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Food and Drug Legislation in Central America and Panama

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IN THE JULY, 1967 ISSUE OF THIS JOURNAL,* an article entitled "The Latin American Common Market and Food Legislation," by Mr. Enrique E. Bledel, contained a brief analysis of food legislation in Latin America as a whole. Mr. Bledel describes efforts to harmonize the legal provisions in force in each country, in connection with the existence of the Latin American Free Trade Association (LAFTA) and the proposed creation, by 1970, of a Latin American Common Market.

While the latter large-scale conception is still not much more than a dream, and will require a lot of intelligent effort and good will, encouragement that it may one day become a reality can be taken from the success of a smaller organism of the same nature and in the same area which can be considered as a pilot project and indeed a nucleus of the proposed larger enterprise—the Central American Common Market.

The Central American Isthmus between the frontiers of Mexico and Colombia, with a total area of only 188,500 square miles and a population estimated at 15,000,000 (although with the rate of population growth highest of all the regions of the world), is divided into six small but fully independent republics (plus the territory of British Honduras or Belize destined for independence shortly but claimed by Guatemala). Since the attainment of independence from Spain in the first half of the nineteenth century efforts to integrate the area politically have not been very successful. In spite of its relatively small size and common history, the area represents extreme geographical, ethnical and cultural diversity and its component parts have been,

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and still are in many cases, entities isolated by geographical obstacles and lack of adequate communications. The independent development of the six republics since independence has also resulted in great diversification of their detailed legislation, including food and drug legislation, in spite of the common original basis.

The organization of the Central American Common Market, with Panama not yet a full member but taking active part as associate member in many of the activities of its institutions, has been an effort to tackle the problem from another end first—economic instead of political.

The success story of this venture, although inevitably slowed down in the most recent few years, is today common knowledge. One of the most notable phenomena has been the remarkable growth of trade—more than tenfold between 1954 and 1963—among the countries of the Common Market: from \$8,300,000 in 1954, it reached \$36,000,000 within a year of its establishment (1961). \$50,000,000 in 1962 and more than \$80,000,000 in 1963.

A further result has been rapid industrial development, increase in both exports and imports to and from the countries outside the zone, and increase in the consumption of consumer products.

In both production and exports, agricultural products occupy the first place in all the countries concerned. Exports from the countries of the Isthmus to those outside the zone have consisted principally of food products, with an average of 70% of the total, while in the intrazonal trade the percentage was 29%, being exceeded only by manufactured goods. The food industry, in relation to others, holds the major part of industrial capital, occupies most labor, adds a major part to the national product and constitutes, as just shown, the second largest item in inter-Central American trade. In 1962 food and beverage manufacturing plants constituted 32.1% of all industrial enterprises, employed 36.9% of total labor, had 47.9% of total fixed capital and produced 50.3% of total gross value of industrial production.

From the quoted figures it can easily be seen that the food industry is the most important activity of all the industrial branches of the Central American Isthmus. Its growth has also been progressing at a fast pace. Between 1955 and 1965, the gross value of the average annual growth of the food industry was 7.6%.

Need for Adequate Legislation

Such fast expansion obviously requires adequate legislation, regulation and normalization to protect both the pocket and the health of the consumer, and to maintain the high quality of exports in order to gain and maintain world markets in the face of fierce competition. This competition has been rapidly increasing, coming not only from industrialized countries but also from the newly emerging countries of Africa and Asia, especially in view of the fact that virtually all the main products exported by Central America—coffee, cotton, bananas, sugar—are also produced in those two continents.

Furthermore, in order to promote intrazonal trade within the Isthmus instead of hampering it, uniformity of legislation and reciprocal acceptance of control measures are essential.

Meanwhile, food legislation in the six countries of the area at the beginning of the Common Market era was quite inadequate to cope with the rapid industrial and commercial expansion, being based mainly on the general Sanitary Codes and isolated regulations (for example, those referring to milk, meat, salt and flour). According to findings of consultants commissioned by the Pan American Health Organization between 1963-1965, "the Codes were either antiquated and disjointed, or were invalidated by other regulations, or their enforcement was impossible due to lack of trained personnel." Only Costa Rica possessed a few food standards, although in all the countries moves were under way to bring the codes and regulations based on them up to date. Progress, however, has been slow.

Two distinct patterns of food and drug control can be distinguished among the countries of the Isthmus; the first is what one could call the "Anglo-Saxon" pattern, where the enforcement of food and drug legislation, including inspection of food and drug factories and collection of samples of both, is vested in the same organization, and analysis is made of both foods and drugs in the same official laboratories. This is the situation that exists in the United States of America, Canada and the United Kingdom. Two of the countries of the Isthmus have this system: Nicaragua and Panama.

The other pattern, which we might call the "European-Continental" type, is where the control of foods and that of drugs are completely separated, being covered by distinct legislation and enforced by different organizations, the drug control being usually entrusted to the pharmaceutical profession, which guards this prerogative rather jealously. This type of situation exists in Costa Rica, El

Salvador, Guatemala and Honduras. It may be added, however, that even in one of the two countries with the joint "Anglo-Saxon" type of food and drug control, namely Panama, marketing of drugs must now be approved by the National College of Pharmacists before being submitted for registration (period: 5 years) to the FDA, which in this case stands for "Farmacias, Drogas y Alimentos"—a department of the Ministry of Labor, Social Security and Public Health, which nevertheless corresponds roughly in its functions to the Food and Drug Administration of the United States.

It may be mentioned that in addition to registration of pharmaceutical products, the Latin American practice of requiring registration of processed foodstuffs has been heretofore in operation in Costa Rica (period: 6 months for imported products, 1 year for national ones, no fee), Guatemala (period: indefinite, nominal fee for analysis previous to registration) and Panama (period: 10 years, fees for registration itself and for an analysis previous to it).

Decrees Issued

Food and drug control was put on a rational basis in Panama through three decrees issued on the basis of the Sanitary Code of November 10, 1947: No. 256 of June 13, 1962 which in 260 articles presents very complete food regulations; No. 93 of February 16, 1962, which regulates drugs in a similar way; and No. 6 of April 18, 1963, which created the above mentioned FDA. Moreover, toward the end of 1961 the University of Panama inaugurated LEA, or Laboratorios Especializados de Analisis, a very amply equipped and staffed laboratory for food and drug analysis, which has been legally designated as the official food and drug laboratory for the Republic, and has been acting as a drug reference laboratory for the whole of the Isthmus and as a center of training for its food and drug laboratory staffs.

The other country with the combined food and drug control, Nicaragua, is not so favored, since its food legislation is based on a very antiquated and deficient Sanitary Code, although the decree No. 568 of March 11, 1961, has rationalized the registration and control of pharmaceuticals. Nevertheless, the FDA, with a name identical with that of the corresponding organization in Panama, is well organized and staffed and carries out vigorous inspection work.

Laboratory facilities are represented by a section of the Public Health Laboratory, as is the case in all the other countries as far as food analysis is concerned, except for Panama and El Salvador.

Of the four countries with separated food control and drug control, three carry out food inspection through sections of the Veterinary Public Health Departments of the Ministries of Health. In one (El Salvador), inspection is the responsibility of the Environmental Health Division, which also has its own food control laboratory.

In Costa Rica, the old Sanitary Code was revised on November 2, 1949, by Decree No. 809/49, with article 249 dealing with food control, but a completely new Code has been under consideration by the National Assembly for some time. There exists a series of regulations on specific foods and a dozen or so food standards elaborated by the Standards, Industrial and Technical Assistance Committee of the Ministry of Agriculture and Industries, established by Law No. 1698 of November 26, 1953 and Executive Decree No. 6 of September 21, 1951, the only national standards committee in Central America.

The College of Pharmacists, in charge of drug control (with analyses carried out at the Faculty of Pharmacy of the University of Costa Rica), lost the registration and control of generic and official drugs to the Registration Council of the Ministry of Health in April, 1966.

In El Salvador, food legislation has been based so far on Article 90 of the almost 40-year-old Sanitary Code of October 13, 1930 (although a new one has been under consideration) and on decrees regulating the production of milk and meat and their products. Registration of processed foodstuffs is now being introduced. Drug control and registration (renewable annually) is ultimately in the hands of the Superior Council of Public Health, but is effected in practice by a pharmacist responsible to it; there is virtually no inspection or analytical control.

In Guatemala, drug registration is for an indefinite period and is effected by the Inspectorate General of Pharmacies and Narcotic Drugs of the Ministry of Health, without any previous or subsequent analytical control, although such is effected for the registration of processed foodstuffs in a relatively well-equipped laboratory.

The legislative basis is the Sanitary Code of April 30, 1937, in which articles 144 and 158 deal with registration and inspection of foodstuffs respectively, and article 40 provides for drug control. There exists also a number of decrees dealing with specific subjects such as milk production, salt iodization, flour enrichment, etc.

Finally, although in Honduras food legislation, inspection and analytical control were perhaps weakest of all the Isthmus, recently vigorous steps have been taken to remedy the situation. This country was the first one to actually promulgate a new Sanitary Code (of November 14, 1966), and on the basis of its Title V, articles 83-103, to present for ministerial approval early this year a very comprehensive food control ordinance.

At the same time, steps were taken to strengthen food inspection and laboratory services. Drug registration (for 3 years) is effected by the College of Chemistry and Pharmacy established by a decree of August 29, 1963, with the local University contracted to effect analyses.

In view of this diversity of legislative and organizational positions and general inadequacy of control services, it is not surprising that the regional organs should feel urgent need for uniform legal provisions, and for reorganization and strengthening of enforcement services, also on a uniform basis.

Requests for Assistance

The six Ministers of Health, gathered at their eighth regular annual meeting in San José, Costa Rica, in 1963, officially requested the assistance of the Pan American Sanitary Bureau, the Regional Office of the World Health Organization (PASB/WHO), in the field of food control.

One of the first needs, it was felt, was the introduction of a set of common minimum sanitary food standards. Although one of the regional institutions, the Central American Research Institute for Industry (ICAITI), had been entrusted with establishing standards for all industrial products, those are the voluntary trading standards specifying quality grades and only a few of those issued to date referred to food products. PASB/WHO commissioned the Adolfo Lutz Institute of Sao Paulo, Brazil for the work of preparing obligatory sanitary standards and at the same time initiating and financing regular annual Seminars of Food and Drug Control for Central America and Panama, grouping representatives of the control services of the six countries. In 1963-1965 a set of about 380 food standards, including analytical methods, lists of permitted additives, etc., was elaborated, revised at the Seminars, presented to the Ministers and recommended by them for inclusion in the legislations of the six countries.

In this work, in addition to national laws and standards of many countries, the provisions of Latin American Food Code and the work of the Joint Food and Agriculture Organization/World Health Organization Codex Alimentarius were taken into account. However, it was felt that the former offered only very general principles while the work of the latter proceeded rather slowly and neither included standards for specifically local Central American products nor took account of local conditions. Therefore, this more detailed set specifically adapted to local needs was felt necessary.

PASB/WHO has also been helping in the strengthening and reorganizing of food inspection and laboratory services in the area. Detailed proposals for their uniform organization and for uniform regulations were made by PASB/WHO consultants especially at the last Food and Drug Seminar (in 1967). These referred particularly to such things as a common system of registration of processed food-stuffs with validity of five years and identical scale of fees, pesticide residue limit lists, etc. They were accepted by the group and recommended by them to the Council of Ministers of Health, who in turn adopted them and recommended their inclusion in national legislations.

By the resolution of the Ministers, the Institute of Nutrition of Central America and Panama (INCAP), situated in Guatemala City and administered by PASB/WHO, was asked to organize a new Division of Food Control and Analysis which would act as a Regional Food Reference Laboratory.

Under PASB/WHO auspices, a large-scale project is now being elaborated by INCAP for an integrated food control organization, which could include all the national food inspection and laboratory services, as well as the new Division of INCAP, the LEA and the standardization section of ICAITI, and it is hoped to obtain the assistance of the Special Fund of the United Nations Development Program for the project.

Summary

If all these labors succeed, it will be yet another important step in the integration activities of the area, the ultimate goal of which might be a political union, the aspiration of the best sons of Central America for some hundred and fifty years. [The End]