabilitation of people showing a reduction in their physical, intellectual and mental capacities as a result of disabling, congenital or acquired disorders.

ARTICLE 191. DEFINITION. Minors are considered to be in a special situation when they lack proper protection, suffer or are exposed to suffering deviations or disturbances in their development or their physical or mental state and also when they are in situations of abandonment or danger, according to special laws.

ARTICLE 192. CARE OF MINORS. The Ministry of Health, in coordination with other Sector institutions and non-governmental bodies, will offer protection, assistance and rehabilitation to special behavior minors and will be aided in competent courts in the fulfillment and carrying out of the measures they decree. It will also undertake actions designed to suppress or reduce the causes that interfere with normal physical, mental and social development of minors and people who due to their social condition are affected in their personal development.

CHAPTER V
UNIVERSITY, TECHNICAL AND ASSISTANT HEALTH-RELATEDPROFESSIONALS

ARTICLE 193. PRACTICE AND REGISTRATION OF UNIVERSITY PROFESSIONALS. Only those who possess the corresponding title or respective incorporation from the University of San Carlos of Guatemala and are actively

admitted to the profession, in the case of university professions, may practice health-related professions. The Ministry of Health will keep a record of such professionals.

ARTICLE 194. REGISTRATION AND PRACTICE OF TECHNICAL, INTERMEDIATE AND ASSISTANT DEGREES. Those who verify their training at institutions authorized or created by the Ministry of Health, the Ministry of Public Education, the nation's universities and the Guatemalan Institute of Social Welfare will be recognized and registered to practice technical, intermediate and assistant degrees.

ARTICLE 195. PRACTICE OF OTHER PROFESSIONS AND TRADES. The Ministry of Health will regulate the performance of physical therapists, masseurs and masseuses, operators of beauty and personal hygiene salons, manicurists, pedicurists, kinesiologists, midwives, acupuncturists, chiropractors, naturopaths, homeopaths and others that carry out direct care activities to people,.

CHAPTER VI
DIAGNOSTIC SUPPORT UNITS FOR THE TREATMENT OF SICKNESS

SECTION I
HEALTH LABORATORIES

ARTICLE 196. DEFINITION. Public and private health laboratories are those that practice and analyze human and animal specimens for the diagnosis, follow-up, treatment and prevention of disease for purposes of medical research and public health, certification of the status of people’s health and judicial proceedings, and classifying them as follows:

a) Pathology anatomy laboratories: Those performing examinations of tissues of human origin meant for diagnosis or research in order to determine structural changes through tissues obtained through surgery, biopsy or necropsy, covering macroscopic and microscopic pathology changes.

b) Clinical laboratories: Those who perform examinations designed for diagnosis or research in the fields of biochemistry, biophysics, hematology, immunology, parasitology, virology, bacteriology, mycology, coprology, urology, cytology, radioisotopes and others in samples of human origin.

c) Forensic laboratories: Those which through the application of anatomical-pathological, histopathological, chemical and toxicological technical methods and others perform examinations for judicial research-related matters.

ARTICLE 197. APPROVAL FOR THEIR OPERATIONS. The Ministry of Health will be responsible for approving the operation of public and private health laboratories, according to the requirements established in the respective regulation.

ARTICLE 198. LABORATORY NETWORK. The Ministry of Health, in coordination with the Guatemalan Institute of Social Welfare and non-governmental organizations, will adapt public and private laboratory networks nationwide, based on profiles of growing complexity, linking it to the network of health establishments, promoting with this organization the user public's access to different types of services it requires.

ARTICLE 199. PROFESSIONALS IN CHARGE OF THE LABORATORIES. The management of every health laboratory must be by a professional who is a specialist in the matter, an active licensee, as established in the respective regulation.

ARTICLE 200. JOINT RESPONSIBILITY. The owner of the laboratory that fails to obey the provisions governing its operation will be jointly responsible with its Director for any harm or damage it may cause.

SECTION II

BLOOD BANKS

ARTICLE 201. DEFINITION. Blood banks and medical transfusion services are centers where the proper procedures are practiced for the utilization of human blood for therapeutic and research use.

ARTICLE 202. REGULATION OF THE BANKS. The establishment and operation of medical transfusion services and blood banks are regulated by the respective law.

ARTICLE 203. PENALTIES. Failure to observe the provisions in this law will be sanctioned as stipulated in the respective book of sanctions.

SECTION III

THE DISPOSAL OF ORGANS AND TISSUES

ARTICLE 204. REGULATION. The disposal of organs and tissues is regulated in the respective law.
ARTICLE 205. PENALTIES. Failure to observe the provisions in this law will be sanctioned as stipulated in the respective book of sanctions.

SECTION IV

RADIOACTIVE FORCES, EQUIPMENT THAT GENERATES IONIZING AND NON-IONIZING RADIATION AND PERSONS EXPOSED TO RADIATION

ARTICLE 206. COMPLIANCE WITH THE RULES. It is obligatory to comply with the provisions issued by the Ministry of Energy and Mines through the competent authority concerning direct and indirect ionizing radiation in order to prevent radiation accidents.

ARTICLE 207. CONTROLS. The Ministry of Health will be in charge of medical oversight and pre-occupational and occupational tests that include clinical and laboratory tests on people who through their jobs may be exposed in the future to ionizing radiation. The Ministry of Energy and Mines, through its competent office, will be in charge of radiology oversight. Any person exposed to ionizing radiation must be monitored through a personal dosimeter system according to the ruling from the competent authority.

ARTICLE 208. AUTHORIZATION FOR HANDLING. Anyone who performs activities of importation, exportation, fabrication, storage, transportation, marketing, supply, maintenance, installation, operation, irradiation of foods and other products, produces, uses, handles, applies or works in other activities related to radioactive sources or equipment that generates ionizing radiation for medical, industrial research, commercial or defense purposes may only do so with the authorization of the Ministry of Energy and Mines when it corresponds to the Ministry of Health.

ARTICLE 209. RADIATION EXPOSURE. No one for occupational reasons, or the general public, may be subjected to the risk of ionizing and non-ionizing radiation exposure that exceeds the dose limits internationally established and those domestically set by the Ministry of Energy and Mines through its competent office.

ARTICLE 210.- SAFETY MEASURES. Institutions or establishments in which workers manipulate radioactive substances or radioactive sources and where equipment generating ionizing radiation are operated will be responsible for seeing that in the establishment under their charge, precautionary steps and protection of the staff are taken by providing them with equipment and means of protection, periodic health checkups and continuous training on safety and hygiene for ionizing radiation. Institutions and persons involved in the handling of radioisotopes and ionizing radiation must have the respective license on which are specified the requirements that the facilities, radioactive sources and equipment generating ionizing radiation must meet.

ARTICLE 211. MEETING REQUIREMENTS. Importation of radioactive articles and electronic devices, as well as fluoroscopes, microwaves or goods for commerce and industry, such as lasers or microwave communications devices, will guarantee that such goods meet all requirements so that emitted radiation is within existing standards and meet the country's provisions. The Ministry of Health is required to report on the risks posed to health by the use of such articles.

ARTICLE 212. SIGNAGE ABOUT THE TYPE OF RADIATION. People who sell or distribute the goods referenced in the preceding article will guarantee that such goods are not banned in the country of origin and bear the signage with information in Spanish on the type of radiation they emit with the appropriate danger warnings.

SECTION V
EQUIPMENT, INSTRUMENTS, PROSTHESES, FUNCTIONAL AIDS AND OTHER HEALTHCARE SUPPLIES

ARTICLE 213. MINISTRY OF HEALTH AUTHORIZATION. The activities of importation, fabrication, marketing and supply, including in the form of donation from a domestic or foreign institution, will require authorization from the Ministry of Health and compliance with the requirements that it can show to safeguard people's lives.

ARTICLE 214. BANS. It is forbidden to import, market and supply, including in the form of a donation from a domestic or foreign entity or institution, the goods cited in this section when they are banned in the country of origin, are in a bad state of repair, are defective in operation or lack the proper labeling that shows their nature or characteristics and are without the manufacturer's instructions in Spanish for their correct use and to prevent the risks they may involve.

ARTICLE 215. QUALITY GUARANTEE CONTROL. The Ministry of Health, through its corresponding offices, will control that equipment and supplies have the manufacturer's quality guarantee, that there is local supply of replacements, maintenance and the warning written in Spanish on the risks they pose, should that be the case.

BOOK III
HEALTH VIOLATIONS AND THEIR SANCTIONS

SOLE TITLE

CHAPTER I

GENERAL PROVISIONS

ARTICLE 216. VIOLATION CONCEPT, Any action or omission that involves a substantial or formal violation of legal norms related to the prevention, promotion, recovery or rehabilitation of health constitutes a punishable violation by the Ministry of Health to the degree and scope established in this Code, its regulations and other health laws.

If from the investigation performed by the Ministry the commission of a crime described in criminal laws is presumed, its hearing and penalty pertain to the competent courts.

Ministry of Health officials and employees who in the performance of their duties learn of the commission of a deed that may be a crime, they must report it immediately to the competent authority under penalty of becoming involved in responsibility.

ARTICLE 217. CONFLICT OF LAWS. Should there be a conflict of laws on violations and sanctions against health, the standards in this Code will prevail over those of any other kind.

ARTICLE 218. RESPONSIBILITY. Individuals or legal entities who directly or indirectly become involved in violations established in this Code and other health laws are considered the responsible perpetrators. Also considered the responsible perpetrators are the legal representatives, professionals or technicians and subordinate staff who cooperate in the active or passive commission of violations.

ARTICLE 219. PENALTIES. The following sanctions will be imposed for violations established in this Code, its regulations and other prevailing health laws, standards and provisions:

a) Written warning formulated by the official or employee duly authorized by the Ministry of Health, in advance and in writing, according to the procedural rules established in this book.

b) Fine, which will be graduated between the equivalents of two to one hundred fifty prevailing minimum monthly salaries for non-agricultural activities, so long as it does not exceed ten percent of the value of the good or service, except for exceptional cases established in this Code.

c) Temporary closure of the establishment for a period no less than five days and no greater than six months, with respective suspension of the health license and, when appropriate, of the benchmark health registration of the products the offender prepares or markets.

d) Cancellation of the health registration for commercial purposes for products which are subject to the control of this Code.

e) Final closure of the establishment.

f) Seizure of the raw materials, foods, medications, instruments, materials, goods and other objects related to the committed violation. When the confiscated objects are not of legal commerce, the authority will decree their seizure, even when they belong to a third party.

g) Ban on temporarily performing an activity or trade.

h) Publication in the two daily newspapers with the highest circulations and at the offender's expense of the final decision on what the imposed sanction consists of in cases established by the respective regulation.

If the offender does not correct the failure with the written warning, when it is legally proper, one or more of the sanctions established in this article will be imposed upon him, keeping in mind the type of violation, the risk or harm caused to people's health, its transcendence to the public and the value of the goods subject to the violation.

ARTICLE 220. REPEAT VIOLATION. A repeat offender is the person who, after having been sanctioned for a health violation, commits the same violation.

In the case of violations sanctioned with a fine, the repeat offender will be sanctioned additionally with an increase of one hundred percent of the first imposed fine, or he will be imposed another kind of sanction from those indicated in Article 219 of this Code.

ARTICLE 221. CAUSES FOR TERMINATION OF RESPONSIBILITY. The responsibility for violations and sanctions established in this Code, its regulations and other applicable health laws, standards and provisions are terminated in the following cases:

a) Compliance with the sanction;

b) Lapse of responsibility; and

c) Lapse of the sanction.

ARTICLE 222. LAPSE. The responsibility for violations and the sanctions established in this Code and other health laws lapse after five years have passed, which begin counting from the date on which the violation was committed and any sanction is imposed, from the date on which the offender was notified of the decision imposed on him.

The period of lapse is interrupted by:

a) Notification to the offender of the order of instruction of the procedure to determine his responsibility.

b) Notification of the decision that determines the offender's responsibility and the sanction imposed upon him.

c) Express or tacit acknowledgement by the person shown as the offender that he committed the violation.

d) Due to any act or written measure by the person shown as the offender in the administrative file or any other type of action caused by an official or professional who is invested with the public faith.

e) The offender waives the statute of limitations completed on his behalf when its time period is up, accepts paying or pays in full or in part the fine imposed, if that was the sanction, or accepts complying with the imposed sanction, if it is another of the types regulated in this Code, its regulations, other health laws, standards and applicable provisions.

CHAPTER II

SPECIAL PART

SECTION I
BREACHES SANCTIONED WITH FINE

ARTICLE 223. VIOLATIONS AGAINST THE PROMOTION OF HEALTH. He who contravenes the provisions established in this Code, its regulations, other laws that promote health, standards or applicable provisions commits a violation against the promotion of health. He who commits one of these violations will be sanctioned with the corresponding fine, according to the values indicated in Article 219 subsection b) of this law.

ARTICLE 224. (Last paragraph amended by Article 4 of Decree 50-2000 by the Congress of the Republic). **SPECIAL CASES.** The following actions constitute special cases of violations against health:

1. Selling alcoholic beverages or tobacco in any of its forms or commercial formulations with toxic substances to minors.

2. Allowing the use of alcoholic beverages or tobacco in any of its forms to minors in any establishment, open or closed, or in the public street.

3. Omitting on the container or product label or in each advertisement for alcoholic beverages the indication in legible font that excess consumption is damaging to health.

4. Omitting on the product pack or each advertisement for cigarettes and other tobacco products the indication with legible font and in Spanish that its use is damaging to health.

5. Smoking in government establishments, public or private group transportation, educational centers at the preprimary, primary and middle levels, and in gas stations.

6. Smoking in public and private medical care centers and places where food is prepared and consumed, unless it is done in areas adapted for the purpose.

7. Smoking in those places where it is clearly indicated that smoking is banned.
8. Hiring and broadcasting advertising spaces containing messages that are harmful to individual or the collective public health.

He who commits these and the violations listed in Article 51 of this Code will be sanctioned with a corresponding fine, according to the values shown in Article 219 subsection b) of the Health Code. Violation of the ban on sales to minors under the age of eighteen will bring about application of a fine of FIVE THOUSAND QUETZALS (Q. 5,000.00) when dealing with commercial establishments, ONE HUNDRED THOUSAND QUETZALS (Q. 100,000.00) when the sale is promoted or done directly by manufacturers, importers and distributors through promotions or distributions to the public. An equal sanction will be applied when such a distribution is made in any of its forms by other agents for propaganda or promotional purposes. The Ministry of Public Health and Social Welfare will ensure that the provision is observed and fulfilled.

Subsequent cases of recidivism will cause the imposed fine to double the first time, and if the law continues to be broken, the procedure will pursuant to Article 229 of the Health Code.

ARTICLE 225. VIOLATIONS AGAINST THE PREVENTION OR PROTECTION OF HEALTH.
He who contravenes the preceptive or prohibitive provisions established in this Code, its regulations, other laws that prevent or protect health, standards or applicable provisions commits a violation against the prevention or protection of health.

He who commits one of these violations will be sanctioned with the corresponding fine, according to the values indicated in Article 219 subsection b) of this Code.

ARTICLE 26. SPECIAL CASES. The following actions constitute special cases of violations against the prevention of health:

1. If officials and responsible employees from public or private health establishments and institutions neglect reporting preventable or communicable diseases, including diseases related to public and veterinary health of which they have knowledge.

2. If the competent health authority fails to inform the establishment in which a person works when it is found that he suffers from a venereal disease or any other sexually communicable disease.

3. If the responsible person from the establishment whose activity raises the risk of contagion of venereal diseases or of any other sexual transmission fails to register the persons who work there with the competent health authority.

4. If the competent health authority neglects periodic supervision of the establishments where through his activity the risk of contagion of venereal disease or any of a sexual contagion is greater.

5. If health personnel from the different public or private institutions who manage organs, organic and hemo-derived fluids, and those who perform acupuncture, piercings and tattoos or any other procedure involving the possibility of contagion of the acquired immunodeficiency virus, fail to comply with the universally accepted standards on biosafety and those established by the Ministry of Health.

6. Doing tests for the clinical diagnosis of acquired immunodeficiency virus, beyond the cases of exception regulated in the law on the matter.
7. If professionals related to the handling of acquired immunodeficiency disease fail to inform the Ministry of Health of the cases of infection to be recorded, according to the law on the matter.

8. If agroindustry or any other kind of company fails to comply with the access to potable water services for their workers and economic subordinates.

9. Felling trees within twenty-five meters contiguous to the banks of rivers, streams, lakes, ponds, springs and water sources.

10. Authorizing or allowing the felling of trees within twenty-five meters contiguous to the banks of rivers, streams, lakes, ponds, springs and water sources.

11. If individuals or public or private legal entities omit the purification of water designed to supply the public.

12. Putting water supply projects into operation without having the certificate issued by the Ministry of Health that registers its potability for human consumption.

13. If individuals or public or private legal entities connect services of potable water without observing the corresponding regulatory standards.

14. Suspending water services to the public, except in cases of *force majeure* or when delay or fraudulent use by the user is duly proven.

15. Using contaminated water for the cultivation of vegetables or the preparation of food products for human consumption.

16. Preventing Ministry of Health officials or employees from inspecting potable water provisions and supplies at any time of day.

17. Discharging contaminants of industrial origin or using untreated wastewater without the favorable ruling from the competent authority into rivers, streams, lakes, ponds, springs or water sources.

18. Discharging untreated wastewater into rivers, lakes, streams and ponds or bodies of water, whether these are on the surface or underground.

19. Disposing of excrement in public places, common lands or vacant lots.

20. Building private systems for the disposal of excrement without obeying the provisions established by the Ministry of Health on the matter.

21. Taking advantage of thermal waters, building, installing or putting into operation swimming pools and public baths without having the ruling and approval from the competent authorities.

22. Failure to comply with established health standards for the construction of works for the elimination and disposal of excrement and waste water.

23. Issuing licenses for construction, repair or modification of public or private works designed for the elimination or disposal of excrement without having the favorable technical ruling from the Ministry of Health.

24. If property owners fail to connect their sanitary facilities to the public sewage system in populations where sanitary sewers exist.

25. If property owners in those populations where there is no sanitary sewer system do not meet the standards established by the Ministry of Health for the use of private excrement disposal systems.

26. Using places for the disposal of solid waste without requesting a prior ruling from the Ministry of Health and the National Environmental Commission.

27. If the official or responsible employee fails to comply with issuing a ruling within the legal time periods when it is requested for the use of thermal waters, the construction of swimming pools or public baths, or the disposal of solid waste.

28. Building private systems for the disposal of excrement without obeying the standards established by the Ministry of Health on the matter.

29. Throwing out or accumulating solid waste of any kind in unauthorized places, around inhabited areas or at sites where harm to the people's health, ornamentation or the landscape may be caused by using improper methods for its transportation and storage or undertaking its use, treatment or final disposal with the corresponding municipal authorization.

30. If owners or holders of plots of land, sites or open spaces in urban and rural areas keep solid waste, undergrowth and standing water.

31. Storing and eliminating organic materials or toxic or radioactive substances or those capable of disseminating pathogenic elements and the waste produced in normal activities from public or private hospitals in a forms and places other than those established in the respective regulation.

32. Storing, transporting, transforming or disposing of any type of residue or solid waste by industrial or commercial companies without having proper systems for this purpose, as established in the respective regulation.

33. If public and private hospitals omit the installation of incinerators for the management and final disposal of hospital waste.

34. Creating environmental contamination breeding grounds by the failure to observe the standards regulating activities of collection, transportation, deposit or elimination of solid waste from agricultural and fishing activities.

35. Permanently installing stables for horses, cattle, pigs and sheds in urban areas.

36. Installing temporary stables for horses, cattle, pigs and sheds without authorization form the competent authority.

37. Putting food processing plants of all types for human consumption into operation without having a favorable ruling from the competent authority.

38. Opposing inspections related to the processing, distribution, and marketing and, in general, control of the quality and harmlessness of foods.
39. Marketing a food product with a commercial name without having the authorization, registration or health certification issued by the Ministry of Health.
40. Failing to comply with health rules and regulations at the expense of quality or harmlessness of a food product registered with a commercial name.
41. Identifying the contents, composition and specific health indications of food products in a language that is not Spanish.
42. Modifying the features of a product with regard to the specifications established in the benchmark health registration or obligatory inscription of foods, medications, cosmetics, personal and home hygiene products, pesticides for household use, stupefactants, psychotropics, phyto- and zootherapeutic, homeopathic or similar products, healing materials or dental materials and equipment.
43. Advertising or labeling foods with different information or that may lead to deceit about their nature, ingredients, quality, contents, property or origin.
44. Using containers or packages that negatively alter the quality of the food products.
45. Modifying or moving establishments that prepare or dispense foods without the corresponding authorization. ^
46. Omitting constant verification of the state of health of people who work in food establishments or dispensaries.
47. Failure to comply or allowing the non-observance of health rules or regulations or technical specifications established for the operation of food establishments.
48. Impeding the health inspection of establishments and places of transitional storage, taking product samples and their health control.
49. Distributing or allowing the distribution of donated food whose harmlessness and quality are not guaranteed.
50. Importing toxic, radioactive or hard-to-degrade waste.
51. Failing to meet the provisions issued by the Ministry of Energy and Mines on direct or indirect ionizing radiation.
52. Omitting, in establishments that use radioactive products, compliance with precautionary, protective or periodic health control measures for the staff exposed to radiation.
53. Importing and marketing radioactive articles, electronic devices or goods for business or industry that emit radiation in unpermitted doses.
54. Omitting information to the user about the health risks posed by the use of radioactive articles and electronic devices.
55. Marketing or distributing radioactive articles or electronic devices that are banned in the country of origin.
56. Importing, exporting, fabricating, storing, transporting, marketing, supplying or using radioactive sources or equipment for medical, research, industrial, commercial or defense purposes
that generate ionizing or non-ionizing radiation without authorization from the Ministry of Energy and Mines or the Ministry of Health, when appropriate.
57. Exposing people to ionizing and non-ionizing radiation in internationally unacceptable doses or not approved by the Ministry of Energy and Mines.
58. Marketing or distributing radioactive articles or electronic devices without indications in Spanish about the type of radiation they emit and warnings about its danger.

He who commits one of these violations will be sanctioned with the corresponding fine, according to the values indicated in Article 219 subsection b) of this Code.

ARTICLE 227. VIOLATIONS AGAINST HEALTH RECOVERY AND REHABILITATION.
He who contravenes the required or prohibitive provisions established in this Code, its regulations, other health laws, standards and applicable provisions, commits a violation against the recovery and rehabilitation of health. He who commits one of these violations will be sanctioned with the corresponding fine, according to the values indicated in Article 219 subsection b) of this Code.

ARTICLE 228. SPECIAL CASES. The following actions constitute special cases of violations against the recovery and rehabilitation of health:

1. Putting private health services into operation without the certificate of quality accreditation issued by the Ministry of Health.

2. Advertising or commercially promoting foods, medication, cosmetics, personal or home hygiene products, pesticides for home use, phytotherapeutic or homeopathic products or similar, surgical, dental or laboratory reagent medical equipment with incomplete, inexact, outdated or other information about their nature, ingredients, quality, contents, properties or origin that prevents the user from applying his criterion and taking the action most in accord with his interests.

3. Marketing foods, medications, cosmetics, personal or home hygiene products, pesticides for home use, stupefactants, psychotropics, phytotherapeutic, homeopathic products or similar, surgical, dental or laboratory reagent medical equipment for diagnostic use with characteristics other than the master recorded in the benchmark health registration or obligatory inscription, or failing to comply with standards of quality and harmlessness in their fabrication.

4. Marketing cosmetics, personal or home hygiene products, phytotherapeutic, homeopathic products or similar, surgical medical equipment, dental materials, equipment or products without their having been inscribed at the Ministry of Health.

5. Marketing foods with a commercial name, pharmaceutical products or medications, stupefactants, psychotropics or pesticides for home use without having the benchmark health registration.

6. Obstructing or unjustifiably standing in the way of the inscription, benchmark health registration or issuance of the health certification for foods, medications, cosmetics, personal or home hygiene products, pesticides for home use, stupefactants, psychotropics, phytotherapeutic, homeopathic products or the like, surgical medical equipment or dental materials, products or equipment or laboratory reagents.
7. Packaging or marketing medications without heeding the standards and regulations issued by the Ministry of Health regarding their supply, prescription, promotion, presentation, labeling, prospect and proper use.

8. Giving or offering economic benefits or materials to owners or employees of centers that distribute or sell medications in order to influence or encourage the consumer's to substitute medicines prescribed through a prescription for others.

9. Accepting economic benefits or materials by owners or employees of centers that distribute or sell medications in order to influence or encourage the consumer's to substitute medicines prescribed through a prescription for others.

10. If the university professional from the concern and other responsible persons included in the respective regulation neglects supervision of a pharmaceutical establishment while it is open to the public or carrying on its operations.

11. Putting pharmaceutical establishments into operation with having prior authorization from the Ministry of Health.

12. Installing or putting public or private health laboratories into operation without the corresponding authorization.

13. Transplanting organs or tissues among living persons without having the donor's and recipient's express prior consent in writing.

14. Transplanting organs and tissues from human beings or cadavers without having a favorable ruling from at least three doctors and surgeons who specialize in the matter who are recognized as such by the College of Physicians and Surgeons.

15. Putting organ and tissue banks into operation without having the corresponding authorization from the Ministry of Health.

16. Failure to comply with the requirements established by the Ministry of Health for the operation of organ and tissue banks.

17. Using cadavers from known persons for transplant, research or teaching purposes without the prior consent given in life and not revoked or from legally close enough relatives in the absence of consent granted during life.

18. Using organs, tissues, instruments, equipment, substances, products or devices that may be harmful to the donor or recipient's health.

19. If services for medical transfusions and blood banks select blood donors without heeding the requirements, standards and techniques established in the respective regulation.

20. Selling or buying blood and its derivatives for therapeutic purposes or scientific research.

21. Supplying blood or its derivatives destined for abroad, except for the exceptions established in the specific law regulating the matter.

22. Putting medical transfusion services and blood banks into operation without the corresponding authorization from the Ministry of Health.

23. Failure to comply with the requirements established by the Ministry of Health for the operation of medical transfusion services and blood banks.

24. Importing, fabricating, marketing or supplying equipment, instruments, prostheses, orthotics, aids and other healthcare supplies without the corresponding authorization.

25. Importing, marketing or supplying, even in the form of a donation, equipment, instruments, prostheses, orthotics, aids and other healthcare supplies that are banned in the country of origin, in a bad state of repair, with operating defects or without the indication of their nature, characteristics and instructions in Spanish for the correct use and warnings about the risks they can cause.

He who commits one of these violations will be sanctioned with the corresponding fine, according to the values indicated in Article 219 subsection b) of this law.

SECTION II
VIOLATIONS SANCTIONED WITH TEMPORARY CLOSURE OF THE ESTABLISHMENT

ARTICLE 229. (Numeral 7 is added for Article 5 of Decree 50-2000 by the Congress of the Republic). **TEMPORARY CLOSURE.** He who commits, among others, any of the following violations, in addition to the corresponding fine, will be sanctioned with temporary closure of the establishment for a period of from five days to six months:

1. Noncompliance with the health standards established for the operation of establishments dedicated to the sex business.

2. Keeping health laboratories operating that are not under the responsibility, management or constant supervision of a professional specialist on the matter.

3. Failing to meet the requirements of technical demands established by the Ministry of Health for the operation of health laboratories.

4. Failure to comply with the requirements established by the Ministry of Health for the operation of organ and tissue banks.

5. Failure to comply with the requirements established by the Ministry of Health for the operation of medical transfusion services and blood banks.

6. Establishing through health inspection the presence of an imminent health danger to users or workers of the establishment due to *force majeure* or unforeseeable circumstances or through noncompliance with the health rules and regulations or technical specifications established for the opening or operation of a food establishment.

7. Recidivism more than twice of the violation or infraction of the prohibitive rules and provisions to which numerals 1, 2, 3 and 8 of Article 224 of this Code refer will cause the offender to have applied temporary closure of the establishment at which the violation was committed, as well as the established sanctions. When the closure or suspension is up, opening will be done under the authorization of the Ministry of Public Health and Social Welfare.

SECTION III
VIOLATIONS SANCTIONED WITH FINAL CLOSURE OF THE ESTABLISHMENT

ARTICLE 230. FINAL CLOSURE OF THE ESTABLISHMENT. He who commits, among others, any of the following violations will be sanctioned with closure of the establishment in addition to the fine:

1. Allowing a person who is infected with a venereal disease or another one that sexually transmitted to have a sex business.

2. Putting into operation a water supply business without having the authorization and corresponding certificate issued by the Ministry of Health.

3. Putting food processing plants of another type of food establishment of any type for human consumption into operation without having a health license issued by the competent authority.

4. Setting up pharmaceutical establishments without authorization from the Ministry of Health.

5. Setting up or putting public or private health laboratories into operation without the corresponding authorization.

6. Putting public or private health services into operation without having the certificate of quality accreditation issued by the Ministry of Health.

7. Putting public or private healthcare establishments into operation without having prior authorization from the Ministry of Health.

8. Putting organ and tissue banks into operation without having the corresponding authorization from the Ministry of Health.

9. Putting medical transfusion services and blood banks into operation without having the corresponding authorization from the Ministry of Health.

10. Maintaining organ and tissue banks in operation that pose a serious danger to the health of donors or recipients.

11. Maintaining organ and tissue banks in operation that pose a serious danger to the health of donors or recipients.

12. Selling or marketing any human organ or tissue.

13. Acquiring blood and its derivatives for valuable consideration.

14. Exposing people in establishments who use radioactive products to ionizing and non-ionizing radiation in doses internationally unacceptable or nationally set by the competent authority from the Ministry of Energy and Mines.

15. In establishments that use radioactive products, neglecting to comply with the precautionary steps, protection or periodic control of health for the staff exposed to radiation.

SECTION IV
VIOLATIONS SANCTIONED WITH CANCELLATION OF THE BENCHMARK HEALTH REGISTRATION OR OBLIGATORY INSCRIPTION

ARTICLE 231. ANNULMENT OF THE BENCHMARK HEALTH REGISTRATION OR OBLIGATORY INSCRIPTION. He who reoffends in the commission of the following violations will be sanctioned with annulment of the benchmark health registration or obligatory inscription, in addition to the corresponding fine:

1. Failing to comply with health rules and regulations at the expense of quality or harmlessness of a food product registered with a commercial name.

2. Identifying the contents, composition and specific health indications of food products in a language other than Spanish.

3. Marketing foods, medications, cosmetics, personal or home hygiene products, pesticides for home use, stupefactants, psychotropics, phytotherapeutic, homeopathic products or similar, surgical, dental or laboratory reagent medical equipment for diagnostic use with characteristics other than the master recorded in the benchmark health registration or obligatory inscription, or failing to comply with standards of quality and harmlessness in their fabrication.

4. Advertising or labeling foods with different information or that can lead to deceit about their nature, ingredients, quality, contents, property or origin.

5. Using containers or packages that negatively alter the quality of the food products.

SECTION V
BREACHES SANCTIONED WITH SEIZURE

ARTICLE 232. SEIZURE. Besides the corresponding fine, seizure will be applied to the objects subject to any of the following violations, among others:

Using raw materials, containers or packing, instruments, materials and objects that alter the quality or harmlessness of food products.

Distributing domestically produced or imported foods that do not meet the requirements for quality and harmlessness, or when its contents, composition or specific health indications are not described in Spanish.

Distributing or allowing the distribution of donated food whose harmlessness and quality are not guaranteed.

Packaging or marketing medications without heeding the regulatory standards issued by the Ministry of Health regarding the supply, prescription, promotion, presentation, labeling, prospect and proper use of same.

Marketing cosmetics, personal or home hygiene products, phytotherapeutic, homeopathic products or similar, surgical medical equipment, dental materials, equipment or products without their having been inscribed at the Ministry of Health.

Marketing foods, medications or pharmaceutical products, stupefactants, psychotropics or pesticides for home use or laboratory reagents without having the benchmark registration.

Using organs, tissues, instruments, equipment, substances, products or devices that may be harmful to the donor or recipient's health.

Importing, exporting, fabricating, storing, transporting, marketing, supplying or using for medical, research, industrial, commercial or defense purposes radioactive sources or equipment that generates ionizing or non-ionizing radiation without authorization from the Ministry of Energy and Mines and, when appropriate, the Ministry of Health.
Importing and marketing radioactive articles, electronic devices or goods for business or industry that emit radiation in unpermitted doses.

Marketing or distributing radioactive articles or electronic devices that are banned in the country of origin.

SECTION VI
VIOLATIONS SANCTIONED WITH THE BAN ON TEMPORARILY PERFORMING AN ACTIVITY OR TRADE

ARTICLE 233. CAUSES FOR THE BAN ON TEMPORARILY PERFORMING AN ACTIVITY OR TRADE. He who commits any of the following violations will be sanctioned with the ban on performing an activity or trade for a period of one to six months:

1. Working in establishments that manufacture, prepare or dispense foods without meeting the personal health requirements that guarantee food harmlessness.

2. Working in hospital centers without periodically verifying their professional or technical currency that guarantees their fitness to serve.

3. Hiring staff that does not verify their professional or technical currency in the specialty they deal with or that allows them to work at hospital centers.

CHAPTER III

PROCEDURAL PROVISIONS

ARTICLE 234. AREA OF APPLICATION. The provisions of this chapter will be applicable to violations, sanctions and crimes regarding health and will have no retroactive effect, unless they favor the offender.

ARTICLE 235. COMPETENCY. Application of the sanctions established in this Code, its regulations, other health laws, rules and applicable provisions pertains to the Ministry of Health, according to the competency assigned in the respective regulation to the bodies composing it, unless the cases constitute a crime. In the administrative paperwork done to determine the commission of a health violation, the competent authority must observe the principles of diligence, speed, impartiality and specialty of action.

ARTICLE 236. INITIATION OF THE PROCEEDING. Public action is granted to report the commission of deeds to the competent authorities from the Ministry of Health that may constitute violations against health as determined in this Code, its regulations, other health laws, rules and applicable provisions. The record must show documentation of the deeds which may constitute violations, and instruction on the corresponding proceedings will be ordered within a period not to exceed three days.

ARTICLE 237. AUTHORIZATION. All proceedings must be initiated by a duly authorized official or employee of the Ministry of Health. This capacity must be verified to the presumed offender. He, his representative, employees or subordinates who are present may intervene and ask that proof he deems proper be left.

Should any inspection document or appearance be nil, a document will be signed stating such a fact. Documents signed by public officials and employees in the performance of their jobs are full proof unless demonstrated otherwise, and they must be filed with the competent authority within twenty-four hours after the action is concluded.

ARTICLE 238. HEARING To impose sanctions for the commission of violations against health, a hearing will be given to the presumed offender by a period of five non-extendable days. If when the hearing is ended, the opening of the discovery process is requested, it will be granted for the absolute period of five days, which will begin starting on the date of the request without need for a ruling or notification. When the time for the end of the hearing has ended or the discovery period has passed, the competent administrative authority will rule with no further paperwork within the next three days and proceed to notify the ruling within no more than the next two days.

The failure of competent officials and employees to comply with the time periods established in this chapter will be sanctioned according to the disciplinary system established in the Law of Civil Service, notwithstanding any criminal or civil responsibilities which may be involved.

The written warning to which Article 219 of this law refers will be formulated to whomever has committed a violation of the provisions of this Code, its regulations, other prevailing health laws, rules and provisions for the first time, and in the case it is ascertained that it has not taken effect within the set time period, imposition of the sanctions that may apply will be undertaken. A written warning will be unnecessary in cases where the committed violation is an imminent danger to people's life, health and safety.

ARTICLE 239. APPLICATION. When the sanctioned judgment is final, the following will proceed:

1. If the sanction consists of the imposition of a fine, it must be paid within the next five days to the tax fund with specific charge to the Ministry of Health, and it will be aimed exclusively at increasing health prevention programs. In the case of non-compliance, the file will be sent to the Office of the Attorney General of the Nation for collection purposes through the coercive-economic route, with the following constituting an executable instrument:

    a) Certification of the ruling that contains the imposed fine.

    b) Certification of the document showing acknowledgement of the debt by way of payment of the fine made by the offender or his legal representative to the competent official or employee.

    c) Notarial document or notarized affidavit fashioned by a notary showing acknowledgement of the debt by way of payment of the fine, made by the offender or his legal representative.

    d) Any other document which by legal provision has executable power.

2. If the sanction consists of the temporary closure of the establishment, when the time period set in the ruling is over and upon request by the offender, its opening and operation will be authorized after proving that the violations which brought about the imposition of that sanction have disappeared.

3. If the sanction consists of the establishment's closure or final closure, at the offender's request and cost, the delivery and acceptance of the goods, furniture, fixtures and equipment included in the establishment will be authorized, proof of which will be left and the file ordered to be closed.

If the sanction consists of annulment of the health license, the offender will be required to turn it over and send it to the office that issued it in order to make the corresponding notation. In case of denial, a report will be sent in order to proceed similarly.

4. If the sanction is seizure of objects and they are of legal trade, they may be donated to public or private charity centers or sold at public auction, so long as the product meets the requirements of quality and harmlessness. Funds obtained will be deposited in tax accounts with specific charge to the Ministry of Health office that created it, which will exclusively designate it for increasing education and training programs and the updating of human resources who work in the hospital network.

If it deals with illegal trade or products that do not meet the requirements for quality and harmlessness, they will be placed at the disposal of the magistrate of the locale so he can proceed according to the law.

5. If the sanction consists of the ban on temporarily performing an activity, profession or trade, the entity that has granted the adaptation will be ordered to control its compliance.

ARTICLE 240. FORMALITIES. The form of the administrative acts and exercise of the right to petition and defense by those administered will be governed by the provisions in the Law of Judicial Review.

FINAL AND TRANSITORY PROVISIONS

ARTICLE 241. – ADMINISTRATIVE SILENCE. All those petitions involving the issuance of a certification, authorization or ruling will be taken as favorable when the competent authority, in accordance with this law and its regulations, does not issue it within the time periods established for such purpose.

ARTICLE 242. EPIGRAPHS. The epigraphs which precede the articles of this law have no interpretative validity and may not be cited with respect to the content and scope of their norms.

ARTICLE 243. REPEAL. Decree Number 45-79 by the Congress of the Republic and all provisions and laws contradicting this decree are hereby repealed.

ARTICLE 244. REGULATIONS. The Executive Branch, through the Ministry of Health, will issue the respective regulations pursuant to the provisions of this law and will readjust those which are necessary for their correct application within a period no greater than three months from when this law takes effect.

ARTICLE 245. TERM OF THE LAW. This law shall take effect three months after the date of its publication in the official gazette.

ARABELLA CASTRO QUIÑONES, PRESIDENT

ANGEL MARIO SALAZAR MIRON
SECRETARY

CESAR FORTUNY ARDON
SECRETARY