

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

FAO/WHO COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN

14th Session

Buenos Aires, Argentina, 29 November - 3 December 2004

INFORMATION AND REPORTS ON FOOD CONTROL AND FOOD SAFETY ISSUES INCLUDING CODEX STANDARDS

GOVERNMENT COMMENTS

(**Brasil**, Chile, **Colombia**, Guatemala, Honduras, **Mexico**, Panama, Paraguay, Venezuela)

BRAZIL

A) OFFICIAL AGENCIES

National food control agencies, including imports and exports

In Brazil, the bodies responsible for food control are the **Ministry of Agriculture, Livestock and Food Supply (Secretariat of Agricultural Protection and Secretariat of Rural Support and Cooperatives)** and the **Ministry of Health (National Health Surveillance Agency)**.

Ministry of Agriculture, Livestock and Food Supply

The general structure of the **Ministry of Agriculture, Livestock and Food Supply (MAPA)** and information on its divisions, sectors and officials can be found on its Web site at:

<http://www.agricultura.gov.br/Html/titulares.asp?nome=&sigla=&funcao=>

The MAPA body responsible for food control is the Secretariat of Agricultural Protection (SDA) whose structure was set out in the Rules of Procedure approved by Edict 319 of 6 May 1996.

The Rules of Procedure can be consulted at the following Web site:

<ftp://ftp.agricultura.gov.br/regimento.doc>

The SDA has three departments: the Department of Animal Protection, the Department of Inspection of Animal Products (DIPOA) and the Department of Plant Protection and Inspection (DDIV).

The functions of the Secretariat of Agricultural Protection include:

- I – providing information for the formulation of agricultural policy on plant and animal protection;
- II – regulating and supervising, under specific legislation:
 - a) plant and animal health protection;
 - b) inspection of animal and animal-based products, beverages, vinegars, wines and wine and grape products;
 - c) control of the production, sale and utilization of veterinary products and pesticides, their components and associated articles;
 - d) laboratory analysis in support of health protection actions, inspection of animal-based products and control of agricultural inputs and beverages, vinegars, wines and wine and grape products.
- III – implementing follow-up action decisions of international organizations and agreements with other governments relating to matters within its competence.

Besides the two Departments directly involved in the control and inspection of animal and plant products, the Cabinet Office of the SDA/MAPA has three Divisions that are responsible for briefing, analysing and advising the Secretary and the Departments on food safety issues:

1. Division on WTO Health Matters;
2. Division on MERCOSUR Health Matters;
3. Division on Technical Cooperation and International Health Agreements.

The SARC has the Department of Promotion and Control of Animal Production, the Department of Promotion and Control of Plant Production and the Department of Cooperatives and Agricultural Association.

Regulatory functions of the Secretariat of Rural Support and Cooperatives include:

- I – helping formulate policy on the production and control of agricultural products, inputs and services and the promotion of plant and animal production, as well as cooperatives and agricultural infrastructure and extension;
- II – overseeing the execution of programmes and actions for the promotion of agricultural and fishery production, agricultural cooperatives and associations, agricultural infrastructure and extension, and the protection, management and conservation of land rehabilitated for agriculture and livestock production;
- III – regulating, through specific legislation, and supervising activities relating to:
 - a) the preservation and enhancement of plant and animal species of economic interest;
 - b) the functioning of horse racing and other horse-riding events;
 - c) the development and promotion of crop, livestock and fishery production;
 - d) control of the production and sale of animal feed, animal breeding materials, seeds and plants, correctives, fertilizers, inoculants and biofertilizers;
 - e) the classification of plant products, by-products and residues of economic value and of professional animal breeding and agricultural mechanization and aviation associations;
 - f) the protection of cultivars and the national registry under Law 9456 of 25 April 1997.

This organizational structure enables the MAPA to control and implement the programmes that need to be applied to the food industry under its institutional responsibility.

IMPORT AND EXPORT

1. The following entities under the **Secretariat of Agricultural Protection** are responsible for the registration, certification, control, accreditation and acceptance of agricultural products for export and/or import:

Department of Animal Protection - DDA

The Animal Laboratory Coordinating Authority (CLA/DDA) is responsible for providing laboratory support for the control of imported products. It has six laboratories and the following basic structure:

Accreditation and Quality Control Service - **SCQ/CLA**

Regional Animal Support Laboratory - **LARA/CLA**

Biological Analysis Section - **SAB/LARA**

Physical and Chemical Analysis Section - **SFQ/LARA**

Animal Support Laboratory - **LAP/CLA**

Department of Plant Protection and Inspection - DDIV

International Affairs Division - **DAI/DDIV**

Plant Protection Coordinating Unit - **CPP/DDIV**

Plant Health Surveillance Division - **DPC/ CPP**

Plant Health Surveillance Service - **SVF/DPC**

Division for the Control of Plant Transit and Quarantine - **DTQ/ CPP**

Pest Risk Analysis Service - **SAR/DTQ**

Plant Transit Control Service – **SFT/DTQ**

Plant Inspection Coordinating Unit - **CIV/DDIV**

Wine and Wine Products Division - **DVIN/ CIV**

Beverages and Vinegar Division - **DBVEN/ CIV**

Registration and Cadastre Service - **SRC/ CIV**

Plant Support Laboratory Coordinating Unit - **CLAV/DDIV**

Regional Plant Support Laboratory - **LARV/ CLAV**

Biological Analysis Section - **SAB/LARV**

Physical and Chemical Analysis Section - **SAF/LARV**

Plant Support Laboratory - **LAV/ CLAV**

Biological Analysis Sector - **SAB/LAV**

Physical and Chemical Analysis Sector - **SAF/LAV**

Department of Inspection of Animal Products - DIPOA

Industrial Operations Division - **DOI/DIPOA**

Meat and Meat Products Inspection Service - **SECAR/ DOI**

Milk and Milk Products Inspection Service - **SELEI/ DOI**

Fish and Fish Products Inspection Service - **SEPES/ DOI**

Technical Standards Division - DNT/DIPOAProduct Standards Service - **SNP/DNT**Equipment Standards Service - **SNE/DNT**Facility Standards Service - **SNI/DNT**International Trade Division - **DCI/DIPOA**Plant Authorization Service - **SHE/DCI**International Agreements Service - **SAI/DCI**Biological Residues Control Service - **SCR/DCI**

In addition to their routine production and facility control activities, the SDA's Technical Departments conduct special control programmes to monitor the quality of agricultural products under their responsibility, in particular:

SAFETY AND QUALITY OF PRODUCTS, FOODS AND BEVERAGES (MULTI-ANNUAL PLAN FOR 2000-2004).

AGROFIT – Online database providing access to information on the correct and safe utilization of pesticides for plant protection purposes, with information and indications on use, dose, crop, method of application and withdrawal period for the guidance of producers, consumers and other interested parties.

Web site: <http://www.agricultura.gov.br/agrofit/>

DATABASE OF ESTABLISHMENTS REGISTERED UNDER THE FEDERAL INSPECTION SYSTEM. Information system covering all animal product establishments registered with the DIPOA/SDA/MAPA.

Web site: <http://www.agricultura.gov.br/sda/sif.asp>

NATIONAL PLAN OF CONTROL OF BIOLOGICAL RESIDUES IN ANIMAL PRODUCTS - PNCRB

The plan has activities to control biological residues in meat (PCRBC). In the pipeline are honey (PCRBM), Milk (PCRBL) and Fish (PCRBP). The aim is to inform the public of the annual programming of control of biological residues in these products, to summarize activities and to report changes to specific PNCRB programmes.

Amended by Regulatory Order 42 of 20 December 1999 - <http://www.agricultura.gov.br/sda/dipoa/>

HACCP PROCEDURES IN ANIMAL PRODUCT INDUSTRIES

This programme provides industries subject to Federal Inspection with basic guidelines on the presentation, implementation, maintenance and verification of the Hazard Analysis and Critical Control Point (HACCP) system for the control of their products.

2. The entities under the **Secretariat of Rural Support and Cooperatives** responsible for registration, certification, control, accreditation and approval of agricultural products for export and/or import are:

The Department of Promotion and Control of Animal Production and the Department of Promotion and Control of Plant Production

In addition to their routine production and facility control activities, the SARC's Technical Departments conduct special control programmes to monitor the quality of agricultural products under their responsibility, in particular:

SAFETY AND QUALITY OF AGRICULTURAL INPUTS (MULTI-ANNUAL PLAN FOR 2000-2004).

HACCP PROCEDURES IN AGRICULTURAL INPUT INDUSTRIES

This programme provides industries subject to Federal Inspection with basic guidelines on the presentation, implementation, maintenance and verification of the Hazard Analysis and Critical Control Point system for the control of their products.

MINISTRY OF HEALTH/NATIONAL HEALTH SURVEILLANCE AGENCY

The National Health Surveillance Agency (ANVISA) was created by Law 9782 of 26 January 1999. It operates under special self-governing regime, i.e. as a regulatory agency with administrative independence, financial autonomy and continuity of managerial staff for the duration of their mandate. In the Federal Public Administration Structure, the agency is attached to the Ministry of Health.

The institutional objective of the agency is to protect public health through sanitary control of the production and marketing of products and services subject to health surveillance, including associated environments, processes, inputs and technologies. The agency is responsible for health control at ports, airports and borders, and for liaising with the Ministry of Foreign Affairs, Ministry of Agriculture, Livestock and Food Supply, Ministry of Industry and Trade, research and analytical laboratories, academia and foreign institutions on international issues relating to health surveillance.

ANVISA coordinates the activities of the National Health Surveillance System (SINVISA). Its actions dovetail with those of the state and local governments for the Unified Health System (SUS).

The National Health Surveillance System is wide-ranging and complex but is being streamlined with the introduction of successive governmental measures to render its work more rapid, more efficient and based on scientific understanding.

The agency is responsible for the regulation, control and inspection of products and services made available to the public.

As regards specific food-related responsibilities, the Food Office of Directorate of Food and Toxicology:

- Coordinates, supervises and controls activities of registration, information, inspection and control of risk by setting standards and guidelines and by promoting the appropriate organization of technical and administrative procedures in order to ensure proper health surveillance of foods, beverages, bottled water, inputs, packaging, food additives, contaminants and residues of veterinary drugs and pesticides;
- Encourages scientific research in health surveillance;
- Promotes the training of health surveillance personnel in programmes such as the HACCP and Good Manufacturing Practices;
- Fosters expansion of the public health laboratory network to meet demand for food analysis;
- Stimulates the accreditation of health surveillance laboratory services at federal, state and municipal level;
- Stimulates and promotes the adoption of scientific methods of risk analysis in health surveillance actions by personnel of the National Health Surveillance System;
- Supports food safety surveillance actions at ports, airports, borders and customs posts;
- Helps prepare and harmonize standards to be agreed in international forums including Codex and MERCOSUR;
- Coordinates technical activities for the incorporation of internationally agreed regulations into national legislation;
- Coordinates activities for the evaluation of specific chemical products such as selected additives and contaminants, as well as active ingredients of veterinary drugs and crop protectants.

Food safety activities and actions pursued by the Brazilian Government include:

- granting autonomy and raising human and financial resource inputs to improve the control and regulation of food production;
- strengthening decentralized control actions of state and municipal governments in the Unified Health System;
- prioritizing inspection in industrial food production, with the adoption of Good Manufacturing Practices and the HACCP;
- participating actively in national and international technical committees working on food safety standards and guidelines.

The organizational structure of ANVISA and its food-related offices can be found on its Web site: www.anvisa.gov.br

ANVISA's food-related offices include the Food Office and its technical offices:

A – Special Products Office, responsible for managing:

- a.1 – food registration procedures;
- a.2 – the formulation of technical regulations for general and special dietary foods, and for general and nutritional labelling;
- a.3 – the general coordination of National Codex Committee (CCAB) topics under the responsibility of ANVISA;
- a.4 – the coordination of the National Codex Committee's Technical Groups on Food Labelling, Methods of Analysis and Sampling, Nutrition and Foods for Special Dietary Uses; Edible Fats and Oils.

B – Science and Technology Office, responsible for managing:

- b.1 – administrative procedures and the evaluation of risk for the registration and/or inclusion and/or extension of food additives and processing aids;
- b.2 – studies and research on food contaminants such as veterinary drug residues;
- b.3 – studies and research on food packaging materials;
- b.4 – Codex issues relating to food additives, processing aids and contaminants;
- b.5 – the updating of technical regulations and other regulatory texts on additives, processing aids and contaminants.

C – Office of Inspection and Control of Food Risk, responsible for managing:

- c.1 – food quality monitoring programmes based on associated health risks;
- c.2 – Codex issues connected to the Committee on Food Hygiene;
- c.3 – the federal coordination of food inspection actions by state and municipal health surveillance units.

D – Office of Technical Competence in Food Safety: responsible for managing:

- d.1 – technical training programmes on the HACCP and Good Manufacturing Practices at federal, state and municipal level, with in-person and distance courses (under development);
- d.2 – technical training programmes on health surveillance, public health and epidemiology of outbreaks of food-borne diseases;
- d.3 – technical training programmes on application of the HACCP and Good Manufacturing Practices for technical staff of micro, small and medium enterprises.

The Food Office also liaises closely with the Toxicology Office and Public Health Laboratories Office of the Directorate of Food and Toxicology, and with ANVISA's Ports, Airports and Borders Office, International Relations Office, Information Office and Inspectorate.

IMPORT AND EXPORT

In Brazil, the control of imported food is centralized and takes place at each national point of entry, at ports, airports and border posts.

The whole food import system is now computerized and accessible on the Internet, with information on controls for each product and the respective agencies responsible for the evaluation, acceptance or rejection of shipments.

ACTIVITIES OF CODEX CONTACT POINT AND NATIONAL CODEX COMMITTEE

Brazil's National Codex Committee, the CCAB, was established in 1980 by Resolution CONMETRO 01/80. Its main duties are to represent the country and defend national interests in the Codex Committees and to promote the use of Codex standards as basic reference for the drafting and updating national food legislation and regulations.

The CCAB has 14 members representing sectors related to food: the Government, industry, consumers and academia. It is coordinated and serviced by the National Institute of Metrology, Standardization and Industrial Quality (INMETRO).

The National Committee comprises an array of technical groups monitoring the work of individual Codex Committees and coordinated by CCAB members. These groups are open to all sectors with an interest in the topic under examination.

As of September 2004, the CCAB had held 193 regular sessions and over 46 extraordinary sessions, serving mainly to monitor the work of the Codex Committees of primary relevance to Brazil. Since the 13th CCLAC session in December 2002, CCAB Codex-related activity has taken the form of replies to circular letters, the drafting of documents and the presentation of Brazil's position at meetings. During this period, Brazil has attended meetings of the following Codex Committees:

- Codex Committee on Food Import and Export Inspection and Certification Systems, Codex Committee on Fresh Fruits and Vegetables, Codex Committee on Fats and Oils, Codex Committee on Food Additives and Contaminants, Codex Committee on Pesticide Residues, Codex Committee on General Principles, Codex Committee on Food Labelling, Executive Committee of the Codex Alimentarius Commission, Codex Alimentarius Commission, Codex Committee on Food Hygiene, Codex Committee on Milk and Milk Products, Ad Hoc Codex Intergovernmental Task Force on Foods Derived from Biotechnology, Codex Committee on Residues of Veterinary Drugs in Foods, Codex Committee on Fish and Fish Products, Ad Hoc Codex Intergovernmental Task Force on Animal Feeding, Codex Committee on Nutrition and Foods for Special Dietary Uses, Ad Hoc Codex Intergovernmental Task Force on Fruit and Vegetable Juices, Codex Committee on Cocoa Products and Chocolate.

In addition to its routine activities, the National Committee holds an annual workshop each November to evaluate its performance, with the participation of all the members of the technical groups.

The CCAB is continuously publicizing its and Codex activities through presentations during food industry courses, conferences and workshops and has set up a dedicated Web site:

CCAB/INMETRO - <<http://www.inmetro.gov.br/qualidade/comites/ccab.asp>>

The site carries the following information:

- structure and functioning of the Codex programme;
- structure and functioning of the CCAB;
- calendar of Codex and CCAB meetings;
- list of Codex standards;
- summary reports of Codex Committee meetings;
- draft Codex guidelines and standards under discussion in Codex Committees;
- list of circular letters under discussion in Codex Committees;
- news.

Brazil also chairs the Codex Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices which has been tasked with reviewing fruit and vegetable juice standards and updating their methods of analysis and sampling, due for completion by 2005.

The CCAB works closely with FAO in conducting technical cooperation and assistance projects and is currently discussing assistance to Angola in setting up its National Codex Committee.

The National Codex Committee is also coordinating a discussion group on strategies to establish risk analysis in Brazil, involving academic experts and bodies representing government, industry and consumers.

The CCAB's contact details are:

CCAB coordination

INMETRO

W3 Norte - Quadra 511, Bloco B, 4º Andar

70750-527 - Brasília – DF - Brasil

Tel: (55 61) 340-2211, 347-7882

Fax: (55 61) 347-3284

E-Mail <codexbrasil@inmetro.gov.br>

B) FOOD LEGISLATION

ANVISA FOOD LEGISLATION

When formulating and updating food legislation, ANVISA invites all parties to preliminary discussions, including representatives of government, industry, academia and consumers. Before adopting any regulatory provision, ANVISA submits proposed regulation to public consultation. The basis and rationale for proposed regulation reflect the decisions of the Codex Alimentarius and MERCOSUR or, in their absence, of recognized international organizations.

Further information on ANVISA legislation can be found on its Web site: www.anvisa.gov.br.

MAPA FOOD LEGISLATION

MAPA food legislation can be consulted on the following sites:

<http://www.agricultura.gov.br/das/dipoa/> for all legislation on animal products (laws, decrees, edicts, service instructions, manuals, specification guidelines, public consultations) ;

<http://www.agricultura.gov.br/ddiv/fr legis.html> for all legislation on beverages (laws, decrees, edicts, service instructions, manuals, specification guidelines, public consultations);

<http://www.agricultura.gov.br/html/legislacao1.htm> for general legislation of the Ministry of Agriculture, Livestock and Food Supply and specific legislation on plant protection.

C) COOPERATION ON FOOD CONTROL AND TRAINING

A number of training seminars/courses were organized on risk analysis in food control, hazard analysis and critical control points and audit of HACCP systems. A project is underway on the evaluation and strengthening of the Bovine Spongiform Encephalopathy (BSE) prevention system and the quality control of animal feed.

CHILE

Structure and Organization of official agencies in charge of legislation and food control and of the National Codex Committee of Chile

A) OFFICIAL AGENCIES

The Ministry of Health is the competent authority for food control of all food products intended for human consumption within the country, whether national or imported. This power is exercised through 29 Health Services, distributed throughout the country. According to the powers conferred by the Sanitary Code, the Ministry of Health is responsible for ensuring the removal-or control—of all factors, elements, or environmental agents affecting citizens' health, security and welfare.

Within the context of food protection proper, the sanitary authority, particularly in relation with its role concerning legislation and supervision as well as its capacity to provide collective protection to people's health, should develop and/or improve epidemiological surveillance of food and increase people's participation in the prevention, promotion and self-health care.

As regards the certification of export food sanitary quality, other State bodies have powers.

Thus, sanitary certification of primary export food is the responsibility of the Agriculture and Livestock Service, dependant on the Ministry of Agriculture.

The Ministry of Agriculture is the competent authority to manage, through the Agriculture and Livestock Service, all requirements concerning the issuance of sanitary and phytosanitary export certificates for products of animal origin and plant products, including the certification of suitability for human consumption for primary products.

Sanitary certification of food of hydrobiological origin is the responsibility of the National Fishing Service, dependant on the Ministry of Economy, Promotion and Reconstruction.

The National Fishing Service is the competent authority for the control of sanitary quality of sea products intended for exportation and for issuance of the appropriate official certificates.

Codex Alimentarius

The National Codex Alimentarius Committee was set up on 10 January 1997, through Supreme Decree No. 19 of the Ministry of Health. It is a cross-ministry, cross-sector committee, as the ministries of Health, Foreign Affairs, Agriculture and Economy participate in it as well as these areas: Food Industry, Trade, Consumers, and Academic Institutes. It is supported by Technical Subcommittees, the Contact Point (Ministry of Health) and the Secretariat of the Codex Committee (currently at the Agriculture and Livestock Service).

The Chair of the National Committee is temporary; it changes every two years among the participating ministries. Currently, the Ministry of Agriculture is the Chair, which is exercised through the Agriculture and Livestock Service.

Institutions Managing Codex Alimentarius Subcommittees in Chile

Ministry	Service/ Department		Codex Alimentarius Subcommittees and their current managers
Ministry of Health	- Departments of Environmental Programs or Sub-department of Environmental Health		- Food Hygiene - Nutrition and Foods for Special Dietary Uses - Fruit juice and Vegetables - Fruit and Vegetable Juices - Foods Derived From Biotechnology
	- Public Health Institute		- Food Additives and Contaminants - Fats and Oils - Methods of Analysis and Sampling
Ministry of Agriculture	- Agriculture and Livestock Service	- Livestock Protection Department	- Residues of Veterinary Drugs in Foods - Milk and Milk Products - Animal Feeding
		- Agriculture Protection Department	- Pesticide Residues
		- Foreign Affairs Department	- Fresh Fruits and Vegetables
Ministry of Economy	- National Fishing Service		- Fish and Fish Products
	- National Consumer Service		- Food Labelling
	- Foreign Trade Department		- Food Import and Export Inspection and Certification Systems
Ministry of Foreign Affairs	- Multilateral Policy Division	- Department of Special Agencies and other Policies	- General Principles

As shown in the chart above, there are 18 Technical Subcommittees, in which there are representatives from the Ministry of Health, Agriculture, Economy and Foreign Affairs, as well as representatives of industries, academic institutions and consumers. These subcommittees are managed by the above-mentioned ministries and related institutions, such as the Agriculture and Livestock Service, the National Consumer Service, the Public Health Institute, etc.

B) FOOD LEGISLATION

CHILEAN FOOD REGULATIONS

Chilean food regulations are updated and, mostly, harmonized with Codex Alimentarius international standards. They aim at providing basic sanitary standards mainly oriented towards safety, health and nutritional value of food. Also, they are oriented to provide standards which are not food standards proper but are related to eating habits and nutritional and health attributes of food.

These regulations have been designed by a cross-disciplinary group of experts, following Codex Alimentarius general and specific guidance, as these standards enable the protection of public health, indicate known risk levels, provide a good opportunity for food trade and reduce obstacles and technical barriers to free circulation of products at the same time.


Chile has designed its programs of protection of locally produced food based on the authorization and systematic inspection of production plants, according to the epidemiological risk and a program of sanitary control and surveillance which considers food sampling; which, overall, provide practical guidance.

Chilean regulations do not consider the existence of Food Registration. The food production sector does not require prior approval of sanitary authorities to design a new product and distribute it in the market. Processed food should comply with the specifications established for them in the Food Sanitary Regulation.

Neither is product registration required for imported food. The control system of locally produced food and imported food is mainly aimed to ensure the safety of food products and facilitate their rapid marketing without unnecessary intervention from the Sanitary Authority between the design of new products, their production and marketing.

C) COOPERATION ACTIVITIES

Chile has established bilateral Cooperation instances at different levels in the relations developed by the country. Free Trade Agreements have included a Sanitary and Phytosanitary Chapter. So have Economic Complementation Agreements (); or else, they contain annexes in the matter. In addition, Forestry Health Agreements have been signed, bilaterally, at institutional level; which may develop an important Cooperation component as well as the objective of implementation of the WTO SPS Agreement.



COLOMBIA

A) OFFICIAL AGENCIES

INSTITUTIONS INVOLVED IN FOOD LEGISLATION AND FOOD CONTROL

- Ministry of Social Protection
- Ministry of Agriculture and Rural Development
- Colombian Institute of Agriculture (ICA)
- Ministry of Trade, Industry and Tourism
- Superintendency of Industry and Trade (SIC)

Ministry of Social Protection

Name of institution, address, telephone, fax, Web site

Ministerio de la Protección Social, Carrera 13 No. 32-76 Bogotá, D.C. Tel. 3365066, Fax: 3360182, Web site: www.minproteccionsocial.gov.co

Date of creation of institution

Law 790 of 2002 merged the Ministry of Labour and Social Security with the Ministry of Health to form the Ministry of Social Protection, which took over the Ministry of Health's responsibilities for food regulation. Going back in history, Law 27 of 1946 established the Ministry of Hygiene which was later often restructured and renamed, including as the Ministry of Public Health, then the Ministry of Health, the name it kept until its merger with the Ministry of Labour and Social Security in February 2003.

Legal operating framework and official status

Decree 205 of 3 February 2003 sets the objectives, organizational structure and functions of the Ministry of Social Protection and Resolution 002 of 4 February 2003 establishes, organizes and appoints the Ministry's internal work groups and specifies their functions. The Ministry is an entity of the national executive branch in the State structure.

Brief description of mission and functions

The primary mission of the Ministry of Social Protection is to formulate, adopt, direct, coordinate, implement, control and monitor the Social Protection System, development plans and guidelines of the National Government. In order to develop social protection policies, the Ministry has to identify and implement strategies, within the framework of its remit, to reduce, mitigate and remedy potential risks to labour markets, the life cycle and health from natural, environmental, social or economic sources.

Main functions relating to food regulation

- a) Formulating, directing and coordinating the National Government's social policy on employment, labour, nutrition, protection and development of the family, pensions and integrated social security.
- b) Defining policies and strategies to deal with risk, promoting concerted action by the State, society, family, individual and others responsible for execution and outputs of the Social Protection System.
- c) Defining, directing, coordinating and stimulating policies and guidelines to strengthen investigation, examination, achievement, dissemination and implementation of national and international advances in the care, protection and development of health and quality of life, and in the prevention of disease.
- d) Defining, regulating and evaluating compliance with technical standards and legal provisions for the control of environmental factors of risk, especially those from consumption and employment.

Starting date of food standardization and regulation functions

First as the Ministry of Hygiene, then as Ministry of Health and now as Ministry of Social Protection, the Ministry has always been involved in food regulation.

Description of organizational structure

Given that the Ministry of Social Protection is the result of the fusion of the Ministry of Labour and Social Security and the Ministry of Health, it has a complex internal structure and organization headed by the Office of the Minister and Advisory Offices, with many sub-units including: the Technical Vice-Minister's Office with four Directorates; the Health and Welfare Vice-Minister's Office with three Directorates; the Labour Relations Vice-Minister's Office with two Directorates, Units and Special Offices; the General Administration; Internal Advisory Coordination Bodies and Special Funds without Legal Status. The organizational structure is given in Annex 1.

Within the Ministry's organization and structure, the Health and Welfare Vice-Minister's Office, the Directorate of Public Health and its Promotion and Prevention Group need to be singled out because of their functions and responsibilities relating directly to food regulation. Decree 205 of 2003 sets the following specific functions for the Health and Welfare Vice-Minister's Office:

- a) Advise the Minister on the formulation of policies and strategies to prevent, mitigate and remedy risks to health and quality of life of individuals, family and society.
- b) Define good manufacturing practices policy and principles in the processing of foods, beverages, medicinal drugs, household products, cosmetics and other products possibly harmful to health.

Along the same lines, the Directorate of Public Health has the following functions:

- a) Define policies, plans, programmes and procedures for the prevention, detection and control of risks to health and the generation of protection factors that could enhance quality of life and promote health.
- b) Formulate and propose policies, plans, programmes, projects and standards on public and psycho-social health, as broadly interpreted, to reduce and mitigate risks to health and quality of life.
- c) Develop health protection policies, programmes and projects to prevent, detect and control potential risks to health and quality of life from the environment, physical and chemical agents and consumption.

Resolution 002 of 2003 gives the following food standardization and regulation functions to the Directorate of Public Health's Promotion and Prevention Group:

- a) Propose, guide and formulate public health standards, policies, plans, programmes, projects and procedures to foster health protection in relation to foods and beverages, chemical substances and industries exposing public health to high risk; ports, airports and border points; quality of water; quality of air; production processes; management and disposal of dangerous liquid and solid residues; public housing and spaces; and consumption and use of drugs, medicines and psycho-active substances.
- b) Oversee the inspection, monitoring and control of food for human consumption, medicines, port sanitary conditions, establishments and public spaces presenting high health risk, ionizing radiation, potentially toxic chemical substances, housing and major public health vectors.
- c) Coordinate the food technical standardization activities of the National Codex Committee, as Technical Secretariat, and act as Codex Contact Point.

The Promotion and Prevention Group is the unit responsible for coordinating and developing the technical aspects of drafting and updating food regulations. It has four professional staff covering different disciplines and a general coordinator who also advises the Health and Welfare Vice-Minister's Office.

Other functions besides standardization and regulation

The Ministry of Social Protection also carries out functions relating to the formulation, direction, coordination, implementation, control and monitoring of the Social Protection System, the General Integrated Social Security System and functions previously assigned by legislation to the Ministry of Labour and Social Security and the Ministry of Health.

Procedure for the elaboration of food standards and regulations

In accordance with the Ministry of Trade, Industry and Tourism's provisions on the organization of the National System of Standardization, Certification and Metrology, the process in the last two years has been as follows.

Draft technical regulations are drawn up by the professionals in the Promotion and Prevention Group on the basis of national technical standards and Codex Alimentarius standards and regulatory proposals submitted the public or private sectors. The proposals are first studied, analysed and discussed with the appropriate official bodies and then revised and discussed with the private sector, producer associations and universities before legal scrutiny and editing. The proposals are then posted on the Ministry's Web site for public consultation, after which relevant amendments are introduced before dispatch to the Ministry of Trade, Industry and Tourism, in its role as Focal Point of WTO, for enactment of the international notification process. The proposals are then sent to the higher echelons of the Ministry for final approval and issue, in the case of regulations issued by Ministerial Resolution, or to the Office of the President of the Republic, in the case of regulations issued by Decree.

Documentation of the Secretariat of the Codex Alimentarius Commission

The Ministry of Social Protection acts as Codex Contact Point through its Promotion and Prevention Group and thus receives all documentation from the Codex Secretariat. These working documents and the Codex standards constitute the primary reference material for food regulation and standardization.

Participation of National Committee members in food standardization and regulation

Involvement of National Codex Committee bodies and entities in the regulation process depends on the topic and scope of the proposed regulation. Key participants are the Ministry of Agriculture and Rural Development and the Colombian Institute of Agriculture (ICA), with the permanent involvement in all regulatory proposals of the National Institute of Surveillance of Medicinal Drugs and Foods (INVIMA), a national body affiliated to the Ministry of Public Health and responsible for implementing health surveillance and food quality control policies. The National Association of Manufacturers (ANDI) represents the producer sector through the Chamber of Food Industries and the Chamber of Fisheries.

Ministry of Agriculture and Rural Development

Name of institution, address, telephone, fax, Web site:

Ministerio de Agricultura y Desarrollo Rural, Avenida Jiménez No. 7-65 Bogotá, D.C., Teléfono 3341199, Fax. 2828173, Página Web: www.minagricultura.gov.co

Date of creation of institution

Law 25 of 1913 established the Ministry of Agriculture and Trade. This was subsequently converted to the Ministry of Industry, then reinstated as the Ministry of Agriculture and Trade until 1938 when it became the Ministry of the Economy with Departments of Commercial Affairs; Agriculture, Livestock; Trade and Industry; Oil; Mines, Lands and Forests. Law 75 of 1947 changed it to the Ministry of Agriculture and Livestock, after which it was again often changed and restructured, including as the Ministry of Agriculture and, finally, as the Ministry of Agriculture and Rural Development.

Legal operating framework and official status

Decree 2478 of 1999 modified the structure of the Ministry and set its functions and those of its subsidiary offices. The Ministry is an entity of the national executive branch in the State structure.

Brief description of mission and functions

Mission

Its mission is to formulate, coordinate and evaluate policies that will promote the competitive, equitable and sustainable advancement of agriculture, forestry, fisheries and rural development, with criteria of decentralization, coordination and participation that will help raise the standard and quality of life of the Colombian people.

Functions relating to food regulation

- a) Formulating agricultural, fisheries and rural development policies, plans and programmes, with an emphasis on participation and planning and in compliance with macro-economic policy.
- b) Coordinating, promoting, monitoring and evaluating implementation of the National Government's policies on agriculture, fisheries and rural development.
- c) Determining policies and guidelines on agricultural and fisheries technology, research and transfer, and adopting general measures on technical assistance, quality, utilization and commercialization of agricultural and plant and animal health products and inputs.

Starting date of food standardization and regulation functions

Since its creation as Ministry of Agriculture and Trade and currently as Ministry of Agriculture and Rural Development, it has had functions that relate to the regulation of agricultural products and inputs, and is co-responsible with the Ministry of Social Protection for the quality and safety of foods deriving from agriculture.

Description of organizational structure

Decree 2478 of 1999 on the structure and organization of the Ministry of Agriculture and Rural Development places at its head the Office of the Minister and the Legal Office, with the Office of the Vice-Minister, six Divisions and the Internal Audit Office. There is also a General Secretariat and Internal Advisory and Coordination Units. The organizational structure is presented in Annex 2.

Within this structure, the Technology Development and Health Protection Division is responsible for applying sectoral policy in science and technology and agricultural health, with the support of five professional staff and the following functions relating to food regulation.

- a) Assisting the Vice-Minister in setting policies and guidelines on research, transfer of agricultural and fishery technology, quality standards, product and input utilization, and animal and plant health.
- b) Coordinating, with relevant public agencies and actors from the private sector and the development community, those aspects that relate to the generation and transfer of technology and the protection of health in agriculture and fisheries.

Other functions besides standardization and regulation

The Ministry of Agriculture and Rural Development is responsible for formulating, coordinating and adopting agricultural, fisheries and rural development policies, plans, programmes and projects and for directing, controlling and evaluating the activities of its affiliated and associated bodies. It also: determines policy for the commercial growth of productive and buffer stands of introduced or indigenous forest species, in accordance with national policy on the environment and renewable natural resources; regulates domestic markets for agricultural and fishery products; determines pricing policy for these products and their inputs in the event of perceived market inadequacies; proposes the adoption of corrective measures or actions; and promotes the formation of farmer associations and agricultural trade organizations, as well as cooperation between these and other agricultural, fisheries and rural development agencies.

Procedure employed for the elaboration of food standards and regulations

Through its professionals, the Technology Development and Health Protection Division drafts proposed regulation for discussion with the relevant official bodies and interested producer sectors. The proposal is then scrutinized technically and legally, before following the legal provisions adopted for the formulation and issue of technical regulations under the National System of Standardization, Certification and Metrology.

However, the Ministry of Agriculture and Rural Development's participation in the drafting of food regulations has mainly been in supporting the work of the Ministry of Social Protection with which, in accordance with Law 09 of 1979, it has shared responsibility for issuing regulations for selected products and activities, including health provisions for slaughterhouses, milk and fishery products. The Ministry of Agriculture and Rural Development has therefore only rarely issued food standards directly.

Documentation of the Secretariat of the Codex Alimentarius Commission

Although the Ministry of Agriculture and Rural Development sits on the National Codex Committee, it only occasionally receives Codex Secretariat documentation from the Contact Point, partly because it is not responsible for coordinating any technical subcommittee of the National Codex Committee.

Colombian Institute of Agriculture (ICA)

Name of institution, address, telephone, fax, Web site:

Instituto Colombiano Agropecuario (ICA), Calle 37 No. 8-43 Pisos 4 y 5, Bogotá, D.C., Teléfonos 2855520 – 3323700, Fax 2884169, Web site: www.ica.gov.co

Date of creation of institution

The ICA was established by Decree 1562 of 1962, after which it has been restructured on several occasions to reflect changes in national policy on science and technology and on health protection in agricultural production. In 1994 the National Government assigned it specialist status in agricultural health, input control and supervision, and the registration of plant breeders.

Legal operating framework and official status

The legal framework for ICA activity is contained in Decree 2141 of 1992, Law 101 of 1993 and Decree 1840 of 1994 which regulates Article 65 of Law 101. Decree 1454 of 2001 modified the structure of the Colombian Institute of Agriculture and determined the functions of its subsidiary units, while Resolution 2950 of 2001 created and organized its Internal Working Groups at national level. The ICA is a national public entity attached to the Ministry of Agriculture and Rural Development. It has legal status, administrative autonomy and independent assets.

Brief description of missions and functions

Mission

Its mission is to contribute to sustainable agricultural development through the prevention, control and reduction of biological and chemical health problems and risks affecting agricultural production and human beings, and to boost national capacity of food and agroindustrial supply to match market demand under conditions of profitability, reduced environmental degradation and higher competitiveness, for the benefit of Colombian society.

Main functions

- a) Develop policies and plans for health protection and agricultural production and productivity of the country.
- b) Exercise agricultural health activities and the technical control of imports, exports, manufacturing, marketing and use of agricultural inputs in order to protect national agricultural production and minimize the risks to food and the environment from using such inputs and to facilitate access of national products to international markets.
- c) Promote and apply strategies of scientific and technological information, communication, training and advice, planning and prospective assessment, regionalization and institutional development that will drive technological development of the agricultural sector.

Starting date of food standardization and regulation functions

Since its inception, the ICA has carried out agricultural health regulation functions, so its regulatory activities have focused essentially on agricultural health protection and the control of agricultural inputs. It has therefore had little involvement in formulating regulations on the quality and safety of foods in primary production.

Nevertheless, the process of institutional change associated with Decree 1454 and Resolution 2950 of 2001 led to the creation of Internal Working Groups within the agricultural and livestock food chains to ensure the safety of unprocessed foods of plant and animal origin, and therefore also to draft regulations. As a result health provisions have been enacted to ensure the safety of primary production of foods of animal and plant origin.

Description of the organizational structure

The new ICA structure in Decree 1454 of 2001 has the General Management Office; Advisory Boards and Committees; the Audit Office and Offices of Planning, Communication and Legal Advice; the Livestock Protection and Regulation Branch; the Agricultural Protection and Regulation Branch; and the Administrative and Financial Branch. Resolution 2950 of 2001 set up Internal Working Groups under each branch. The organizational structure is given in Annex 3.

Important in this structure are the Livestock and the Agricultural Protection and Regulation Branches and their respective Internal Working Groups on Safety in Agricultural Food Chains, which are tasked with exercising technical and scientific control to secure safe livestock and agricultural primary products, to prevent biological and chemical risks to animal and human health and to contribute towards food safety. The Working Groups are thus assigned the following regulatory food functions:

- a) Establish and update regulations on good veterinary practices and good agricultural practices for the rational use of drugs, additives and pesticides and good sanitary, phytosanitary and management practices.
- b) Elaborate and update regulations and procedures for the safety of foods of animal and plant origin obtained in primary production.
- c) Propose, review and update safety regulations and procedures in the livestock and crop chains.

Other functions besides standardization and regulation

In addition to its agricultural health regulation responsibilities, the ICA advises the Ministry of Agriculture and Rural Development on the formulation of policy and plans for agricultural research, technology transfer and the prevention of biological and chemical health risks to animal and plant species, develops strategies to bolster agricultural development, and plans and executes plant and animal protection actions.

Procedure employed in the elaboration of food standards and regulations

Draft regulations are prepared by the Internal Working Groups of the respective Offices for discussion with the competent official bodies, where the subject and scope of the legislation so require, and agreed with the producer associations concerned. The proposal is then studied for technical approval in the appropriate Office before being examined from a legal perspective. It then follows the normal legislative course for elaboration and issue of technical regulations under the National System of Standardization, Certification and Metrology.

Documentation of the Secretariat of the Codex Alimentarius Commission

The Colombian Institute of Agriculture (ICA) is a member of the National Codex Committee and is also responsible for coordinating the technical subcommittees on veterinary drug residues in food and feed, so it receives from the Contact Point and the Technical Secretariat of the National Codex Committee corresponding documentation sent by the Codex Secretariat.

Ministry of Trade, Industry and Tourism

Name of institution, address, telephone, fax and Web site:

Ministerio de Comercio, Industria y Turismo, Carrera 13 No. 28-01 Pisos 5 a 9, Tel. 3505500 Bogotá, D.C.
Web site: www.mincomex.gov.co

Date of creation of the institution

Law 790 of 2002 merged the Ministries of Economic Development and of External Trade into the Ministry of Trade, Industry and Tourism.

Legal operating framework and official status

Decree 210 of 2003 sets out the objectives and organizational structure of the Ministry of Trade, Industry and Tourism, which is an entity of the national executive branch in the State structure.

Brief description of mission and functions

Mission

The main function of the Ministry of Trade, Industry and Tourism is to formulate, adopt, direct and coordinate general social and economic development policy relating to industrial competitiveness, integration and development, micro, small and medium business, the external trade of goods, services and technology, the promotion of foreign investment, internal trade and tourism; and to implement external trade policies, general plans, programmes and projects.

Functions relating to standardization and regulation

- a) Formulate policies for market regulation, standardization, evaluation of compliance, quality, promotion of competition, protection of consumers and industrial property.
- b) Define policy on the promotion of competition, industrial property, consumer protection, business development, private initiative and unrestricted economic activity, productivity and competitiveness and promotion of export activity.
- c) Formulate and adopt standardization policy, plans, programmes and regulations.

Starting date of food standardization and regulation functions

The Ministry of Trade, Industry and Tourism has continued to conduct the standardization and regulation functions of the prior Ministry of Economic Development. Although not directly active in food standardization and regulation, the Ministry oversees the National System of Standardization, Certification and Metrology and is thus responsible for issuing provisions for it to function properly within the framework of WTO agreements.

Description of organizational structure

Decree 210 of 2003 sets out the organizational structure of the Ministry, which comprises the Office of the Minister and its Advisory Offices on Planning, International Legal Affairs, Economic Studies, Audit and Information Systems; the Office of the Vice-Minister of External Trade with four Divisions and three Branches; the Office of the Vice-Minister of Business Development with five Divisions; the General Secretariat and Internal Advisory and Coordination Units. The organizational structure is given in Annex 4.

Within this structure, the Regulatory Division of the Office of the Vice-Minister of Business Development has standardization and regulation functions:

- a) Formulating, implementing and following up public policies of regulation, standardization, accreditation, compliance assessment, certification, metrology, quality, promotion of competition and consumer protection, and formulating, coordinating and designing associated studies.
- b) Directing the National System of Standardization, Accreditation, Certification and Metrology; formulating, coordinating and designing corresponding studies and carrying out actions needed for its development and its national and international recognition.
- c) Directing, coordinating and administering Colombia's contact point with regard to standardization, technical barriers to trade, sanitary and phytosanitary measures and compliance assessment procedures, and administering and updating the national information system of mandatory technical regulations and standards at national and international level.
- d) Coordinating at national level the elaboration of technical regulations required to defend the country's legitimate objectives, and studying and approving the annual programme of regulations required, in conjunction with the producer sectors and entities involved, and formulating those outside the competence of other entities or authorities, checking that the technical regulations will not create unnecessary barriers to trade, as specified under current legislation and international agreements to which Colombia is party.
- e) Chairing and exercising as the General Secretariat of the National Codex Committee.

Other functions besides standardization and regulation

Other functions of the Ministry of Trade, Industry and Tourism include the formulation of economic and social development policies; the development of micro, small and medium businesses; external trade and the promotion of exports; productivity and competitiveness; the promotion of competition; incentives for domestic and foreign investment; tourism and competitiveness of Colombia's tourism products; trade relations with other countries.

Procedure for the elaboration of food standards and regulations

The Ministry of Trade, Industry and Tourism has no direct involvement in the formulation and issue of food standards and regulations. However, as body in charge of the National System of Standardization, Certification and Metrology, it is responsible for coordinating the formulation of technical regulations with the bodies concerned, following them up and checking that their procedures, content and criteria comply with national legislation and international agreements. In addition, as WTO focal point, the Ministry is responsible for furthering the international notification of sanitary and phytosanitary measures and technical regulations, and for administering the corresponding national information system.

Documentation of the Secretariat of the Codex Alimentarius Commission

The Ministry is General Secretariat of the National Codex Committee and also coordinates the Subcommittee on General Principles. It therefore receives Codex Secretariat documentation from the Contact Point.

Superintendency of Industry and Trade (SIC)

Name of institution, address, telephone, fax and web site:

Superintendencia de Industria y Comercio (SIC), Carrera 13 No. 27-00 Pisos 5, 7 y 10 Tel. 3820840 Fax. 3505220, E-mail: info@sic.gov.co , Web site: www.sic.gov.co, Bogotá, D.C.

Date of creation of institution

Article 25 of Decree 2974 of 3 December 1968 establishes the Superintendency of Industry and Trade attached to the Ministry of Economic Development.

Legal operating framework and status in the State structure

Decree 2153 of 30 December 1992 restructures the Superintendency of Industry and Trade and establishes its operating framework. Decree 2269 of 1993 ratifies its functions of accreditation and supervision of the certification and inspection agencies and sampling and testing laboratories that operate within the National System of Standardization, Certification and Metrology and empowers it to adopt measures for the System to function properly.

The SIC is a national technical agency attached to the Ministry of Trade, Industry and Tourism, with administrative, financial and budgetary autonomy.

Brief description of mission and functionsFunctions relating to standardization and regulation

- a) Adopting measures needed for the proper functioning of the National System of Standardization, Certification and Metrology.
- b) Establishing, coordinating, directing and monitoring the national programmes of industrial control of quality, weights, measures and metrology, and organizing quality and metrology control laboratories, that it considers essential for its functions.
- c) Determining minimum quality and performance requisites for goods and services when officially setting technical standards.
- d) Establishing provisions to regulate activities within the National System of Standardization, Certification and Metrology.
- e) Establishing technical regulations on procedures, methods and requirements for the accreditation of certification and inspection agencies, sampling and testing laboratories and metrology laboratories.
- f) Determining standards for the installation of the international system of units in industry and trade.

Starting date of food standardization and regulation functions

Decree 2153 of 1992 assigned the Superintendency regulatory functions which were subsequently ratified by Decree 2269 of 1993. Thus, although performing specifically in food standardization and regulation, it is responsible for adopting measures for the National System of Standardization, Certification and Metrology to function properly, given its role as institution responsible for accrediting and supervising agencies within the System.

Description of organizational structure

Decree 2153 of 1992 established the structure of the SIC, made up of the Office of the Superintendent and its Planning, Systems, Quality, Communications and Legal Officers; the Offices of the Assistant Superintendents for the Promotion of Competition, Industrial Property and Consumer Protection; the General Secretariat and Advisory and Coordination Bodies. The organizational structure is given in Annex 5.

Particularly relevant are the Office of the Assistant Superintendent for Consumer Protection and its Consumer Protection, Technical Standards and Metrology Divisions, because of their regulatory, accreditation and supervisory functions in developing the National System of Standardization, Certification and Metrology.

Other functions besides standardization and regulation

The Superintendence of Industry and Trade is essentially a surveillance and control body and, as such, is responsible for ensuring compliance with provisions relating to the promotion of competition and the avoidance of restrictive trade practices in domestic markets; protecting the consumer, investigating interferences in market competition and imposing sanctions for the infringement of rules; administering the national system of industrial property; advising the National Government and participating in policy-making in all areas relating to consumer protection, promotion of competition and industrial property.

Process employed for the formulation of food standards and regulations

The SIC has no functions relating to the formulation and issue of food standards and regulations. However, it is responsible for establishing, coordinating, directing and monitoring national programmes of industrial control of quality, weights, measures and metrology, and for adopting measures for the National System of Standardization, Certification and Metrology to function properly. Important in this connection is Resolution 3742 of 2 February 2001 which lists criteria and conditions for the issue of technical regulations by the competent entities.

Documentation of the Secretariat of the Codex Alimentarius Commission

The Superintendency of Industry and Trade sits on the National Codex Committee but only occasionally receives Codex Secretariat documentation from the Contact Point, partly because it is not responsible for coordinating any technical subcommittee of the National Codex Committee.

Activities of the Codex Contact Point and National Codex Committee

Organization, structure and functioning of the Contact Point

- a) The Ministry of Health (now of Social Protection) was appointed Codex Contact Point by Presidential Decree 977 of 29 May 1998.
- b) The Contact Point has one professional officer who provides technical support and also carries out administrative functions, for one hour per day for about 20 hours per month. This time is specifically allocated by the institution to Codex activities. There is also an agreement with a university whereby intern students in their final semester of food engineering provide secretarial support to the Contact Point, mainly for the classification and filing of documents.

The professional carries out the following functions:

- c) Receiving, classifying and filing Codex Commission Secretariat documents by topic and forwarding them to the bodies that coordinate the technical subcommittees; collating subcommittee comments on working documents for onforwarding to the respective Codex Committee and the CAC Secretariat; assisting the technical subcommittees of the National Codex Committee; processing and forwarding invitations to Codex meetings and informing the chairperson of the respective Committee and the CAC Secretariat of the delegates to attend; and providing support in the organization and running the Codex Library located in the Ministry of Social Protection.

Status of the National Codex Committee

Organization, structure and functioning of the National Codex Committee (NCC)

The NCC was established by Decree 977 of 29 May 1999 to advise the National Government on national policy on standards, principles and procedures being processed by the Codex Alimentarius Commission, its Executive Committee and its subsidiary bodies. The NCC has functioned without interruption since its inception.

N.B: Last February the National Government merged the Ministries of Economic Development and of External Trade into the Ministry of Trade, Industry and Tourism, so the NCC General Secretariat functions of the Ministry of Development were transferred to the new Ministry.

- a) The Committee is attached to the Ministry of Trade, Industry and Tourism which provides its General Secretariat. It also has a Technical Secretariat provided by the Ministry of Social Protection. The Committee is made up of representatives of the Ministry of Trade, Industry and Tourism, in the Chair, the Ministry of Social Protection, the Ministry of External Relations, the Ministry of Agriculture and Rural Development, the Colombian Institute of Agriculture (ICA), the National Institute of Food and Drug Surveillance (INVIMA), the Colombian Institute of Technical Standards and Certification (ICONTEC), and the Superintendency of Industry and Trade. It also includes a delegate from the trade associations and one representing consumers. Decree 977 stipulates the functions of the Committee, the General Secretariat and the Technical Secretariat.
- b) The NCC delegates are appointed directly by the senior management of each entity; in the case of the trade associations, these are currently represented by the Director of the Chamber of Food Industries of the National Association of Manufacturers (ANDI) while the consumers are represented by the Colombian Confederation of Consumers (CCC) and by the Consumers of Colombia (COCO) by invitation of the NCC. In accordance with Decree 977 of 1998, the NCC has its approved Rules of Procedure that cover functions, delegations, meetings, proceedings, coordinating bodies and the establishment of national technical subcommittees. The NCC meets every quarter at the invitation of the General Secretariat.
- c) Each technical subcommittee is coordinated by the body competent and specialized in its respective field. The following subcommittees are currently active under their respective coordinating bodies; those underlined have been functioning continuously and have generally posted good results, while those with an asterisk indicate recent creation:
 - o General principles: Ministry of Trade, Industry and Tourism.
 - o Food Hygiene, Pesticide Residues, Nutrition and Food for Special Dietary Uses and Biotechnology (*): Ministry of Social Protection.
 - o Veterinary Drug Residues and Animal Feeding: ICA
 - o Food Additives and Contaminants, Methods of Analysis and Sampling and Food Import and Export Inspection and Certification Systems: INVIMA
 - o Food Labelling: ICONTEC

As regards the subcommittees on commodities, the only ones in operation are the Subcommittee on Meat Hygiene (*) which is coordinated by the Bogota Health Secretariat and the Subcommittees on Milk and Milk Products and on Fresh Fruits and Vegetables coordinated by ICONTEC.

- d) Each entity has an officer to coordinate subcommittee activities and given the following functions: forming the working group with representatives from the public and private sector, trade associations, consumers, universities and scientific organizations with an interest and expertise in the topic area; scheduling meetings; drafting invitations; providing the working documents; leading meetings; recording proceedings; drafting findings and comments for onforwarding to the NCC Technical Secretariat.
- e) The NCC is based at the headquarters of the Ministry of Trade, Industry and Tourism while each subcommittee functions in its coordinating entity. The NCC receives technical support from an official of the Ministry of Trade, Industry and Tourism for its General Secretariat and one from the Ministry of Social Protection for its Technical Secretariat, each spending about one hour a day or 20 hours a month on this assignment – the time specifically allocated to the NCC by their respective institutions.

C. Common features of the Contact Point and the National Codex Committee

1. System of information

- a) As the same institution acts as Contact Point and Technical Secretariat of the NCC, the channelling of information and distribution of documents to the subcommittees is more rapid, which partly facilitates the work of the NCC and technical subcommittees.
- b) Documentation from the Codex Commission Secretariat (FAO Rome) has been received since October 2002 in hardcopy or by e-mail through the Codex-L and Codex-Direct-L mailing list. The Contact Point and NCC have Internet access to the Web site of the Codex Alimentarius Commission.
- c) Each committee archives the hardcopy and electronic documents received, according to symbol, year and numerical sequence, with a note of the number of copies and the language of each document received. A copy of each working document is forwarded to the Technical Secretariat of the NCC which it shares with the Contact Point and a copy is sent to the respective technical subcommittee.
- d) The Technical Secretariat sends hardcopy and, where available, electronic documentation to the respective subcommittees and archives each working document and all related correspondence. With the exception of information that the Technical Secretariat provides to interested visitors or individuals, the NCC is not in a position to provide information on the Codex or the work of the Committee to government sectors, industry, consumer organizations or the general public.
- e) Each subcommittee organizes its own registry of working documents according to Codex topic symbol, relevant meeting and chronological entry of proceedings, outputs and correspondence.
- f) The Contact Point and NCC have a Codex Documentation Centre in the Library in the Ministry of Social Protection, with all standards, guidelines, codes and recommendations and the 1998 CD-Rom with this information, for consultation by the public. It also has all the reports of the Codex Alimentarius meetings (ALINORM documents) for consultation by anyone interested in the work of the Codex.
- g) The NCC does not have a Web site but features on that of the Ministry of Social Protection: www.minprotecciónsocial.gov.co.

2. Examination and reply to documents sent by the Codex Commission Secretariat

The Technical Secretariat, which also acts as Codex Contact Point, sends the working documents to each subcommittee, with an indication of the deadline for comments. The subcommittee coordinator schedules the working meetings, invites the participants and, after the documents have been examined, reports the subcommittee's findings, comments and position to the Technical Secretariat. Where appropriate, the Technical Secretariat will act as technical filter before the Contact Point communicates the country's comments and position to the Chair of the respective Committee and to the Codex Commission Secretariat in Rome.

3. Plan of work of the Contact Point and National Codex Committee

The Contact Point does not have a written plan of work or an annual programme of activities. The NCC on the other hand has an annual plan of work with responsibilities for the General Secretariat and the Technical Secretariat, including regular meetings, subcommittee examination of documents, presentation of reports, follow-up and participation in Codex meetings. However, not all member entities plan or include NCC or Codex activities in their annual plan of operations.

B) FOOD LEGISLATION

We always draw upon Codex Standards for our technical regulations.

We currently lack technical details for products that have not yet been regulated.

C) COOPERATION ACTIVITIES

We have received cooperation from the:

- United States on meat inspection
- The AECI and Spanish Embassy on food control

GUATEMALA

I. EXCHANGE OF INFORMATION

A) OFFICIAL AGENCIES

In Guatemala, the Health Code (Decree 90-97) in Book II, Title V addresses food, establishments and stores. Article 130 identifies the scope of action for every government body, as follows:

Ministry of Agriculture, Livestock and Food. It is in charge of controlling the stages of production, transformation, storage, transport, importation and exportation of non-processed food.

Ministry of Public Health and Social Assistance. It is in charge of controlling the stages of processing, distribution, transportation and marketing of processed food of any kind, national or imported, including the granting of the sanitary licence for the setting up of non-processed food establishments, the sanitary certification or sanitary registration of reference of products and the assessment of their conformity, controlling good manufacturing practices.

Town Councils. Authorization of establishments related to the management and sale of food in town markets in accordance with standards established by the Ministry of Agriculture, Livestock and Food, as well as street food fairs and food stores on the streets.

Ministry of Economy. It is in charge of controls in the area of metrology and industrial property.

Ministry of Energy and Mines. It is (jointly with the Ministry of Public Health and Social Assistance) in charge of the certification of radioactivity levels in food as well as the assessment of radioactivity effects and the suitability for consumption of such foods.

In the reorganization of the Executive Government of Guatemala, during the 1996-2000 Administration, regulatory bodies were included in the structure of the Ministry of Agriculture, Livestock and Food and the Ministry of Public Health and Social Assistance. The Division of Standards and Regulations is within the Ministry of Agriculture, Livestock and Food with its Office of Standards and Procedures with the Area of Non-Processed Food Safety (A.G.746-99). The aim of this division is to contribute in the protection, preservation, conservation, exploitation and sustainable use of agricultural and hydrobiological resources, renewable natural resources, as well as the prevention and control of non-processed natural food in all stages through the participatory definition of clear standards and control their correct application. The Ministry of Public Health and Social Assistance has set up a Division of Standards and Regulations within each of the five Regulation Departments including that of Food Regulation and Control. The mission of this department comprises ten items, five of which are related with the design, issuance, readjustment or dissemination of food standards.

In both ministries, these divisions have been in charge of facilitating technical and administrative procedures related to the issuance of standards aimed at promoting production, conservation and marketing.

The Guatemalan Standard Commission, attached to the Ministry of Economy, has been the body in charge of standard development since its creation in 1962. These were the first food standards published in the *Diario Oficial* in 1976, some on dairy products. The Commission has 114 standards on food specifications, one on fishing specifications, three on water specifications, five on hygiene production practices, 173 standards on testing methods and four specific standards on sampling.

A.1 Codex Alimentarius in Guatemala

In the Ministerial Agreement of 1986 the Technical Director of Food Control is assigned Official Codex Alimentarius Contact Point. The Government Agreement 214-2002, Regulation for the Creation of the National Codex Alimentarius Committee of Guatemala, reaffirms, in Article 3, that the Head of the Area of Non-Processed Food Safety of the Division of Standards and Regulations of the Ministry of Agriculture is the Contact Point. It also establishes an internal system called National Codex Committee, which is in charge of coordinating the work conducted by the various sectors involved in food regulation (governmental bodies, associations or boards of the food industry and consumer organizations) and establish the country's position in relation with Codex standards being developed. Currently, eight bodies of the public and private sector make up the Codex National Committee, which has an internal regulation on the work of technical committees. There are 13 local technical committees: 7 active committees, 3 set up initiating work and 6 in development.


B) FOOD LEGISLATION

Food legislation derives from the Health Code, enacted in 1997. In 1999, the Regulation on Food Safety (A.G. 969-99) was issued. There are also technical regulations, procedures and standards specifying the control of primary production, establishments and processing and distribution plants, and food marketing.

Article 183 of the Health Code makes specific reference to the Codex Alimentarius and its application in Guatemala. In addition, Guatemala actively participates in the regional effort (Customs Union: Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua); it adapts Codex standards to develop regional food safety legislation.

C) COOPERATION ACTIVITIES

Guatemala participated in the FAO Regional Project (TCP-RLA 0065), which supported National Committees during 2001 and 2002. Then, the IDB/ Ministry of Agriculture, Livestock and Food, through the Project: Program Supporting Restructuring of Food and Agriculture Production support the Strengthening of Codex Alimentarius in Guatemala. OIRSA and IICA have developed projects on diagnosis of meat health and safety and of food safety programs. Canada has provided training in HACCP, technical cooperation with Cuba and Spanish Cooperation have developed courses on good manufacturing practices for small fishermen. WHO/PAHO have continually helped the National Health Laboratory as well as other activities related to food safety at the Ministry of Public Health and Social Assistance.



HONDURAS

A) OFFICIAL AGENCIES

In Honduras, there are three agencies responsible for regulating food production, trade and control, namely: the Division of Sanitary and Environmental Regulation of the State Department of Health, the National Service of Agricultural Health of the State Department of Agriculture and Livestock, and the Division of Consumption and Protection of the State Department of Industry and Trade.

The State Department of Agriculture and Livestock of Honduras, through the Office of the General Director of the National Service of Agricultural Health and the Technical Subdivisions of Animal Health and Plant Health, is in charge of regulating the processed, semi-processed and fresh food, either from animal or vegetal origin. To that end, it develops regulations and guidelines referred to international rules, particularly Codex Alimentarius, and authorizes farm-origin exports and imports.

The State Department of Health of Honduras has a specific set of regulations titled "Regulations on the Control of Food Hygiene", enforces the provisions of Book II of the Health Code, on health promotion and protection, Title II on food and beverages. Foods, food additives and food packages are subject to the food rules and methods set out in the context of Codex Alimentarius and accepted by the Republic of Honduras under these Regulations and the Best Manufacturing Practices of the food industry.

In order to strengthen the regulating function of animal- and vegetal-origin products and byproducts according to competencies, and to coordinate the control and surveillance of zoonoses, food-borne diseases and the official agencies responsible for food legislation, the State Department of Agriculture and Livestock and the State Department of Health entered into an Administrative and Technical Cooperation Agreement, which provided for the parties' responsibilities regarding food control and surveillance and under which it was developed an operating plan for its implementation.

Activities of the Codex Contact Point and national committees.

Under Executive Order No. 0141 dated on March 1992, it was created and regulated the Codex National Committee in Honduras dependent on the Department of Public Health. Later, under Executive Order No. 521-03 dated on June 2 2003, Executive Order No. 0141 is amended and the Technical Secretariat dependent on the Department of Agriculture and Livestock was created.

The Codex National Committee in Honduras is a technical body whose chairmanship rotates and is always held by a member owning the governmental agencies of Health, Agriculture and Livestock, and Industry and Trade in that order. In addition to these institutions, the Department of Natural Resources and the Environment, the Department of Finances, the Council of Private Corporations of Honduras, the Council of Science and Technology of Honduras, the National Association of Industrials, the Council of Higher Education, and the Committee of Consumer Defense are also represented in the Codex National Committee.

The Technical Secretariat depends on the Department of Agriculture and Livestock, is in charge of the Codex Committee Secretariat and also the Contact Point, which is in the Division of Food Safety/Codex Alimentarius. Today, the Codex National Committee is chaired by the Department of Agriculture and Livestock.

B) FOOD LEGISLATION

The Departments of Agriculture, Health, and Industry and Trade (Standardization Office) hold preliminary working meetings to reach agreement regarding the regulations to be enacted. Nowadays, the Department of Agriculture is working on the update of the Phytosanitary Act and has already included texts and codes related to Codex, OIE and CIPF.

C) COOPERATION ACTIVITIES

As to this matter, Honduras is working together with the Central American Customs Union and is in touch with other countries like the US, Chile, the EU, etc. The component of inspection training and laboratory is included.

MEXICO

Mexico is grateful for the opportunity to send comments on circular letter CL 2004/24-LAC.

A) OFFICIAL AGENCIES: In Mexico, responsibility for food control and safety resides essentially in two official agencies:

The National Food Health, Safety and Quality Service (SENASICA), which reports to the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA).

The Federal Commission for Protection against Health Risks (COFEPRIS) which reports to the Secretariat of Health (SSA).

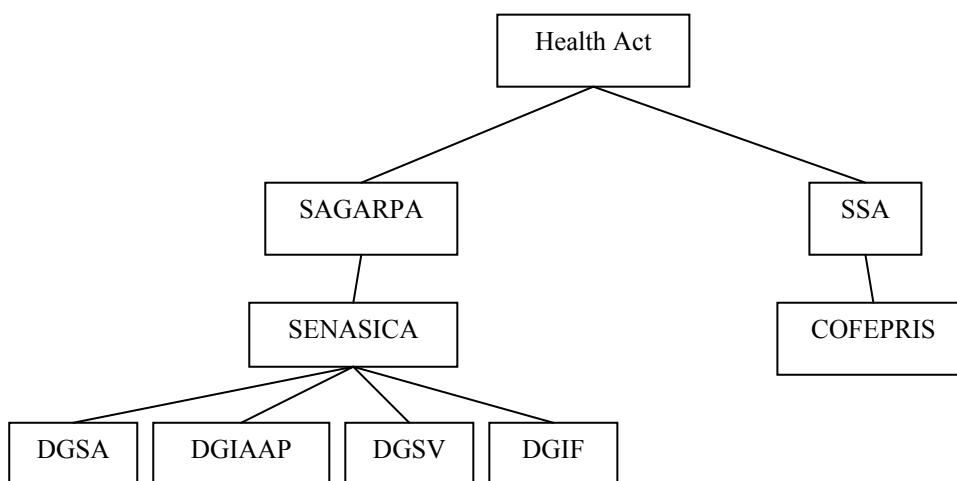
A1) SENASICA

As consumers became more aware of the importance of food hygiene, quality and health, they began to ask the authorities for greater control over domestic and imported foods.

Other important influences have been market globalization and the signature of international, regional and bilateral agreements which, while reducing customs barriers, have at the same time tightened health restrictions because of outbreaks of food-borne diseases.

The Mexican Government's strategy has been to set regulations and standards to protect consumer health and develop markets for food products on the basis of their safety. This led to the National Food Safety System which combines the efforts of the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) and the Secretariat of Health. The system is jointly coordinated by the National Food Health, Safety and Quality Service (SENASICA) and the Federal Commission for Protection against Health Risks (COFEPRIS).

An organizational diagram of the official agencies responsible for food legislation and control in Mexico looks like this:



Health Act

In 1983, with the establishment of the Department of Health, the President of the Republic sent the proposed Health Act to Congress as the regulatory instrument for Article 4.30 of the Constitution. The Act was passed in 1984 enshrining the right of all individuals to health protection and defining the conditions and modalities of access to the country's health services.

- **SAGARPA:** In December 2000 the Mexican Government included food as a new element in the substantive work of the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food. SAGARPA took on responsibility for food safety in July 2001 as set out in its Rules of Procedure and in the Law on Sustainable Rural Development. .
- *SAGARPA is an arm of the Federal Executive Authority tasked with providing policy support to foster and better tap the comparative advantages of the agricultural sector, to integrate rural activities into other production chains of the economy and to stimulate the collaboration of producer organizations with its own programmes and projects and with the proposed agricultural goals and objectives of the National Development Plan.*
- **SENASICA:** On 10 July 2001, SAGARPA's Rules of Procedure published in the Federal Gazette identified the following duties for the National Food Health, Safety and Quality Service (SENASICA):
 - Determine policies and guidelines to enhance the safety of foods of animal, plant, aquacultural and fisheries origin;
 - Propose general provisions, through official Mexican regulations and standards, aimed at preventing, controlling and combating pests and diseases that affect agriculture, livestock, crops, aquaculture and fisheries;
 - Regulate and evaluate ongoing food safety programmes conducted in coordination with state governments and subsidiary bodies;
 - Inspect and certify, in accordance with the law, establishments, production units, processes, systems, transportation, storage and outlets where food is handled;
 - Recognize, authorize and, as appropriate, certify food production, processing, verification and inspection systems in order to guarantee the safety of food for domestic consumption or export.
- *SENASICA, formerly the National Commission on Plant and Livestock Health (CONASAG), was established in 1996 as a decentralized arm of SAGARPA tasked with ensuring that marketed products were free of plant or animal health risk, thus enhancing the competitiveness of Mexican products on domestic markets for the benefit of Mexican producers. SENASICA is made up of specialist directorates to help it in this task.*
 - **Directorate of Plant Health (DGSA):** *This Directorate oversees the implementation of plant health policies and strategies through the management and application of phytosanitary legislation and procedures in order to prevent, control and eliminate pests and diseases that affect agriculture in the country.*
 - **Directorate of Animal Health (DGSA):** *Its task is to plan, organize, direct, control and regulate livestock health and hygiene services through the provision of animal health protection services, the conduct of studies and application of technologies and through actions aimed at monitoring, preventing, controlling and/or eradicating, as necessary, diseases that affect the livestock population in order to enhance domestic production, sales and productivity.*
 - **Directorate of Agricultural, Aquacultural and Fisheries Safety (DGIAAP):** *Its objective is to help ensure the quality and safety of foods derived from agriculture, aquaculture and fisheries through policies, a regulatory framework, plans, activities and services aimed at fostering and regulating the application and certification of systems to reduce contaminant risk in the production and primary processing of food for human consumption, and the proper use and handling of plant and animal health and production inputs, in support of the competitiveness of the country's agricultural producers and for the benefit of consumer health.*

- **Directorate of Phytosanitary Inspection (DGIF):** *This defines and evaluates programmes, policies and strategies of control and supervision of plant and animal health through international agricultural health inspection offices at ports, airports and borders, inspection points, and plant and animal health protection cordons based on existing regulations, in order to prevent the entry into the country of pests and diseases that affect agricultural production and to prevent the spread of crop and livestock pests and diseases present on the national territory, in doing so helping promote effective plant and animal health protection campaigns and reducing risks to public health.*

There are also support bodies such as the National Advisory Committee on the Standardization of Phytosanitary Protection (CONAPROF) that assist SENASICA in drawing up Mexico's Official Standards and in applying the verification and certification processes. These bodies envisaged under Federal legislation on plant and animal health are made up of producer organizations, academic groups, public and private institutions as well as approved verification and certification bodies playing a major role in the achievement of SENASICA's objectives.

SENASICA also runs special programmes against the fruitfly, the Mediterranean fly and cotton pests, aimed at preventing, controlling and eliminating specific or collective pests impacting strongly on the national economy. These programmes have an infrastructure that reflects SENASICA's responsibility for plant and animal health protection in the country. Finally, SENASICA has a strategic plant health plan, a budget, evaluation and control instruments and institutional policies.

B) FOOD LEGISLATION

Under Mexican legislation, the public sector has to act strictly within the regulatory framework. SENASICA thus operates within the legislative obligations of a wide body of law:

- **The Political Constitution of the United Mexican States.**
- **The Federal Public Administration Act** which indicates the juridical nature of the decentralized administrative bodies, as in the case of SENASICA, and provides for the existence and powers of SAGARPA as agency of the Federal Executive.
- **Federal Law on Animal Health:** Enforcement of this law falls to SAGARPA as regards diagnosis, prevention, control and eradication of animal pests and diseases.
- **Federal Law on Plant Health:** This is the basic legislation for SENASICA's authority over plant health as it seeks to promote and check compliance with phytosanitary measures; to diagnose and prevent the dissemination of pests that affect crops, their products and by-products; to determine phytosanitary measures; and to regulate the biological effectiveness, application, use and management of inputs, as well as to develop and provide phytosanitary activities and services.
- **Federal Law on the Administrative Procedure:** This framework law on administration is an instrument that allows SENASICA to carry out its mandated public service activities in a proper manner.
- **Federal Law on Metrology and Standardization:** This regulates standardization, accreditation, compliance and verification; in other words, it establishes the process for the elaboration of Mexican Official Standards that set the criteria and specifications expected of products, processes, installations and services, when these are of potential risk to human, animal or plant health. These provisions are also mandatory for individuals.
- **SAGARPA's Rules of Procedure:** These provide SENASICA with juridical status as decentralized administrative organ of SAGARPA and determine its sphere of competence.

SENASICA proposes Official Standards on plant and animal health through CONAPROF and the National Advisory Committee on the Standardization of Animal Health Protection (CONAPROZ), on the basis of the mandate of international agreements on WTO sanitary and phytosanitary measures, the Federal Law on Metrology and Standardization, the Federal Laws on Plant and Animal Health, and the Federal Law on Administrative Procedure.

The Official Standards follow set procedure to ensure transparency and equity, to avoid acting as disguised barriers to trade and to assess their regulatory impact so as to make sure that benefits outweigh restrictions.

The Official Standards regulate production processes through campaigns to confine, control and eradicate pests and diseases that affect agriculture, livestock, aquaculture, their products and their derived products. They also regulate activity, exports, imports as well as plant and animal sanitary installations, services and techniques. Agreements and decrees are also issued to modify plant and animal health status.

SENASICA has so far published in the Federal Gazette 51 official Mexican phytosanitary standards, 12 agreements with declarations of pest-free zones, four published this year, three agreements on low prevalence and two national emergency instruments. It has also published 60 official Mexican animal health standards. During the course of 2004 the Federal Gazette has published two amendments to Mexican Official Standards (NOM-012-ZOO-1993 and NOM-041-ZOO-1995), a free zone agreement and an agreement on classification criteria for veterinary drugs marketed in the country, thus facilitating the correct application of NOM-064-ZOO-2000, and nine food safety agreements.

In contingencies, SENASICA has the authority to publish emergency standards which remain in force for six months and can be extended by up six further months, after which they have to be approved by CONAPROF or CONAPROZ, as appropriate, and made permanent.

C) COOPERATION ACTIVITIES

SENASICA carries out a variety of activities in coordination with state governments and subsidiary bodies:

- **Promotion and awareness raising:** It provides training to establish measurable systems of reduction of chemical, microbiological and physical risk in the production and manufacturing processes. The aim is to introduce Good Practice Programmes into the production process, thereby adding value and easing market access.
- **Approval and accreditation:** Through authorized experts, certification agencies, inspection units, sampling laboratories affiliated to SENASICA.
- **Supervision, inspection, verification and certification:** Recognition, inspection, verification and certification by individuals and entities with harmonized functions and acting according to established criteria.
- **Monitoring:** Domestic and imported, processed and unprocessed products, using standard procedures for taking and sending samples to determine compliance with contamination limits.
- **Traceability:** Agricultural, aquaculture and fishery products at any time or stage of the production process.

A2) COFEPRIS

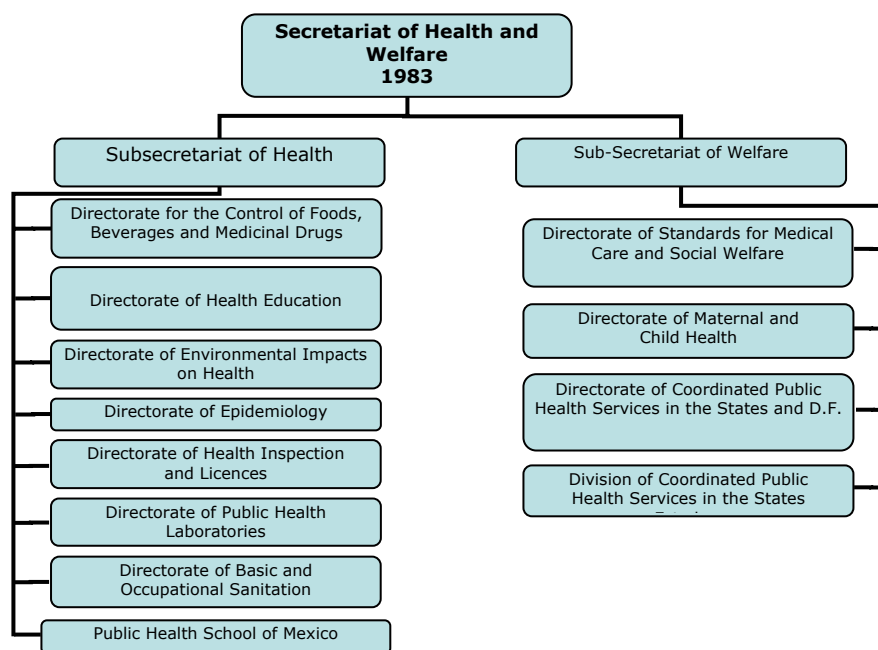
Throughout Mexico's history, health regulation and promotion have followed different approaches depending on the political, religious, social and economic tenets of the time. While there has always been concern for health, the variables that impact on public health are such that the State requires each individual to participate if the risks to health are to be avoided or reduced.

Health regulation and promotion underwent many significant changes between the first Health Code of 1891 and the Health Act of 1984. The first occurred in 1908 when Congress was presented with a reform making the Federal Government responsible for the general health of the Republic; the second was in 1917 when the General Health Council was required to stipulate preventive measures and to issue general provisions requiring obligatory compliance throughout the country; the third was in 1943, with the creation of the Secretariat of Health and Welfare by merging the Department of Public Health and the Secretariat of Public Welfare. Another significant change occurred in the late 1970s with the plans to build a National Health Service. The emphasis was primary healthcare and its point of departure was the extension of coverage.

Structural change in healthcare

A structural change in healthcare occurred between 1982 and 1988, with legislative renovation and administrative reform marked by the transfer of SSA resources and welfare and rehabilitation functions to the National System for Integrated Family Development (DIF), while environmental improvement functions were transferred to the Secretariat of Urban Development and Ecology (SEDUE). There was further legislative renovation with the promulgation of the Health Act to replace the Health Code, state health laws, technical regulations and standards, and conditions for the decentralization of services.

Figure 1



The right to health protection enshrined in Article 4 of the Constitution gave it independent status, unrelated to social security benefits, and extended it to all Mexicans regardless of social, professional or occupational status. The focus was on prevention, community participation and the co-responsibility of individuals as the key to achieving health for all. The Constitution also indicated that State planning would address the aspirations and demands of society and incorporate these into development plans and programmes, which provided the conditions for the National Development Plan that would guide the programmes of the federal public administration.

In August 1984, the Subsecretariats of Health and Welfare were disbanded and replaced by a Subsecretariat of Health Regulation and Development, with Directorates of Sanitary Control of Goods and Services; Control of Inputs for Health; Research and Technological Development; and Health Education; and by a Subsecretariat of Health Services.

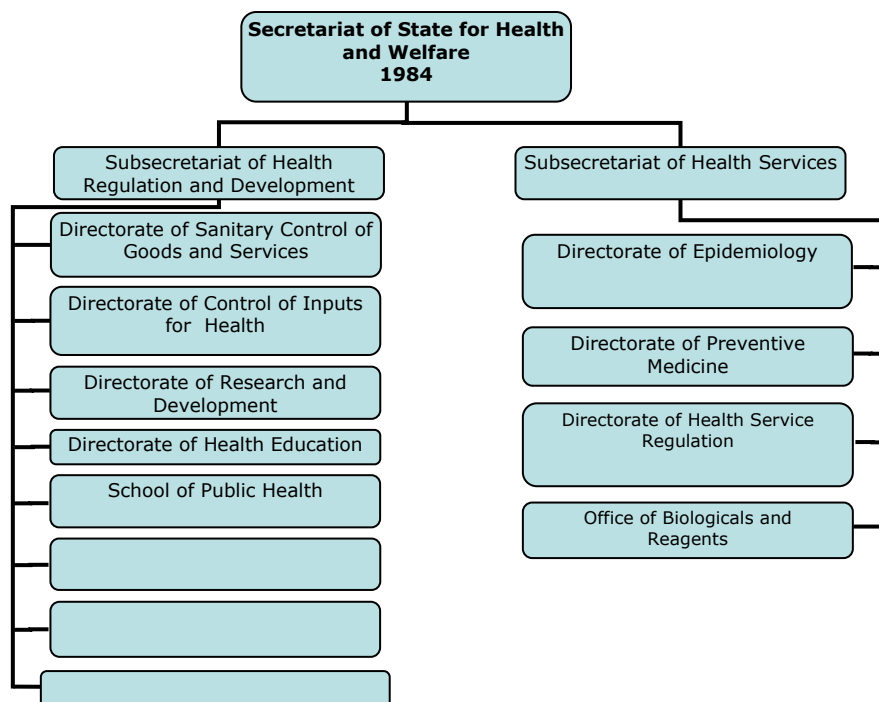


Figure 2

In 1985, the Secretariat of Health and Welfare changed its name to SSA stressing that, more than a change in name, this represented the reshaping of a new secretariat that covered aspects of individual and social public health and offered greater effectiveness of services through the establishment of a National Health System.

Mexico's response to burgeoning imports, to the perspective of globalization and to its impending membership of GATT and signature of other international treaties and conventions was to set up, in 1987, the Intersecretarial Commission for the Control of Pests, Fertilizers and Toxic Substances (CICOPLAFEST) to coordinate the actions of the Secretariats of Trade and Industry, of Agriculture and Water Resources, of Urban Development and Ecology, and of Health with regard to the monitoring and control of pests, fertilizers and toxic substances. A total of 31 state health regulation programmes also came into effect and regulatory provisions on the sanitary control of goods and services were published in follow-up to the Health Act.

Modernization of public regulation

A further batch of reforms sought to replace the old vertical, compartmentalized model with a new universal, participatory and pluralistic model. As indicated in the law, the objectives of the National Health System were to be achieved through four functions: a) provision of services; b) financing; c) management; and d) generation of health resources.

The evidential record for the Presidency of the Republic 1988-1994 illustrates that the purpose of health regulation was to avoid risk and harm to the health of the population in general, while, at the same time, promoting practices that would be beneficial to individual and collective health. Until then, the health inspection system had suffered from a serious malfunction in that subjective interpretations of regulatory texts had been used more to detect oversights and failings of personnel than to seek solutions. Exercise of authority was inflexible and bureaucratic and entailed endless procedures and documentation, which was fertile ground for corruption. At least two remedial actions were urgently required to render the process more transparent and efficient: administrative simplification and procedural modernization. A series of actions to modernize sanitary regulation were undertaken with this in mind:

1. Registration and health licences only for medicines, health products, pesticides, fertilizers and toxic substances;
2. Cancellation of health control cards;
3. Reduction in authorizations of responsibility, only retaining those for the pharmaceutical industry and for pharmacies and drugstores dispensing psychotropic and narcotic drugs;
4. Obligation to indicate the characteristics and properties of goods, applications, risks and uses for the guidance of consumers, by means of standard health and market labelling with information on product identification;
5. Inclusion of warnings with notice and increased severity of penalty;
6. Replacement of random inspection with sanitary inspection as a juridical measure undertaken to ensure regulatory compliance of establishments and products.

With the Federal Law on Metrology and Standardization of July 1992, the SSA became party to the change from technical standards of general health to Mexican Official Standards (NOM). This made it possible to determine all the legislative provisions that applied to the State, to the producers and suppliers of goods and services and to all others associated with or interested in the fields covered by the NOMs. The National Advisory Committee on the Standardization of Health Regulation and Promotion was also formerly set up in 1992.

The SSA published five NOMs in 1992 and produced a regulatory impact statement for 15 proposed NOMs to avoid overregulation and to ensure that the NOMs would impact positively the cost-benefit ratio. Updating of the Regulation on the Sanitary Control of Activities, Establishments, Products and Services also began (concluded on 8 August 1998) and various provisions of the Regulation on the Sanitary Control of Advertising (Official Gazette of 10 June 1993) were amended, supplemented or abolished.

The process of decentralizing the health services to the federative bodies began in 1995. Between 1995 and 1996, two regulatory agreements were published demarcating high-risk control areas and reducing bureaucratic procedures for companies. Certainty became a fundamental factor in this regulatory phase. In 1996, at the request of the Secretariat of Trade and Industry, the SSA registered 115 procedures with their corresponding justification and legal basis, which spelt out the process of simplification that had been introduced into health regulation.

The beginning of a new stage

On 5 July 2001, the Official Gazette announced the creation of the Federal Commission for Protection against Health Risks (COFEPRIS) tasked with: applying national health risk protection policy; improving and exercising the regulation, control, sanitary surveillance and evaluation of health risks from products, activities and establishments under its competence; and carrying out SSA's functions on the environmental impact on health, occupational health, hazardous residues, basic sanitation, accidents involving toxic, dangerous or radioactive substances and health protection in advertising.

COFEPRIS was created with Directorates of Sanitary Control of Products and Services; Environmental and Occupational Health; Medicines and Technologies for Health; Sanitary Control of Advertising and the National Public Health Laboratory.

COFEPRIS generally coordinates its work with each federative body through the sanitary regulation division of the public health services of the federative bodies that conduct sanitary regulation and promotion through departmental organizations covering products and services, environmental health and medicinal drugs, and a state public health laboratory.

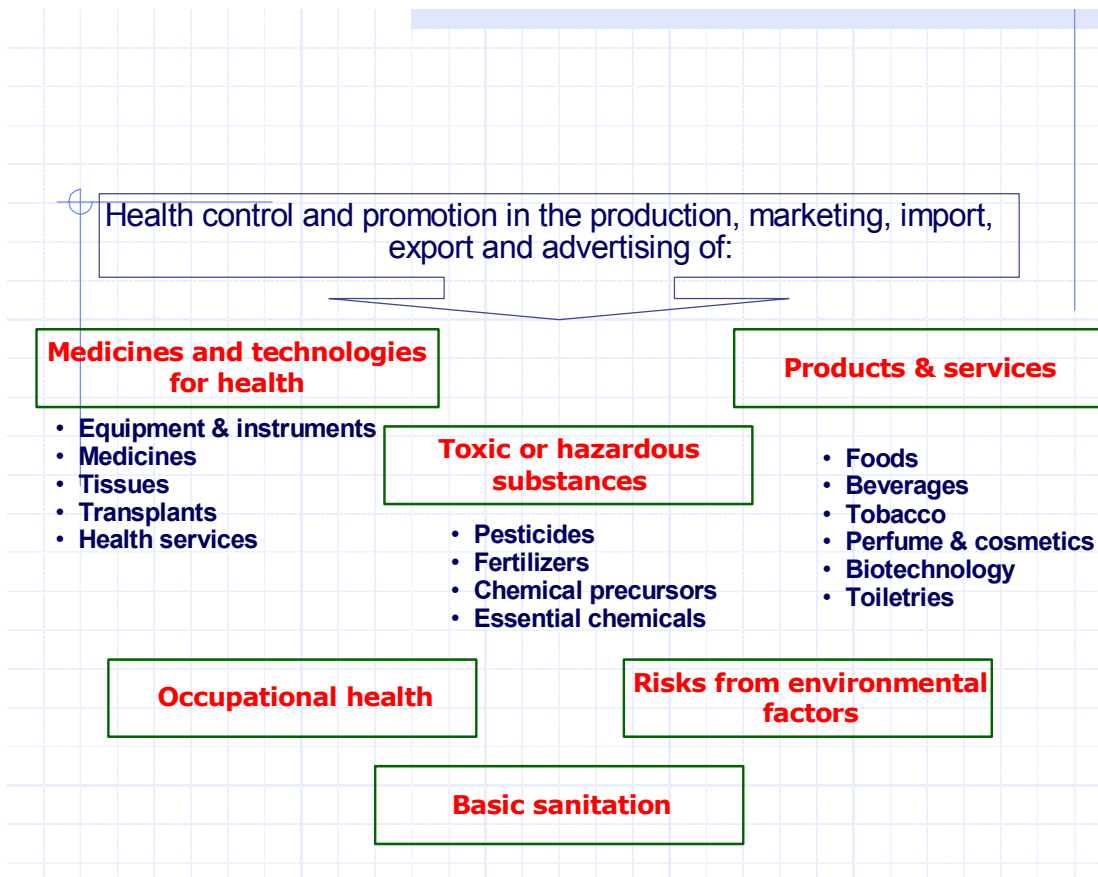
Most of the country's 232 sanitary jurisdictions come under the corresponding public health services and include a sanitary regulation coordinating unit headed by the chief of jurisdiction.

Challenges

Strengthening the influence of sanitary authorities means reappraising the importance of health in the present social and economic context, contrasting it with the development model and eliciting a greater participation in sanitary matters of bodies removed from the Federal Government.

The administration therefore proposed bringing all health regulation and promotion functions under one institutional roof to unify and standardize policies and to endow it with sufficient technical, administrative and operational autonomy. Hence the emergence of COFEPRIS.

COFEPRIS area of competence



In a broader perspective, the creation of COFEPRIS strengthens the lead role of SSA stated in the National Health Programme (PRONASA) and reflects the intention to modernize health surveillance and promotion.

This body will help specialize regulatory functions to work in a framework of synergies, integrating sanitary surveillance and verification functions and implementing national protection policy against health risks.

The approach adopted in the last 20 years to reduce and eliminate adverse impacts on health from the quality of products and services and environmental factors, by strengthening and modernizing sanitary regulation and promotion, has achieved significant results. Evidence of this lies in the changes made to the distinct Health Act regulations on products and services, health inputs, advertising, international health, transplant of organs and tissue, and health research, and in the publication of a battery of corresponding Mexican Official Standards.

However, dynamic change in science and technology and in the national and global social, political and economic environment have called for new approaches, in particular the use of scientific information to move faster towards the PRONASA objectives.

The challenge of equity calls for new instruments to address the backlog of accumulated problems, such as infectious diseases, undernutrition and problems of maternal and child health, while at the same time dealing with emerging problems, such as non-communicable diseases, occupational risks and the effects of the environment and advertising on health. Reducing and eliminating health risks will play a key role in avoiding and reducing disastrous health expenses, especially for the more vulnerable sections of the population.

Evaluation of risk

While regulatory instruments continue to be indispensable for the legal framework of health control, we now need to redefine their development and application in a new perspective which, based on risk evaluation, focuses on the timely and efficient application of protection measures. We need to consider that the specific characteristics of individuals, families and communities, their habits and customs, and their living and working conditions determine their exposure patterns and thus their likelihood of falling ill or dying. Capacity to measure these risks will permit intervention with protection measures to effectively reduce or eliminate them.

Evaluation of risk attempts to anticipate factors affecting individuals or population groups and to quantify the probability of their falling ill, having an accident or dying from a specific cause. Prior identification of risk helps programme timely interventions to protect the population effectively, reducing or eliminating the risk factors. With this in mind, it is important to note that the discipline of risk evaluation is still evolving and that not all the health risks have been properly assessed. Existing structures and processes therefore need to be modified and the technical capacity of staff needs to be developed to accommodate this new approach.

The approach to risk is therefore based on the assumption that the more precise the measurement, the greater the understanding of the need to help and the more effective the response, making it a useful tool for planning.

Given that many health-risk factors arise from the use and consumption of foods, beverages, medicines, medical equipment, perfumes, cosmetics, toiletries, plant nutrients, pesticides and other products and substances and from environmental and occupational factors, risk evaluation will be useful for:

- Identifying sources of potential harm and populations at risk;
- Measuring the probability of harm occurring;
- Measuring the scale of the resulting impact on health and the economy;
- Anticipating the protection actions needed to reduce or eliminate the risks, both regulatory and non-regulatory;
- Defining consistent policies.

Protection against health risk

Prioritizing the evaluation of health risk will help select and apply measures to avoid, reduce or eliminate such risks, which is primary prevention in the basic sense of protection. The concept of protection against health risk thus comes to the fore in changing the focus of health regulation, control and promotion, as prescribed in existing legislation. This change in conceptual focus requires legal and administrative change to achieve:

- The unification and standardization of health risk protection policies;
- The reorganization of processes in central health regulation and promotion units;
- Completion of the process of coordination with the federative bodies;
- Specific and systematic attention to local, regional and national health risks; and
- Greater and more effective participation of the different levels making up the country's sanitary infrastructure.

Conceptual framework of protection against health risk

Protection against risk to health, seen as a basic function of public health, thus entails a series of preventive actions by the State to direct health regulation, control and promotion towards the assurance of pre-emptive, flexible and efficient response by the health authorities for the identification, characterization and quantification of risks to health arising from sanitary conditions of the human habitat, products used or consumed, establishments, services and advertising. This can only take place through effective coordination of the sanitary units operating in the different spheres of government.

Fields of action

Activities will be pursued in four fields:

Risk evaluation and analysis, which, through the identification of hazards, the evaluation of exposure and dose response and the characterization of risk, permits timely and effective identification and implementation of the most appropriate forms of protection against public health risks. Risk analysis thus lies at the heart of the process to protect the public against health risks and provides a framework for promotion, regulation and control.

Promotion with non-regulatory actions facilitates control of environmental hazards. In this context, it is a key risk management tool as it strengthens the involvement and co-responsibility of community and health authorities in the three tiers of government, fosters enhanced regulatory provisions and unfolds in an eminently preventive context.

Regulation is the legal basis for health control. It establishes policies for the administration of services through laws, regulations, standards, decrees, agreements and conventions. It includes research, studies, technical appraisals and organizational and administrative guidelines. It also includes the standardization of factors relating to basic sanitation, environmental and occupational health, international health and health advertising.

Control corresponds to all oversight actions of health authorities to check that establishments, services, activities, products, equipment and individuals comply with legislative sanitary requirements and conditions. It checks and ensures that individuals subject to regulation comply with provisions.

Delivery

Delivery is through two channels: COFEPRIS and PROSA

The Federal Commission for Protection against Health Risks

The traditional structure for implementing health risk protection was compartmentalized into specialist fields and assigned to different SSA administrative units. Although activities were conducted according to the legal framework, this arrangement in fact produced very disparate policies, strategies and administrative actions which caused complications between the authority and the producer sectors.

It was therefore thought that the health authorities and business companies, and therefore the population at large, would benefit from a standardization of operations, policies, strategies and administrative mechanisms for carrying out health regulation, promotion and control, as the authorities would operate in an environment of greater transparency and certainty, especially if supported in their work by better technical and scientific evidence.

It was thought necessary to reinforce the role of COFEPRIS to strengthen the SSA lead role, by incorporating it into the organizational structure of the Health Act through a decree adding four fundamental aspects to Article 17:

1. Statement that COFEPRIS would be responsible for carrying out SSA duties of health regulation, control and promotion under Article 3 of the Health Act and a description of COFEPRIS jurisdiction:

- Evaluation of risk to health in areas under its competence;
- Implementation of national policy on protection against health risks and on the prevention and control of detrimental effects of environmental factors on human health, occupational health and basic sanitation;
- Elaboration and issue of official standards;
- Evaluation, issue or repeal of authorizations and other acts of authority;
- Issue of official health certificates;
- Sanitary control and surveillance of products, activities and establishments;
- Health control and surveillance of advertising;
- International health other than that relating to individuals;
- Imposition of sanctions and application of safety measures;
- Coordination with SSA administrative units to implement disease prevention and control actions; and epidemiological surveillance.

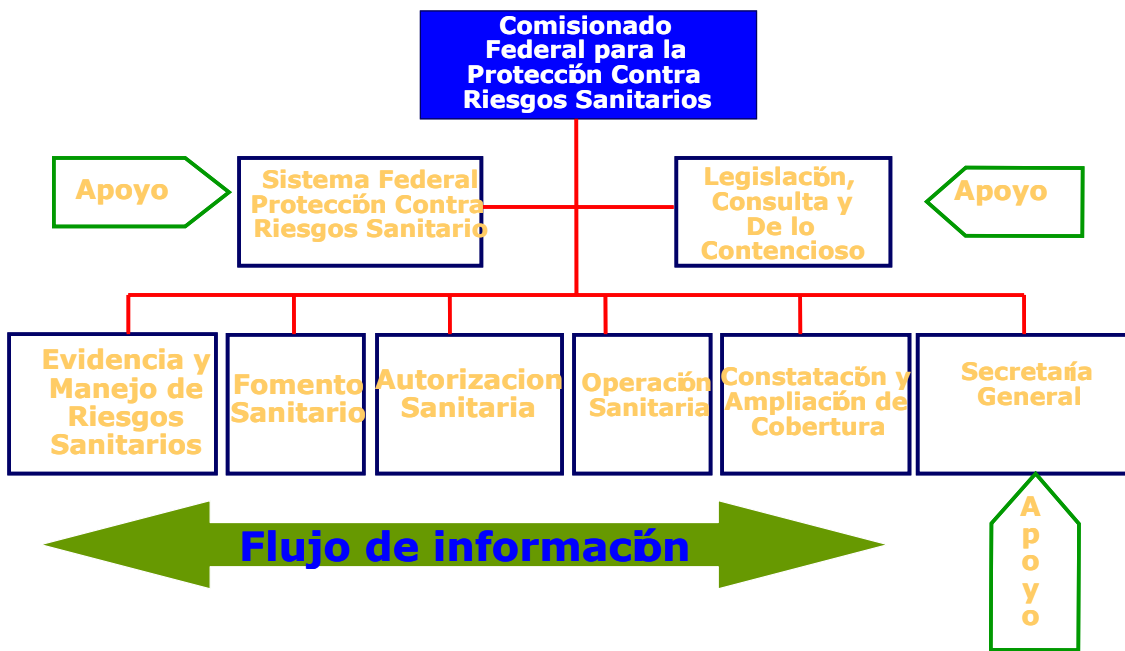
2. Statement on the administrative, technical and operating autonomy of COFEPRIS and its budget to comprise:

- Allocations from the Federal Expenditures Budget;
- Fees, earnings and miscellaneous income from the exercise of its duties in accordance with the provisions of the Federal Law on Revenues and the Federal Expenditures Budget for the corresponding fiscal year;
- Financial resources assigned to it, together with resources successively allocated to its operations; and
- Other legally acquired resources.

3. Requisites for resources received by COFEPRIS as fees and earnings and used for the maintenance, conservation and performance of its services, in accordance with the provisions of the Federal Expenditures Budget.

4. Requisites for nomination of the Federal Commissioner by the President of the Republic.

Estructura Orgánica



(Translator's note: regrettably unable to enter this chart but have provided the English translation below, starting from top then reading across)

Organizational Structure

Federal Commissioner for Protection against Health Risks

Support

Federal System of Protection against Health Risks

Legislation, Consultation and Arbitration

Support

Evidence and Management of Health Risks

Health Promotion

Health Authorization

Health Operations

Observation and Extension of Cover

General Secretariat

Flow of Information

Support

The Federal System of Protection against Health Risks

The legal reform that led to the creation of COFEPRIS has is underpinned by the fact that the design of health regulation, control and promotion policy is under the exclusive legal competence of the Federal Government, which is why it is centralized in the SSA. However, the exercise of responsibilities is in fact decentralized towards the governments of the federative bodies by coordination agreement.

Exercise of the federative bodies' authority of health control and promotion is determined by their capacity and priorities. In this connection, the establishment of a Federal System of Protection against Health Risks (PROSA) implies shared operational responsibility, the building of response capacity, financing and equity to resolutely address major national challenges. It also implies a broadening of competence under the federative coordination model for: statal and jurisdictional risk analysis, health promotion, authorizations, surveillance, information and emergency situations.

This is congruent with PRONASA's move to strengthen federalism within a cooperative approach, conserving the principles of solidarity and co-responsibility. From the health perspective, cooperative federalism articulates a system that can strengthen and consolidate the federation, in a framework of mutual respect of responsibilities of the different tiers of government and under a process of ongoing review, in which the balanced distribution of authority reflects the changing needs of the National Health System and hence the establishment of coordination agreements between the decentralized institutions and the federation. The intrinsic aim is to take decisions and resources down to the frontline of activity, to bring services closer to the country's citizens and to achieve a more equitable distribution of opportunities and guarantees among the different tiers of government.

The contribution of federative institutions to protection against health risk follows a long tradition of health regulation, control and promotion actions. There is ample evidence of such participation: the sanitary control of establishments, services and products; the delivery of priority programmes and response to environmental and health emergencies; and the sanitary control of imports. Their role is therefore not only necessary but irreplaceable for the functioning and development of PROSA.

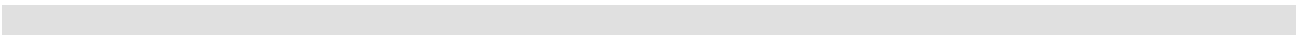
Liaison with the Mexican National Codex Committee (CMCAC)

One key function of the COFEPRIS Coordinating Office is to propose and coordinate a general strategy of negotiation, processing, updating, representation and follow-up to international commitments and forums on aspects within the competence of the Federal Commission, with the technical collaboration of commissions.

One central responsibility of COFEPRIS is the coordination of seven subcommittees of the Mexican National Codex Committee.

- Subcommittee No. 4 on Nutrition and Foods for Special Dietary Uses
- Subcommittee No. 7 on Methods of Analysis and Sampling
- Subcommittee No. 10 on Food Additives and Contaminants
- Subcommittee No. 16 on Food Hygiene
- Subcommittee No. 18 on Food Import and Export Inspection and Certification Systems
- Subcommittee No. 3 on Pesticide Residues
- Subcommittee No. 17 on Meat Hygiene

Experts also provide technical input and attend the meetings of the following Codex Alimentarius Committees:

- General Principles
 - Executive Committee
 - Codex Alimentarius Commission
 - Food Labelling
 - Latin America and the Caribbean
 - Fresh Fruits and Vegetables
 - Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology.
- 

PANAMA

We believe that the work of the Codex Commission is of utmost importance in order to achieve food legislation properly harmonized, so that a common language is used in the issues related to import/export and food control systems.

There should be on-going training activities, which should involve both the public and the private sector and consumers.

Relevant mechanisms enabling agile bilateral and sub-regional contact in relation with food legislation and food safety should be designed.

A) OFFICIAL AGENCIES

In Panama, the following official bodies are in charge of food legislation and food control:

- Ministry of Trade and Industry through the General Division of Standards and Industrial Technology, which is the National Regulation Agency.
- Ministry of Health through the Food Protection Department.
- Ministry of Agricultural Development through the National Plant Health Division and the National Animal Health Division.

Structure and Organization

Ministry of Trade and Industry:

The General Division of Industry Standards and Technology of the Ministry of Trade and Industry is the National Regulation Agency acknowledged by the State.

The General Division of Industry Standards and Technology is protected by Title II of the Law of 15 July 1997. This title addresses the provisions on Technical Regulation, Conformity Assessment, and Certification on Quality, Metrology and Conversion to the International Unit System.

The General Division of Industry Standards and Technology is the Codex Alimentarius Contact Point and the National Codex Committee Technical Secretariat. The Decree which establishes the creation of the Committee was updated for the purposes of organization and functioning of the Committee (Executive Decree No. 41 dated 20 November 2001).

MINISTRY OF HEALTH

FOOD PROTECTION DEPARTMENT

STRUCTURE AND ORGANIZATION OF THE FOOD PROTECTION PROGRAM

Within the organic structure of the Ministry of Health, the Food Protection Department is dependant on the General Division of Public Health (institutional authority at central level), which conducts work related to regulation tasks (guidelines), Regulator (supervision/accreditation), Official Control and Surveillance, Sanitary Control and Advice concerning food, food safety and food quality.

We are also in charge of developing basic principles on food hygiene (prevention, protection, security and promotion) as well as verifying effective and efficient complying with the standards set.

In order to achieve this goal, its central organization, it comprises the following sections:

- **Sanitary Analysis and Registration of Food Section:**

It is responsible for the registration and description of information about any food, alcoholic or non-alcoholic beverage, soap, detergent, food for special diets entering the national territory for marketing. These should comply with technical standards and with requirements and procedures in order to be registered. It also has a database with information of registered food and is in charge of food surveillance and advertising.

- **Food Hygiene and Control Section**

Among other activities it is in charge of verifying the sanitary conditions of food sale stores. It is also responsible for the official post-sanitary registration monitoring and control of registered food, and coordinates—with regional authorities—programs on food fortification, sampling and delivery to the official laboratory: salt iodization, wheat flour, bivalves (saxitoxins). It also keeps information and monitors the cases and outbreaks of foodborne diseases in our country.

- **National Inspection of Food Plants Section:**

It is responsible for the assessment and verification of the programs to ensure BPM, SSOP and HACCP establishment quality in food plants, through audits of the systems applied by industries.

For its development, it has been divided into:

- Meat product of animal origin and by-product program (commercial industrialization of bovines, pigs, poultry, etc, as well as toxic residue program
- Milk and milk product program
- Fish industry product and by-product program
- Various Food products program (bread-making, energetic beverages, oil refining, wheat flour mills, etc).

The structure of the Food Protection Department has coverage in most provinces in the country. For this purpose it has 12 representations at regional level, fulfilling the responsibilities of operational activities.

Thus, problems concerning foodborne disease control and prevention (tourism, food security) are identified. Official controls, verification of pre-requisites (BPM, SSOP y HACCP), aspects involved in food import and export, operational procedures and criteria for decision making are strengthened.

II. LEGAL FRAMEWORK

Sanitary legislation is varied and encompasses various issues. Therefore, part of it is outlined below:

- The Constitution of the Republic of Panama
- The Sanitary Code, Law No. 66 dated 10 November 1947
- Decree No. 256 dated 13 June 1962
- Law No. 60 2 dated December 1977
- Executive Decree No. 1195 dated 3 December 1992
- Executive Decree No. 423 dated 15 July 1993
- Executive Decree No. 65 dated 9 June 1998
- Executive Decree No. 352 dated 10 October 2001
- Regulation No. 468 dated 2 November 1997
- Regulation No. 81 dated 3 June 2002

Ministry of Agricultural Development

National Direction of Plant Health

At national level the degree of compliance with the contents or terms of reference established in National Legal Standards (Laws, Decrees, Regulations, etc) regarding food safety should be reviewed. In particular, with regard to Plant Health, the degree of compliance with provisions under Law No. 27 dated 9 July 1996 on Maximum Residue Limits of pesticides in food should be reviewed

Activities of the Codex Contact Point and the National Codex Committee:

Last year a working commission made up of representatives of the Committee developed Proposed Guidelines for the development of a Project on Sustainability of the Contact Point and the National Codex Committee from a technical, administrative and financial point of view.

The working method for the development of the proposal was reading and analyzing the specific conclusions and recommendations of each national workshop carried out in the framework of the TCP/RLA/0065 FAO project in which we participated, as well as the general conclusions and recommendations of the project, with the aim of selecting the activities that could be undertaken by the Committee as part of the 2004-2005 work plan. These activities were assessed again, included and developed in accordance with the four areas indicated below:

- Spread of information about the existence and tasks of the National Codex Committee of Panama among the authorities with decision-making power and International Agencies authorized in the country.
- Food Legislation.
- Food safety workshops.
- National Accreditation Council and procedures for food import and export.

B) FOOD LEGISLATION

As regards existing priority products Standards under review—or which should be reviewed—for its harmonization or equivalence with Codex Standards we can mention:

- Food Labelling
- Fresh Fruit and Vegetable:
 - Standard on Oranges
 - Standard on Pineapple
- Milk and Milk Products:
 - Standard on Yoghurt
 - Standard on Ice cream
- Fruit Juice and Nectar
- Bottled Water

As regards General Subject Committees related to the safety of food on which there are no national regulations, Codex Alimentarius standards are taken as reference.

C) COOPERATION ACTIVITIES

As National Regulation Agency, we are in contact and exchange information and training in the area of Regulation with similar agencies in the area and with regional agencies, as is the case of the COPANT - Council of the Pan-American Commission on Technical Standards.

PARAGUAY

A) OFFICIAL AGENCIES

In our country there are several official agencies responsible for food control; namely the Ministry of Public Health and Social Welfare, through the National Institute of Food and Nutrition, the Ministry of Agriculture and Livestock, the Ministry of Industry and Trade, the Town Council of Asunción and other municipalities and governments in their areas of competence.

The Ministry of Public Health and Social Welfare through the National Institute of Food and Nutrition conducts hygiene inspections, sanitary inspections and sampling for food product verification at the places where food is processed, sold, stored and/or fractionated in the country.

The Town Council of Asunción carries out food control in the capital city, in accordance with the roles assigned by the City Organic Law.

The Ministry of Agriculture and Livestock is in charge of Good Manufacturing Practice Application Control Programs at Meat Processing Plants, National Plan of Control of Residues in Animal Products, National Plan of Pathogen Reduction (E. Coli 0157 H7, Salmonella sp) at Meat Processing Plants. It also performs the control and inspection of activities related to agricultural production, forestry and agricultural industry, as well as the evaluation and control of the application of sanitary standards and quality standards of products and inputs, for their national and international trade.

Furthermore, there is a program of SURVEILLANCE OF FOODBORNE DISEASES, implemented by the National Institute of Food and Nutrition, the Ministry of Agriculture and Livestock, the National Institute of Technology and Regulation and the Town Council of Asunción in their areas of competence for foodborne disease control, Regulation MSP and BS N° 479/95.

The National Institute of Technology and Regulation (INTN in Spanish) works assigning Official Control Agencies as technical support in their control activities (supply of services or expert advice). This is also the case with some chemical laboratories of academic institutions like that of the School of Chemistry.

The General Division of Consumer Defence, dependant on the Ministry of Industry and Trade and other Consumer Defence Offices of the various municipalities is in charge of acting on their own initiative or receive citizens' reports for the protection of basic consumer rights (life, health, security from the risks caused by the provision of products and services considered harmful or dangerous.

Issues related to importation/exportation

Customs authorities are in charge of the entry into national territory of products forbidden by the respective enforcement authorities due to the negative effects on health and public security, national economy, ethics and good customs.

The General Customs Direction does not permit the importation of food products, beverages and additives of plant, animal or mineral origin without the Sanitary Registration issued by the National Institute of Food and Nutrition (technical office of the Ministry of Public Health and Social Welfare), which—through the Food Production Department—is in charge of granting the Certificate of Registration Validity of food products imported for human consumption. For cases of importation of food of animal or plant origin, appropriate authorization of the Ministry of Agriculture and Livestock shall be required.

Res. 515/00 of the Ministry of Agriculture and Livestock regulates the importation of food of animal origin.

The Ministry of Agriculture and Livestock, in its specific technical departments is competent in issues related to the importation and exportation of seeds and the use, or non-use, in national territory of different types of seeds and plant products.

The INTN works in the area of Imports and Exports through the voluntary Certification of products on Companies' request.

In accordance with Laws 838/26 and 881/81, regulated by regulation 30/99, the Town Council of Asunción—through the Imported Food division is in charge of authorizing the entry of imported food into the country at the various customs in the capital area.

Activities of Codex Contact Points and National Committees

The National Codex Committee—Paraguay was set up by Decree 17487 of the Executive Power dated 11 June 1997. This Committee is composed of a permanent representative and an alternative representative of the Ministries of Public Health and Social Welfare, of Industry and Trade, of Agriculture and Livestock, and of Foreign Affairs; as well as representatives of the National Institute of Technology and Regulation, the Institute of Municipal Development, the Town Council of Asunción, the Council of Universities, the Federation of Production, Industry and Trade, the Industrial Union of Paraguay and the Rural Association of Paraguay. The Chairmanship is exercised on a rotation basis; for a one-year term each. Currently, the Council of Universities is the Chair Pro-Tempore; the National Institute of Technology and Regulation has been the Codex Contact Point in Paraguay since 1968 and has been the Permanent Executive Secretariat of the Committee since the creation. Within the CONACAP there are Technical Subcommittees (active and inactive), in accordance with committees established at international level. It is worth mentioning that the creation of the National Committee was strengthened by FAO project TCP/PAR/6611.

Also, it is worth pointing out that the efforts of the Committee are being directed towards the provision of information to all interested parties and achieving their effective participation in Codex work, as a follow-up of the output of the FAO Cooperation Project, TCP/PAR/2801, "Contact Point and National Codex Alimentarius Committee Strengthening", which lasted 20 months and finished in April 2004.

B) FOOD LEGISLATION

Below are listed some provisions regulating Food Control:

Law 269/ 1917 "Creation of the Direction of Livestock and Meat Inspection".

Law 937/82, by which the National Institute of Technology and Regulation is designated National Metrology Laboratory and its regulation Decree 1988/99 of the Executive Power. The National Institute of Technology and Regulation acts as technical support of bodies conducting controls.

Law, 836/80 Sanitary Code, and the Decrees and Regulations of the Ministry of Public Health and Social Welfare and Law 115, which amends Law 836/80.

Decree 1635/1990, which regulates Art. 175 of Law 836/80, Sanitary Code, where sanitary registration of food products, beverages and additives intended for human consumption is declared obligatory throughout national territory for manufacturers, representatives, importers, fractionators and others.

Law 1173/85, Customs Code.

Law 1173/85 on Seeds and Cultivar protection and its regulatory decree 7797/2000.

Law, 81/92, which establishes the organic and functional structure of the Ministry of Agriculture and Livestock, Law 1146/66, Decrees and Regulations of the Ministry of Agriculture and Livestock which establish the requirements for cattle product control.

Law 123/91, by which new phytosanitary protection standards are adopted.

Decree 1552/96, by which the National Institute of Technology and Regulation is designated National Certification Agency.

Law 1334/98 of Consumer and User Defence, which is partially regulated by Decree 2533 of the Executive Power dated 16 April 1999.

Paraguay is part of economic bloc MERCOSUR, where Party States harmonize their food legislation, mainly based on Codex Alimentarius criteria.

At national level, some standards are equivalent to Codex documents and some are not. For example, there are some national standards which are different from Codex ones in their treatment of final conservation or are applicable to other product presentations.

There is a Regulation of the Ministry of Public Health and Social Welfare of 1993 which determines Codex Alimentarius food standards and sanitary regulations as reference.


In this respect, within the framework of Project TCP/PAR/2801, the paper “Current Status of Paraguay’s Food Legislation as compared to Codex Alimentarius Standards” was prepared and an Action Plan to update food legislation in accordance with Codex was designed. The paper is available on this website: www.rlc.fao.org/prior/comagric/docs.htm

C) COOPERATION ACTIVITIES

As already pointed out, the FAO Cooperation Project, TCP/PAR/2801, has recently finished.

The National Institute of Technology and Regulation has signed agreements of Technical Cooperation with the JICA in the field of packaging, microbiology and food control in Paraguay.

There are other Technical consultancies of International Bodies in our country, like FAO/WHO, PAHO/WHO, UNICEF, IICA, OIE, JICA, among others.



VENEZUELA**A) OFFICIAL AGENCIES****A.1) Institutions participating in the development of food standards and regulations**

- **Ministry of Production and Trade, Autonomous National Service of Standardization, Quality, Metrology and Technical Regulations (SENCAMER), located in Centro Comercial los Cedros, Avenida Libertador, Caracas, Venezuela. Telephone number: 0212-7616474, Fax: 0212-7314210, e-mail: sencamer@cantv.net, web page: www.sencamer.gov.ve**

Competent National Authorities:

- Ministry of Production and Trade.
- Vice-minister of Industry
- Vice-minister of Trade
- Autonomous National Service of Standardization, Quality, Metrology and Technical Regulations (SENCAMER).

Authorities with Delegated Competencies:

- Regional SENCAMER offices (Aragua, Lara, Zulia, Bolívar, Falcón).

It was set up on 30 December 1998, as a result of a merger of the Autonomous National Service of Metrology (SANAMET) and the Autonomous National Service of Standardization (SENCORCA).

Legal Framework

Organic Law of the Venezuelan System for Quality, Official Gazette No. 37555 dated 23 October 2002.

Mission and Roles

SENCAMER is the department of the Ministry of Production and Trade in charge of ensuring the functioning of the National System for Quality as support to the socio-economic development model of the country.

Its main roles are as follows:

- Designing and regulating policies on metrological control of the State
- Coordinating the conduct of metrology programs developed by national laboratories
- Controlling national patterns of measuring and calibration of the State
- Verifying measuring instruments throughout the country
- Setting requisites for accreditation of organizations contained in the conformity assessment system, in accordance with international guidelines in the matter
- Implementing policies and strategies on the design and application of standards and technical regulations intended to improve the competitiveness of industry and trade and, particularly, consumer and user protection
- Providing Codex Alimentarius Contact Point
- Providing the Technical Secretariat of the National Codex Committee

Since the entry into force of the new Law of the Venezuelan System for Quality (4 February 2003), published in Official Gazette No. 37555 (23 October 2002), SENCAMER has adjusted to the innovative requirement of the new regulation.

SENCAMER is made up of the Technical Directions of Metrology, Technical Regulations and Accreditation, and four Regional Directions. It also includes the Secretariat of the National Codex Committee in its structure.

The process of developing standards is carried out by the Committee of Food Products CT10.

With regard to technical regulations, SENCAMER is the Contact Point of notification in accordance with the provisions under the Agreement on Technical Barriers to Trade and as Codex Alimentarius Contact Point.

SENCAMER has not received the relevant documents of this authority although notifications have been made to the Codex Commission Secretariat in this regard.

- Ministry of Health and Social Development (MSDS), Food Hygiene Direction, located in Centro Simón Bolívar, edificio sur, third floor, office 313, El Silencio, Caracas, Venezuela. Telephone number: 0212-4843066, Fax: 0212-4843066, e-mail: equialimentos@msds.gov.ve, web page: www.msds.gov.ve

The MSDS is in charge of the program of food import and export inspection and certification, through the Food Hygiene Direction and Regional and District Food Control Services operating in each of the states into which the country is geopolitically divided.

Competent National Authorities:

- Ministry of Health and Social Development
- Vice-minister of Health
- Director of Environmental Health and Sanitary Auditing
- Director of Food Hygiene

Authorities with Delegated Competencies:

- State Directors of Health
- State Sanitary Auditors
- State Coordinators of Food Hygiene
- District Coordinators of Food Hygiene

The MSDS was set up on 30 August 1999; the Direction of Food Hygiene, however, has been running since 1995 (it was the Food Hygiene Division from 1974 to 1995).

Legal Framework

Organic Law of the National Health System (Decree Law), Official Gazette No. 5263 dated 17 September 1998.

General Food Regulation (Decree Law), Official Gazette No. 25864 dated 16 January 1959.

Regulation on Street Food Stores, Official Gazette No. 34 423 dated 7 March 1990.

Regulation on Supplementary Standards of the General Food Regulation, Official Gazette No. 35921 dated 15 March 1996.

Regulation on Requirements for Sanitary Permission to Establishments and for Food Transport Vehicles, Official Gazette No. 5097 dated 18 September 1996.

Regulation on Standards on Good Practices for Processing, Storage and Transport of Food for human Consumption, Official Gazette No. 36081 dated 7 November 1996.

Regulation on Standards on Good Practices for the Functioning of Food Micro-businesses, Official Gazette No. 36100 dated 4 December 1996.

Mission and Roles

The Direction of Food Hygiene is the department of the Ministry of Health and Social Development in charge of the regulation, monitoring, surveillance and sanitary control in every level of the food chain, in order to minimize risk factors to prevent the presence of foodborne diseases.

Its main roles are as follows:

- Establishing the guidelines of the food hygiene program as a framework of reference for their application at a national level
- Developing standards and regulations of the food hygiene program
- Applying out controls in each level of the food chain
- Assess the food hygiene program for decision making
- Issuing sanitary certification regarding food
- Applying the sub-program of sanitary food registration
- Applying the sub-program of control of materials, containers and packages intended for contact with food
- Being responsible for the surveillance of foodborne diseases
- Coordinating and organizing events in order to circulate the current regulations of the food hygiene program

The Food Hygiene Division—set up in 1974 and designated Direction in 1995—has conducted work related to standardization and regulation since its creation.

The Direction of Food Hygiene is made up of the departments of Food Registration, Food Control and Hygiene Control of Buildings, Equipment and Packaging, and the Research Section.

In every regional entity there is a Service of Food Hygiene in charge of surveillance and control of the program within its jurisdiction. Another body working in connection with food analysis is the National Institute of Hygiene “Rafael Rangel”, as a laboratory of national reference, which is a reference to other public and private laboratories to conduct analytical tests in food control. It is also worth mentioning that, for work related to surveillance of fortified food products, there is the technical and analytical support of the National Institute of Nutrition.

The national program of food hygiene has veterinarians, engineers, pharmacists, biologists, doctors, lawyers and food inspectors—around 650 officials.

In addition to standardization and regulation tasks, other activities of surveillance and control of food and research on foodborne diseases are carried out.

- Fund for Standardization and Certification of Quality (FONDONORMA), located at Andrés Bello Ave., torre Fondo Común, eleventh and twelfth floors, Caracas, Venezuela. Telephone number: 0212-5754111 (master), extension 208, Fax: 0212-5741312, e-mail: msaccucci@fondonorma.org.ve, web page: www.fondonorma.org.ve

FONDONORMA was set up on 27 September 1973. The Venezuelan Commission on Industry Standards (COVENIN), however, had been working since 1959.

Legal Framework

It is a non-profit civil association. It has legal status and its own resources.

Official Gazette No. 35216 dated 21 May 1993, Regulation No. 1450, which authorizes Fondonorma to conduct activities related to standardization and certification of quality.

It is recognized by the Venezuelan government as a body which develops standardization activities. As regards certification, Fondonorma has received national accreditation by SENCAMER as well as accreditation by international bodies like the Institute of Industrial Metrology, Standardization and Quality (INMETRO)—Brazil and COFRAC—France and has been an IQNET member since 2000. It is also a member of the International Organization for Standardization (ISO).

Mission and Roles

- Conducting standardization processes and certification activities with the aim to improve the quality and competitiveness of the sector of production and service supplier to the country
- Helping consumer and user protection, the development and training of human resources, and the circulation of specialized documentation resulting from standardization and concerning quality and certification

National standardization activities are carried out through technical committees and technical commissions whose activity is developed in accordance with ISO provisions.

Standardization is developed through strategic technical committees. The official sector, the industrial sector, research institutes, universities, consumer associations, traders in general and any parties interested in standardization processes participate in such committees, with no discrimination of any kind and on the basis of consensus.

Food Product Committee CT10 is responsible for the development of Venezuelan COVENIN Standards in the food sector. It was set up in 1973. Its scope is the study and development of standards on definitions, test methods, specifications for food products—natural and derived from agricultural products and sea products.

The CT10 is made up of representatives from the Ministry of Health and Social Development, the Ministry of Production and Trade, the Ministry of Agriculture and Lands, the State Research Centre for Experimental Agroindustrial Production (CIEPE), the Simón Bolívar University, the National Hygiene Institute, the National Nutrition Institute, the National Consumer Defence and Education Institute (INDECU), the Food Standard Committee of the Venezuelan Food Industry Board, Associations from various sectors, Consumer Associations and other representatives from the country's production activities. It has carried out food product standardization activities since 1973.

The bodies managing Fondonorma aims are: the Assembly, the Superior Council, the Executive Committee and the General Manager.

The supreme direction of the Association is the responsibility of the Assembly. It is made up of 275 members and it designs policies, strategies, leading standards and other provisions which will provide guidance in connection with the management of the association on quality standardization and certification.

The Superior Council is made up of 21 members, the official representation of whom corresponds to a third of the members. One of the roles of the Council is approval of Venezuelan draft COVENIN standards.

The Executive Committee is made up of 5 members: the President of the Superior Council, a representative of the Ministry of Production and Trade and three members elected by the Superior Council of representatives from the private sector. The main role of the Committee is to control the activities of the association.

The body works with a staff of 65 people distributed among the different areas.

In addition to standardization activities, Fondonorma supplies quality certification services and delivers courses related to the activities developed.

This institution does not receive information from the Codex Commission Secretariat.

- **Ministry of Agriculture and Lands, National Fish and Aquaculture Institute**

Located in Torre Este de Parque Central, tenth floor, Caracas, Venezuela. Telephone number: 0212-5714889, Fax: 0212-4843066, e-mail: ntablante@hotmail.com, web page: www.mat.gov.ve

Competent National Authorities:

- Ministry of Agriculture and Lands
- Vice-minister of Development of Agricultural Production Circuits and Food and Agricultural Circuits
- National President of INAPESCA
- Fish and Aquaculture Health Manager

Authorities with Delegated Competencies:

- State Sub-managers of INAPESCA (Anzoátegui, Apure, Barinas, Bolívar, Centro, Falcón, Nueva Esparta, Sucre, Zulia)

Legal Framework

It is an autonomous institute. It has legal status and its own resources, independent from the National Treasury attached to the Ministry of Agriculture and Lands, set up in accordance with Decree with the force of law No. 1524 dated 3 November 2001, Official Gazette No. 37323 dated 13 November 2001.

Mission and Roles

It is in charge of the management of hydrobiological resources under sustainability criteria. Its mission is the regulation of the fishing and aquaculture resources of the country with the aim of achieving a responsible, sustainable use, in accordance with the existing legal framework, applying policies designed by the Ministry of Agriculture and Lands in order to promote, develop and coordinate the activities of the sector in terms of the achievement of the objectives contained in of the economic and social development plans of the country.

It has the competence to control, register, inspect and certify the sanitary conditions of fish products and aquaculture products in the stages of storage, transport, processing and marketing. It is also responsible for the sanitary evaluation and certification of fish product and by-product processing companies.

It has carries our standardization and regulation activities since 1994.

This body is made up of:

1. Fish Regulation Manager
2. Fishing Development Manager
3. Application, Surveillance and Control Manager
4. Aquaculture Development Promotion Manager
5. Fish and Aquaculture Health Manager

- **Ministry of Agriculture and Lands, Autonomous National Agricultural Service (SASA)**

Located in Torre Este de Parque Central, twelfth floor, telephone number: 0212-5090379, fax: 0212-5714117, e-mail: sasadir@hotmail.com, web page: www.mat.gov.ve

Competent National Authorities:

- Ministry of Agriculture and Lands
- Vice-minister of Development of Agricultural Production Circuits and Food and Agricultural Circuits
- National Director of SASA
- National Director of Animal Health of SASA
- National Director of Animal Health of SASA

Authorities with Delegated Competencies:

- State SASA Offices

Legal Framework

Autonomous Service attached to the Ministry of Agriculture and Lands, set up through Decree No. 2064 dated 7 January 1992, in accordance with Official Gazette No. 3181.

Mission and Roles

- Ensuring the quality of agricultural products through integral development of sanitary programs aimed to satisfy the needs of the production sector and the agroindustrial sector by means of modern technology and excellent personnel---engaged, well-trained people. This will enable us to have a productive and competitive economy to achieve food security in the country.

Its main roles are outlined below:

- Studying, preventing, fight and eradicate diseases, pests and other pathogenic agents damaging to products, by-products or input of the animal and plant sub-sectors
- Managing, developing and providing sanitary control services, diagnoses, issuance of registration, authorizations, certifications, permission and guidelines
- Regulating, managing the surveillance and control of importation, exportation, marketing and transport of the animal and plant sub-sectors
- Regulating the treatment, quarantine or destruction of products, by-products and input of the animal, plant and fishing sector, where they are affected by infectious diseases, pests or other pathogenic agents which can spread and thus be damaging to the agricultural sector
- Planning, carrying out, supervising, controlling and designing sanitary programs and campaigns, as well as diagnosing, fighting and eradicating existing pests and diseases
- Ensuring compliance with standards and procedures established for the registration and control of the quality of products and by-products of animal and plant origin and animal and plant use.
- Establishing the ports, airports, border posts and postal customs through which the import and export of products, by-products and input of animal and plant sub-sectors will be permitted
- Keeping record of, auditing and controlling companies of pharmaceutical, chemical, and biological products; fertilizers, pesticides and others
- Advising public and private bodies on the establishment of programs intended to improve genetic quality of the various species of agricultural resources

It has carried out standardization and regulation activities since its creation.

The Autonomous Agricultural Health Service is made up of the directions of animal health and plant health and the office of epidemiological surveillance and support. In every regional entity there is an agricultural health service in charge of program surveillance within its jurisdiction.

The personnel working in this program are mostly veterinarians and agricultural engineers.

In addition to standardization and regulation activities, work on surveillance and sanitary and phytosanitary control is carried out.

A. 2) Codex Contact Point activities and National Committees' activities

State of affairs of the Contact Point and the National Codex Committee

Contact Point

Autonomous National Service of Standardization, Quality, Metrology and Technical Regulations (SENCAMER). Address: Avenida Libertador, Centro Comercial los Cedros, PH. Caracas, Venezuela. Telephone number: 7616474 Ext. 1203, fax: 7314210, e-mail: sencamer@cantv.net.

Head

Ms María Milagros Toro, General Director of SENCAMER.

Codex Contact Point activities

- Providing a link between the Codex Commission Secretariat and the country
- Coordinating Codex activities in the country
- Receiving and circulating final Codex texts and working papers
- Submitting comments on Codex documents or drafts to the Commission, Subsidiary bodies and/or the Codex Secretariat
- Working with the National Codex Committee and providing a link with all sectors
- Serving as a channel of information and coordination with other Codex members
- Proceeding with Codex invitations
- Promoting Codex activities in the country

National Codex Committee (CNC). Main roles

It is made up of official bodies, the industry, consumer associations and universities:

- Advising the government on food standardization
- Serving as coordinator between the various involved bodies
- Analyzing standards during the elaboration process and propose comments (country position)
- Circulate standards

CNC Technical Subcommittees. Main roles

- Gathering, analysing and channelling the concerns of the various national sectors in relation with food safety, standardization, hygiene, and quality.
- Analyzing the documents received by the Technical Secretariat and submit comments on them, as well as making comments on specific technical aspects of Codex Alimentarius Commission documents, which may be requested by the National Committee

- Requesting and revising existing technical information on sanitary, technological, economic and control-related aspects, which may help recommend to approve, adopt or dispense with Codex Alimentarius standards
- Advising the Committee and the Technical Secretariat on specific issues in their areas
- Other roles assigned by the National Codex Alimentarius Committee

B) FOOD LEGISLATION

Standards and technical regulations are being updated on the basis of Codex standards and documents. Great progress has been made in the area of food additives, contaminants and pesticides. Also, the development of standards on good Agricultural practices has been undertaken. The revision of the technical regulation on Good Manufacturing Practices will be started on the basis of Codex provisions on Good Manufacturing Practices.

The updating and harmonization of standards of technical regulations is under way and its completion is scheduled for the year 2005.

C) COOPERATION ACTIVITIES

Project TCP/RLA/2904 “Enhancing the Management of National Codex Alimentarius Committees in Andean Countries” was developed between 2003 and 2004. This Project has been useful for the exchange of information on food legislation and food control between Andean countries. 171 people have been trained on various Codex issues through the project.