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ıe Food Law of Argentina

JULIO E. ALFARO and JULIUS G. ZIMMERMAN

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

This month's issue of the JOURNAL is devoted to a research study, co-authored by *Julio E. Alfaro* and *Julius G. Zimmerman*, on "The Food Law of Argentina." The study contains the historical background of what is now the model Latin-American Food Code —developed through the endeavors of Dr. Carlos A. Grau, based on his earlier efforts in providing a model for the "Reglamento Alimentario" (Argentine Food Code).

The article begins with the constitutional basis of Argentine food law and its scope (which includes a broad definition of "food"—encompassing food additives, products not destined for human ingestion, drugs and animal feed). In addition, the article deals with a registration system (that is, registration of foodstuffs for exportation and importation as well as the registration of manufacturing plants and other establishments); the regulation of commodity identification (labeling and trademarks); the regulation of wine and other alcoholic beverages, manufacturing establishments and storage facilities for products, subproducts and derivatives of animal source; and specific legislation dealing with pesticide chemicals and their residue.

The paper concludes with a synopsis of international cooperation in dealing with harmonization of food laws and regulations. Mr. Alfaro is currently serving as attorney on the staff of the Latin American Zone Counsel in Miami, Florida; Mr. Zimmerman, an attorney in New York City, is Editor of Foreign Law of the JOURNAL; both Mr. Alfaro and Mr. Zimmerman are members of the Inter-American Bar Association. The article begins on page 545.

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Food·Drug·Cosmetic Law
Journal

The Food Law of Argentina

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Section 1. Federalism and Food Law Uniformity

1.1. Constitutional Pattern

THE ARGENTINE CONSTITUTION has adopted a federal model for a country which presently consists of 22 autonomous provinces, one Federal District and three National Territories. The structural axis of such a model is, necessarily, the power distribution rule that separates federal and provincial jurisdictions. In very general terms, the federal powers are those expressly delegated, while the provincial powers are those implicitly retained.[1]

The federal power scope is double:

(a) *Territorial*—The territorial powers of the federal government extend to all federal territories, irrespective of the subject matter involved. The most important of those federal territories, the municipal district of the capital city of Buenos Aires, is also subject to the overlapping jurisdiction of the municipal authori-

[1] National Constitution—(1853/60)—Articles 5, 104, 106, 108. Specifically, Articles 104 and 108 read:

"The provinces retain all powers not expressly delegated to the Federal government by this Constitution, and also those expressly reserved at the time of their incorporation in the Union." (The reference to reserved powers is addressed to pre-constitutional pacts, and has no practical significance.) "The provinces will not exercise the power delegated to the Nation." (In this context, Nation means federal government.)

ties. However, the federal power has been traditionally understood as preemptive.

(b) *Substantive*—The substantive powers of the federal government extend to specific subject matters as delegated to the Federal Government by the Constitution, irrespective of the territorial jurisdiction involved. It must be noted that the Argentine Constitution—unlike the United States Constitution—has delegated to the Federal Government the power to enact most of the substantive law of the land, namely the Civil, Commercial, Criminal and Natural Resources Codes.[2]

The functional interplay between the federal jurisdiction, as stated above, and the provincial (and *a fortiori* municipal) jurisdictions, is regulated by the commerce clause. Akin to its American counterpart, the clause is a somewhat hybrid power distribution rule. It cannot be described as substantive, since it does not refer to specific legislative issues; neither can it be deemed territorial, for it is addressed to cover situations of interterritorial flow of goods.[3]

Under the commerce clause of the Constitution, the federal authorities are empowered to legislate on subject matters involving "maritime and terrestrial commerce with foreign nations and of the provinces *inter se*."[4]

Despite the fact that substantive power allocation in the federal government significantly erodes the value of the clause as a uniforming tool, it has been extensively resorted to as a rationale, even to the point of conceptual abuse.[5]

1.2. The Constitutional Basis of Food Law

How does food legislation fit within the above constitutional pattern?

It is clear that the food subject matter has not been delegated expressly to the federal authorities. The central government—and specifically the Legislature—may only pass food laws when and insofar as international or interprovincial commerce are involved, i.e., based upon the power granted by the commerce cause.

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[2] *Ibid.* Article 67, paragraph 11.

[3] *Ibid.* Article 67, paragraph 12. Also see Articles 26 and 10, on free navigation of the internal rivers, and free internal flow of goods.

[4] *Ibid.*

[5] A good instance of abuse is Law 19982 (November 29, 1972/ Boletin Oficial, December 5, 1972) on commercial identification. The legislative message prefacing the law reads: "(T)he criterion has been followed that calls for the rules on the subject to be national, since they are meant to regulate a commerce that, at least *potentially*, is always *interjurisdictional*. . . ." (Emphasis supplied.) This is tantamount to negating the power distribution rule contained in the clause. (Excessive elusiveness equals non-existence.)

In all other situations, the provinces retain legislative jurisdiction over the food subject matter. Municipalities may only regulate the field pursuant to express delegation by the provincial authorities.[6]

Local jurisdiction stems from the power distribution rule of the Constitution, and not from categories of a doctrinary nature, as the advocates of police power have often held.[7]

From such a perspective, there are only two conceivable ways of achieving food law uniformity:

(a) *Voluntary uniformity.*—The federal legislature might enact food law applying to federal territories and to commerce clause situations. Such law could then be sponsored as a model act of sorts, and its subsequent adoption by all local jurisdictions obtained.[8]

(b) *Compulsory uniformity.*—The food subject matter could be expressly delegated to the federal government through a constitutional amendment.[9]

Both alternatives are mutually exclusive, and inescapable as a matter of law.

1.3. The Historical Background of Argentine Food Law

A retrospective overview of food legislation in Argentina shows a pattern consistently determined by the above-posed constitutional dilemma.

Comprehensive legislation was initially attempted at the local level. Federal legislation remained partial, mainly addressed to cover administrative problems, or restricted substantive issues involving international or interprovincial commerce.

The Food Regulations of the Province of Buenos Aires (1928), can be safely regarded as the first systematic effort in the food law field. Besides enacting a comprehensive Bromatopeia, the Regulations

[6] National Constitution, Articles 5, 106.

[7] Police power is an analytical concept so difficult to grasp that it can be disregarded as useless. To witness, the so-called broad notion of police power: "(T)he juridical activity of the State that seeks to regulate the necessary equilibrium between the individual existence and the common good when disturbed. . . ." (Bartolomé Fiorini, Poder de Policia, Ed. Alfa, Bs Aires, 1962.)

[8] The Federal Food Act Draft of 1965 would have relied upon an ancillary Bromatopeia for subsequent local adoption. The Reglamento Alimentario Nacional of 1953 did almost become the effective Bromatopeia of the country through voluntary adoption by the provinces.

[9] The 1949 constitutional amendment examined in the text is a good instance.

inaugurated the requirement of preventive registration of foodstuffs and food establishments.[10]

The Province of Santa Fe, the other fundamental food law jurisdiction in Argentina, approved its Bromatological Code on December 16, 1941 (Provincial Law 2998). The Code borrowed heavily from the Buenos Aires Regulations.

The rest of the provinces and municipalities continued to lack comprehensive legislation, and merely dealt with specific problems and general protection of public health.

In 1947, Federal Law 13012 called for the drafting of a Sanitary Code.[11] The contents of the prospective Code were carefully outlined, and the Federal Executive appointed for the task. The idea was to protect public hygiene through the broad listing of personal standards of care; bromatology was not involved.

But, although different, bromatology and hygiene are indeed germane. Thus, one of the provisions within Law 13012 also called for the drafting of a set of bromatological rules, and assigned the task to the Ministry of Public Health.[12]

Law 13012 and the Sanitary Code set in motion thereby were soon to be rendered moot through constitutional amendment. A series of changes introduced to the fundamental charter in 1949 included the grant of power to the federal legislature to pass a Sanitary Code. Such grant could have been interpreted as a blank authorization to regulate the closely connected food area, but the opportunity seems to have been overlooked. Instead, a broad draft of a Sanitary Code, along the lines of Law 13012, was prepared but never enacted.[13]

Controversial Law 13012 retained marginal importance. Its main legislative offspring was Federal Decree 382, which, purporting to implement the provision on the subject, organized a drafting committee to prepare a Bromatological Code.[14] The final version was submitted to the Federal Executive, and was approved through Decree 141 of January 8, 1953, as "Reglamento Alimentario."[15] The adjective "Nacional" was later added to it through widespread usage.

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[10] Specifically, see Articles 966 and 967 thereof. The Regulations were subsequently revised, updated and expanded in 1937, 1944 and 1948.

[11] Law 13012 (Boletin Oficial, October 16, 1947).

[12] *Ibid.* Article 3, paragraph 23.

[13] The draft was approved through Resolution 38463 (September 20, 1951), Ministry of Public Health. The Executive never submitted it to the Congress.

[14] Decree, Federal Executive, 382, January 1951. The legal foundation upon Law 13012 is constitutionally necessary.

[15] The draftsman of the Buenos Aires Food Regulations and of the Regla-

(Continued on next page.)

At this point, two comments on the Reglamento seem pertinent. On the one hand, it was the culmination of a legislative trend that can be traced back to the original Buenos Aires Food Regulations; its bromatological rules could hardly be deemed improvised.[16] On the other hand, the scope of jurisdiction of the Reglamento was orthodox federal, that is to say that it applied to federal territories and to commerce clause situations.

Despite the latter feature, sponsoring by a strong administration caused the Reglamento to be subsequently adopted by most local jurisdictions, to the point that, by early 1955, food law uniformity was almost a reality.[17]

However, after the fall of the government in the second half of that year (1955), a legislative reversion started. Many provinces chose to pass local legislation, and in some instances to return to their prior legal pattern.[18] Additionally, a new constitutional amendment declared invalid the 1949 amendment, and the Sanitary Code was erased from the list of those delegated to the federal government (1957).

The existence of diverse and often conflicting local laws caused the position of the food industry to be all but untenable by early 1964. Substantial lobbying ensued, and a draft of the Federal Food Act was ready in 1965.[19]

(Footnote 15 continued.)
mento Alimentario Nacional was Dr. Carlos A. Grau, a famed Argentine bromatologist. Dr. Grau also intervened in the drafting of the Latin American Food Regulations. It is unnecessary to analyze the provisions of the Reglamento; since, as explained in the text, it has since been enacted as the Argentine Food Code with very minor changes.

[16] *Ibid.*

[17] Most jurisdictions adopted the Reglamento as their local law. (For instance, Santa Fe, through Prov. Decree 994, February 12, 1954.)

[18] The Province of Santa Fe repealed the Reglamento through Prov. Decree 8441, August 23, 1960. The 1941 Regulations were declared valid again. The Province of Buenos Aires did not return to its old Food Regulations but enacted new ones in 1963 (August 16, 1963); these regulations were later revised through Prov. Decree 7414, August 10, 1967. Other jurisdictions enacted brand new regulations.

[19] Efforts were channeled through the Argentine Industrial Association, which gathered a cross section membership of the food industry. A National Convention of Bromatology met in April 1964, and pursuant to its recommendation a legislative committee was organized. The draft it submitted to the Federal Executive in 1965 was never approved. It consisted of a Federal Act which only regulated the administrative aspects; standards of identity were left to an ancillary Bromatopeia which would be agreed upon by the local jurisdictions. The approach was analogous to the one that had been taken with respect to the extant Argentine Pharmacopeia, the rationale being that technical rules need not be pushed through at a substantive legislation level.

The effort was not to be successful, though. The year 1966 brought another military take-over, and yet another constitutional change. The Statute of the Revolution made the Constitution a charter of conditional validity, dependent on the discretion of the *de facto* authorities. Legislative powers were concentrated in the Federal Executive.

The ensuing government remained in power until May 1973, at which date the original Constitution was once again reinstated. In the interregnum a substantial amount of legislation was approved, including the Argentine Food Code.[20]

1.4. The Argentine Food Code

The code was born with a double constitutional defect:

(a) First, it originated in a *de facto* government, and hence was a *de facto* law. However, constitutional doctrine in Argentina is peaceful in the sense that *de facto* law is valid unless expressly repealed by the succeeding constitutional legislature. The vice is thus subject to automatic cure upon reinstatement of the constitutional government. The risk of repeal at this stage is as great as in the case of any other valid law.

(b) Second, it violated the power distribution set forth in the Constitution, since it purported to apply throughout the national territory in disregard of local jurisdictions. It is doubtful that this vice can be cured in the mode described in the previous paragraph. The defect, obviously substantive, continues to taint the Code, and makes it vulnerable to attack by private parties or local governmental units.

To our knowledge, private parties have not so far questioned the constitutional validity of the Code. Local governments, instead, have not been entirely acquiescent.

The registration system devised by the Code called for a single registration per product.[21] Such registration, though filed with the local authorities with jurisdiction over the place of production and/or manufacture, would have granted rights of circulation and marketing throughout the country, for it was based upon a pattern of automatic relay of information and of multiple feedback to all local registers for due annotation.

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[20] Law 18284 (July 18, 1969/Boletin Oficial, September 20, 1971). Decree 2126 (June 30, 1971/Boletin Oficial, September 20, 1971).

[21] See Section 2.6 on page 561.

The system has never been effective because of a failure in the organizational substratum. The result is that a food manufacturer planning extensive marketing (which will almost always be the case) is presently compelled to seek registration with each and every local register and with the federal authorities as well, though in most cases, once a registration has been obtained, the procedure will be to submit evidence of prior registration. Subsequent registrations will tend to be ministerial acts. Registration with the federal authorities is always essential, since otherwise the product will not be qualified for interprovincial marketing.

The breakdown of the centralized registration system has triggered a resurgence of local administrative provisions, in more or less extreme fashion.

The province of Santa Fe has chosen to "adopt" the Code, thus transforming it into local law.[22] The adopting legislation, furthermore, provides for the supplementary validity of the Bromatological Regulations of 1941, and requires full compliance with local administrative procedure.

The province of Buenos Aires, without express legislation in that sense, has consistently held that the Food Regulations of 1967 are supplementary, and only accepts applications for registration if filed according to provincial rules and in provincial forms.

A similar stance has been taken recently by the municipality of Buenos Aires, though no prior Bromatopeia is, in this case, vindicated.

Awkwardly enough, all three jurisdictions pretend that the effects of registration regulated in the Code as appurtenant to the procedure therein, attach likewise to registrations granted pursuant to the local rules, so that approved products are to be allowed to circulate and be marketed throughout the country. Such selective questioning of the Code seems to indicate that local dissatisfaction only exists at a sheer bureaucratic level.

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[22] Provincial Law 6884 (December 13, 1972/Boletin Oficial, December 18, 1972).

Section 2. The Federal Food Code

2.1. Scope of the Argentine Food Code

Law 18284 and its regulatory Decree, declared effective throughout the Argentine territory, the hygienic-sanitary, bromatological and commodity identification provisions of the Reglamento Alimentario Nacional. (Decree 141/53.)[23] Pursuant to specific powers granted therein, the Federal Executive proceeded to review and slightly amend the text of the Reglamento. This accounts for the time lapse between the enactment of the above-stated Law and Decree, and the publication (and, hence, effectiveness) of the Argentine Food Code. Throughout this paper, we will reserve the name Food Code to the enacted Bromatopeia, that is to say the provisions of the old Reglamento Alimentario Nacional. When reference is made to cover Law 18284 or Regulatory Decree 2126/71, such reference will be express. Since all three sets of rules start from Article 1, this terminology will avoid confusion.

At the outset, it must be noted that the semantic distinction of three types of provisions within the approved old Reglamento (hygienic-sanitary, bromatological, and commodity identification) serves no legislative purpose. In fact, there are provisions of a different type which have, nonetheless, been enacted (i.e. those administrative provisions of Articles 1 through 17 of the Code) and there are provisions of the types mentioned which have not been enacted (i.e. those regulating articles of daily use).

The Code defines as food "all substances or mixtures of substances—whether natural or processed—that when ingested by man bring to the organism the materials and energy needed for the development of biological processes. The word 'food' includes, likewise, all substances or mixtures of substances ingested because of habit, custom or as coadjuvants, whether they have nutritional value or not." (Article 6, paragraph 2 of the Bromatopeia.)[24]

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[23] Law 18284 (July 18, 1969/Boletín Oficial, July 28, 1969), enacting the provisions of Decree 141/53 (Bromatopeia); Regulatory Decree 2126 (June 30, 1971/Boletin Oficial, September 20, 1971); Argentine Food Code, comprising Law 18284, Regulatory Decree 2126, and the Bromatopeia itself (Boletín Oficial, September 20, 1971). Date of effectiveness set forth therein: September 29, 1971. As amended through Law 20668 (Boletín Oficial, May 15, 1974, with respect to Article 17 of Law 18284), and other Decrees of the Federal Executive and Resolutions of the Secretariat of Public Health cited as footnotes to the text when appropriate.

[24] For cross reference to other definitions: Reglamento Alimentario (Decree 141/53), at Article 5, paragraph 2; Draft of Federal Food Act (1965) at Article 3, point 1; Buenos Aires Food

(Continued on next page.)

The definition has followed the pattern of the so-called "legal definitions," which include not only nutriments proper but all other substances destined for human ingestion.

The provisions of the Code apply to all substances that fit within the broad definition set forth above, save for cases of express application of different laws and regulations (i.e., Law on Wines).

The legal provisions are not clear, however, on whether all foodstuffs must comply with the administrative requirement of prior approval and registration. The language of Article 2 of the Bromatopeia is sweeping enough to cover all foodstuffs and their raw materials.

It does not seem sound, though, to indiscriminately apply the complex registration system to natural or fresh food sold by weight or other measurement, and involving no industrial process or packaging. In this sense, Article 3 of Decree 2126/71 seems to suggest that only packaged food (usually identified by a trademark) which has been subject to some form of industrial processing (packaging is one of them) must comply with prior registration requirements.[25] Administrative practice is consistent with such interpretation.

Inasmuch as the Bromatopeia establishes standards of identity for foodstuffs, all foodstuffs seeking approval must comply with such standards. This poses a question on the status of nonstandardized foodstuffs. The application of the Constitutional principle that "no inhabitant will be obliged to do what the law does not command, nor deprived from doing what the law does not forbid,"[26] would make all nonstandardized products and their manufacturing, *legal per se*. A Bromatopeia implies, however, the inversion of that legal principle: The inhabitants are only allowed to do what the law defines as permissible. (This inversion is more clear in the so-called "positive list of food additives" which we will examine below.)

Notwithstanding the above, it would not be fair to forbid *a priori* all nonstandardized foodstuffs, and, thus, Article 3 of the Bromatopeia provides: "Every processed foodstuff not defined in the present Code, might be subject to approval by the corresponding Health Authority, provided that its raw materials, processing techniques, bromatological qualities, packaging and labeling, meet the conditions

(Footnote 24 continued.)
Regulations (1963—67), at Article 10; Bromatological Regulations of Santa Fe (1941—48), at Article 7; Codex Alimentarius Sudamericano (1930), at Article 1; and Latin American Food Code (1959), at Article 5, point 3.

[25] Regulatory Decree 2126/71, at Article 3, paragraphs (c), (e), (i), (j) and (k). Food Regulations of the province of Buenos Aires (1967), at Article 2.

[26] National Constitution, Article 19.

set forth in this Code." Which means that a case-by-case approval (and registration) of nonstandardized foodstuffs is possible.

2.2. Food Additives

The legal definition of food additives, like the legal definition of foodstuffs, bears little resemblance to the chemical definition.[27]

The Argentine Food Code has a general definition of food additives: "(A)ny substance or mixture of substances that directly or indirectly modify the physical, chemical or biological characteristics of foodstuffs, for purposes of improvement, preservation, or stabilization, provided that:

(a) they are innocuous as such or in their effect as additives under the conditions of intended use;

(b) their use is justified by technological, sanitary, nutrimental or psychosensorial reasons;

(c) they comply with the requirements of denomination and purity established by the Code."[28]

Such general definition encompasses food additives proper legislated in Title XVIII of the Code and various substances included in Title XVI on corrective and coadjuvant agents, as follows:

(I) *Bitter substances:*[29] Substances of this type with certain contents are generally prohibited and several others are expressly admitted. Nothing is said as to additions to the list of admitted substances, though it might be assumed that the Federal Health Authority is empowered to amend such list (and *a fortiori* to case-by-case approvals).

(II) *Foaming agents:*[30] As in the previous instance, there is a general admission of some types and a general prohibition of others. There is no actual list.

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[27] A generally admitted definition of food additives (intentional food additives) reads: "A food additive is a substance, or mixture or substances, other than a basic foodstuff, which is present in food as a result of any aspect of production, storage, or packaging. The term does not include chance contaminants." (Food Protection Committee (1959), Principles and Procedures for evaluating the safety of food additives (NAS-NRC Publ. No. 750, Washington, D. C.)). Such a definition obviously exceeds the subject matter scope of this section of the article.

[28] Argentine Food Code, Article 6, paragraph 3.

[29] *Ibid.* Article 1292 and following: "(N)on deleterious vegetables, or their extracts, or active ingredients, to which aperitif qualities are attributed."

[30] *Ibid.* Article 1295 and following. Definition in Article 1295 reads: "(T)hose causing the formation of a permanent foam."

(III) *Aromatic-flavoring agents:*[31] Aromatic flavoring agents are subdivided into:

(a) natural essences or essential oils;

(b) extracts;

(c) balsams, oil resins and oil-gum resins;

(d) chemical compounds from essential oils or extracts; and

(e) synthetic or artificial chemical flavoring or aromatic compounds.

Natural essences or essential oils, are defined, and a list of those admitted for use is included.[32] The Federal Health Authority may amend the list.

Extracts are also defined, and a list of permitted extracts is included.[33] Likewise, the Federal Health Authority may amend the list.

Balsams, oil resins and oil-gum resins are merely defined.

Chemical compounds from essential oils or extracts are defined, and a list of permitted compounds is included.[34] Nothing is said as to amendment of the list; it is understood that the Federal Health Authority may amend it.

Synthetic or artificial chemical flavoring or aromatic compounds are enumerated in their specific Code section, but, their individual standards of identity are regulated in the list of food additives

[31] *Ibid.* Article 1298. The definition therein reads: "(P)reparation containing the flavoring or aromatic principles of a plant or part of it and the artificial substances of allowed use, able of acting upon the senses of smell and taste, lending to or reinforcing in a foodstuff its flavor or aromatic characteristics."

[32] *Ibid.* Article 1300. An essential oil is defined therein as "the volatile product of vegetable source obtained through an adequate process." The list of permitted essential oils is included in the very same article, and has been amended through:

Secretariat of Public Health, Resolution 1017 (Boletín del día, Ministry of Social Welfare, April 6, 1972);

Ibid. Resolution 5210 (Boletín del día, Ministry of Social Welfare, December 29, 1972).

Both Resolutions have increased the total number of permitted essential oils to 47. (Numbers 38.1; 2.1; 12.1; 36.1; 37.1; 39.1 and 39.2 have been added to the list.)

[33] *Ibid.* Article 1306 defines extracts thus: "(P)roducts obtained through hot or cold draining by means of an adequate process from: either vegetables or parts of vegetables containing flavoring-aromatic substances, or essential oils, or balsams, or oil resins and oil-gum resins, utilizing appropriate dissolvers which might or might not be eliminated." The list of permitted extracts is spelled out in Article 1307 and comprises seven items.

[34] *Ibid.* Article 1308 defines them as "products obtained through exudation, either free or caused by the use of certain vegetable species."

proper, in which they are formally included.[35] The Federal Health Authority may amend the list.

(IV) *Coloring agents:* Coloring agents are not defined. There is a general prohibition of use for certain coloring agents containing particular substances, and a list of permitted coloring agents.[36] These substances must comply with the requirements of quality and purity of the Title on food additives proper and with the "Rules on identity and purity of food additives" prepared by the Food and Agriculture Organization and World Health Organization (FAO/WHO). The Code does not specifically empower the Federal Health Authority to amend the list, but permits a case-by-case approval of non-listed agents.[37] It has been generally understood, though, that the Health Authority has that power.

(V) *Food additives proper:* The rest of food additives—proper according to the terminology of the Food Code, but a residuary category according to a functional classification—are dealt with in Title XVIII, Article 1391 and following.

The definition within that Title adds two requisites to the general definition quoted above, namely that: (i) the substances must be included in the positive list (Article 1398); and (ii) they must be used only in the preparation of those foodstuffs for which they have been authorized.

Provided that they comply with the standards in the Code, food additives may be added to food for purposes of maintaining or improving its nutritional value, increasing its stability or preservation, increasing consumers' acceptance of an otherwise unappealing foodstuff, or allowing production in terms of economies of scale and durability.[38]

Conversely, they may not be used for purposes of hiding defective manufacturing processes, decreasing the nutritional value of foodstuffs, replacing feasible alternative techniques or deceiving the consumer.[39]

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[35] *Ibid.* Article 1311 contains no definition. There is an enumeration, though, which is duplicated in Article 1398 on food additives proper. (As amended by Resolution 5210 of the Secretariat of Public Health, cited in footnote 32 *supra;* and by Resolution of the same authority, No. 655, Boletín del día, Ministry of Social Welfare, May 3, 1974.)

[36] The list is included in Article 1324 of the Code. (As amended through Resolution of the Secretariat of Public Health No. 1017, cited in footnote 32 *supra.*) The list contains the standards of identity, and these agents are not listed with food additives proper in Article 1398.

[37] *Ibid.* Article 1327.

[38] *Ibid.* Article 1392.

[39] *Ibid.* Article 1393.

The positive list of food additives is included in Article 1398 of the Code, and presently covers some 187 authorized substances.[40]

The Code refers in Article 1399 to the following sources of information for purposes of laboratory analysis of food additives and verification of their proper composition: (i) Food Chemicals Codex (Washington 1966 and subsequent editions); (ii) FAO/WHO Rules on identity and purity of food additives (Rome, 1963); and (iii) Argentine National Pharmacopeia (1966).

The Federal Health Authority is empowered to amend the list of Article 1398.[41]

One of the most controversial issues involving the substantive provisions of the Bromatopeia concerned Brominated Vegetable Oils (originally regulated as an accepted stabilizer in No. 1 of the positive list). The amount of their permitted use in soft drinks was reduced to 17 parts per million on grounds of consumer safety.[42] A 90-day term was set for the manufacturers to submit their new formulae to the authorities. Since the new limit proved to be too low, and replacement by essential oils (as sponsored by the authorities) not always feasible, the original deadline was subject to an extension. Eventually, the extension expired: thus the limitation remains valid and must be complied with by all those concerned.

Food additives of any of the five classes enumerated above may only be used in the amounts and/or percentages determined in the standards of identity set for each and every foodstuff.[43] It will not suffice for an additive to be listed without more, but it must be specifically permitted for the foodstuff in which it will be used.

Regarding labeling provisions, additives are subject to dissimilar requirements:

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[40] *Ibid.* Article 1398, amended as follows:

Resolutions by the Secretariat of Public Health—No. 1017 (cited in footnote 32 *supra*); No. 655 (cited in footnote 35 *supra*); No. 52 (Boletín del día, Ministry of Social Welfare, January 12, 1973); No. 2227 (Boletín del día, Ministry of Social Welfare, May 22, 1973).

Decree by the Federal Executive, No. 444 (February 6, 1974/Boletín Oficial, February 11, 1974).

[41] *Ibid.* Article 1400.

[42] Decree 444, Federal Executive. Cited in footnote 40 *supra.*

[43] Argentine Food Code, Article 8 reads: "It is hereby prohibited to add to foodstuffs, substances or ingredients (additives) which are not expressly and *in each case* admitted by the present Code." (Emphasis supplied.) "They may be added at the time of manufacture or preparation of the foodstuff, in the proportion that may be necessary for the intended or permitted purpose, but they may not be added later on, for purposes of hiding, minimizing or correcting deficiencies in manufacture, handling or preservation."

(I) Food additives proper (Article 1391 and following) are subject to a mere functional disclosure, namely a broad reference to the function as classified in the Code i. e., stabilizer, preservative, etc.). (No specific mention of the particular additive is necessary.) The general statement, however, implies the responsibility of the manufacturer for having used only an authorized additive, within the authorized limits or proportions, and in the authorized products as established in the corresponding standards of identity.[44]

(II) Aromatic-flavoring agents seem to be subject to specific declaration of the additive used, though it can be argued that such requirement applies to the sale of the additives themselves, and thus to the corresponding containers, and not to the sale of a foodstuff containing the additive.[45]

2.3. Articles of Daily Use

When reorganizing the provisions of the Reglamento Alimentario for purposes of its enactment as a Bromatopeia effective throughout the country, the Federal Executive eliminated Title XX of the old body of regulations, which dealt with articles of daily use. (These included stationery, domestic fuels, disinfectants, deodorants, germicides, insecticides, fungicides, rat poisions, soaps and detergents, toys and school equipment, toilet products, cosmetic and make-up products, products for polishing, cleaning and dyeing metals, furnitures, leather, etc., candles and industrial poisons.)

Though not destined for human ingestion, and hence not within the definition of foodstuffs, it is obvious that such articles are in direct and close contact with users, and they might prove to be hazardous through involuntary ingestion or contamination by some of the substances entering into their composition.

The gap in the new legislation caused the passing of Decree 1986 (May, 1970), which declared effective all non-food provisions of the old Reglamento Alimentario while the Secretariat of Public Health was drafting a new law on the matter.

Since such draft has never been completed, the "temporary provisions" of said Decree continue to be effective, but limited to federal territorial jurisdiction. Local authorities currently apply local rules (that is, Province of Buenos Aires, Decree of 1965).

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[44] *Ibid.* Article 1396.

[45] *Ibid.* Article 1315 (as amended by Decree 444/Federal Executive, cited under footnote 40 *supra*), and Articles 1316 and 1318.

2.4. Drugs and "In Between" Substances

The Argentine legislation has traditionally dealt with drugs in a separate body of rules. The standards of identity are set forth in the Pharmacopeia, whose first edition was released in 1898, and which is periodically revised by a Permanent Committee.

Federal administrative control of the composition of drugs has been regulated by Law 16463 (1964), including approval and registration of products and laboratories.[46] The law has an orthodox federal jurisdiction, that is to say, it applies in cases of federal territorial jurisdiction and in cases where interprovincial commerce is involved. Otherwise, local regulations prevail.

The legislative status of "in between" substances is debatable. The definition of foodstuff to be found in the Food Code is broad enough to cover every substance destined to be ingested by human beings. The distinctive criterion has to be sought then in the definition of drug or medicine within Law 16643. In its last analysis, such definition regards as a drug "every product used or applied in human medicine." The tautology, in fact, leaves the actual classification to case-by-case administrative decisions.

In general, the question of whether a product is used or applied to human medicine may be answered from two different standpoints: (i) a *subjective* one, that would regard as material the avowed intention of the manufacturer, and hence, all products that claim therapeutic qualities would be deemed drugs and would require approval by the corresponding authorities as such; and (ii) an *objective* one, that would regard as material the general past and present usage of the product or substance.

It is clear that in case therapeutic qualities are claimed by the manufacturer, the product will be considered as medicine or drug for purposes of denial of approval and registration by the Health Authorities. (See Article 235 of the Food Code.) But this rule of thumb proves particularly feeble in view of the fact that the corresponding drug authorities may *anyhow* deny registration of the product as a drug. In addition, there might be products which do not claim therapeutic qualities, but which are in fact drugs generally used in human medicine.

The rule serves one purpose, though, and that is the protection of the consumer against unfair commercial practices. In fact, in an

[46] Law 16463 (July 23, 1964/Boletín Oficial, August 8, 1964); Regulatory Decree 5883 (August 4, 1964/Boletín Oficial, August 11, 1964).

administrative decision regarding therapeutic teas (camomile, etc.), the declarations that the manufacturer effected through advertising, etc., were deemed material, and registration as a food product was denied.

The query remains unanswered, however, as to what would be the outcome of denial of registration *both as a drug and as a foodstuff.*

2.5. Foodstuffs and Drugs for Animals

The Argentine Food Code does not cover foodstuffs or drugs for animals. The definition of "food" in the Code (Article 6, paragraph 2) is explicitly qualified by the phrase "destined for human consumption." Thus, the regulation of products intended for consumption by animals is to be found in the unsystematic pattern of various other norms:

(i) Decree 7845 (October 18, 1964), as regulated by Resolution of the Secretariat of Agriculture No. 1156 (November 3, 1965).

It defines as animal foodstuffs "all products, whether concentrated or not, raw materials and/or their mixtures, industrial products and sub-products whether of vegetable or animal source, mineral and vitamin supplements, and any other additive prepared and marketed for consumption by the animal organism." Such a definition hinges upon the commercial intention attached to the foodstuff, and hence only refers to the feeding of cattle, poultry and other commercially exploited species.

Foodstuffs for animals thus defined are subject to prior approval by the proper authorities and so are the respective manufacturers. The authority having the jurisdiction over foodstuffs for animals is the Dirección General de Producción y Fomento Ganadero (Directorate for the cattle industry), subordinate to the Secretariat of Agriculture. When seeking approval, the manufacturer must submit a chemical analysis of the foodstuff and a listing of the raw materials used. The number of the granted approval, as well as the analytical composition of the product, its destination, the instructions for use, must be stated on the labels. The Directorate is empowered to inspect plants and collect samples in order to verify compliance with the regulations. In case of violations, the Secretariat of Agriculture may impose fines and seize infringing merchandise.

(ii) Law 17259 (May 2, 1967) as regulated by Decree 4277 (June 12, 1967).

It provides for the mandatory addition of potassium iodine to salt destined to human or animal ingestion, as a measure to prevent certain endemic illnesses.

(iii) Law 3959 on Animal Sanitation (November 1900) as amended by Law 17160 (February 2, 1967/Boletín Oficial February 15, 1967).

It regulates the inspection of products, subproducts and derivatives of animal source. Both norms, examined elsewhere in this paper (see Section 4.2 below) contain incidental references to hygienic and bromatological standards applicable to foodstuffs for animals. That is also the case with Laws 18073 and 18796 on pesticides.

(iv) Law 13636 (September 30, 1949) as regulated by Decree 583 (January 31, 1967).

This is the body of law governing the subject of *veterinary drugs,* that is to say, drugs intended for cure of animal illnesses. It provides that the "importation, exportation, manufacture, possession, distribution and/or sale of products destined for diagnosis, prevention and treatment of animal illnesses, are subject to the control of the Secretariat of Agriculture." Such control is performed through the "Servicio de Luchas Sanitarias" (SELSA), an agency subordinate to the Secretariat.

All manufacturers of drugs for animals must obtain a prior registration from the authority and each one of their plants must be authorized to operate. The approval of the individual products is subject to the following procedure: First the manufacturer will be given a provisional registration certificate, and later a definitive one. The provisional certificate enables the manufacturer to market the product. In the meantime, the control authority will conduct the relevant tests and analyses. The definitive certificates authorizing animal drugs have a validity of 10 years and are subject to renewal.

Animal drugs must be sold in proper containers bearing proper labeling. The control authority is empowered to inspect manufacturing plants and may impose fines in case of violations.

2.6. Amendment Procedure

The Argentine Food Code, as any other law, can only be amended by another law of Congress.

It is readily obvious that such a procedure of amendment, if followed in all cases, would prove to be excessively cumbersome to keep

an eminently technical body of rules updated—rules whose legal fluidity is in direct relationship with the fluidity of scientific and technological improvements.

Thus, Article 20 of Law 18384 states that the "Federal Executive will keep updated the technical provisions of the Argentine Food Code. . . ."

There can be some foreseeable quibbling regarding the meaning of the phrase "technical provisions." The literal interpretation would understand them as referring to all the provisions in the Bromatopeia save for the administrative provisions, bromatology being the technical field involved. This would have the seemingly paradoxical effect of requiring a law of Congress to amend provisions dealing with the administrative procedure in case of infringements of the Code, or with the system of registration of foodstuffs and establishments which are admittedly less important than the substantive provision of the Code.

The Federal Executive has been granted powers for the organization of qualified Task Groups to study and recommend amendments to the articles of the Code. Those powers are discretional.[47]

The organization of the Task Groups has been dealt with through a Resolution of the Federal Secretariat of Public Health (April, 1973) which secures proper intervention of representatives of the Provinces of Buenos Aires and Santa Fe, the two main food law jurisdictions, and of university scholars.[48]

More specifically, there are some cases in which the Bromatopeia has regulated a still simpler procedure of amendment. The list of food additives of Article 1398 can be amended through resolution of the Administrative Agency, namely the Federal Secretariat of Public Health (Article 1400). The same streamlined procedure is contemplated in case of aromatic substances within the broad title on correctives and coadjuvants (Article 1300), and, for all practical purposes for coloring agents (though the language, in this case, seems to refer more to a case-by-case approval of non-listed coloring agents than to an enlargement of the list).

[47] Provincial Law 6884 (cited in footnote 22 *supra*) provided that any amendment to the Argentine Food Code required the intervention of the provincial authorities. This interpretation runs counter to the text of the Code.

[48] Resolution 177 by the Secretariat of Public Health (April 17, 1973/Boletín del día, Ministry of Social Welfare, May 31, 1973).

Eventually, it became evident that the power granted to the Federal Secretariat of Public Health to amend the list of additives of Article 1398 was rather narrow. While the Agency was entitled to change the list of permitted additives in general, it was not allowed to effect consistent changes in the particular articles defining standards of identity which contained any of the additives of the aforesaid list. (For this last purpose, a decree by the Federal Executive was needed.)

To solve that problem, Decree 444[49] has authorized the Federal Secretariat of Public Health to introduce amendments to *any of the articles* of the Code when and insofar as a food additive is involved.

2.7. The Registration System

2.7.1. *Registration of Foodstuffs*

All foodstuffs[50] must be registered with the corresponding Health Authorities *before* commencement of manufacture, production or subdivision activities.[51] Such registration implies approval and, hence, compliance with the requirements set forth in the Argentine Food Code.

The corresponding authorities are those with jurisdiction over the place where the foodstuff is manufactured, produced or subdivided, that is to say, the manufacturing plant.[52] If there are several manufacturing plants, or else, locations of production or subdivision, the applicant may select any of the corresponding jurisdictions to apply for the registration of the foodstuff, provided that he mentions, in the application, the existence of the other plants, etc.

There are three possible authorities with which the application for registration of a foodstuff might be filed:

(i) The Federal Health Authority (Secretariat of Public Health);[53]

(ii) The Provincial Health Authorities;

(iii) The Municipal Health Authorities of the Federal District of the Capital City (Buenos Aires).

Original registration will be effected, in most cases, by the latter two authorities, since federal territorial jurisdiction is exceptional,

[49] Decree 444, Federal Executive (as cited in footnote 40 *supra*).

[50] Such foodstuff should meet the conditions set forth in the definitions of Article 6 of the Code, and, furthermore, be apt for registration in the sense discussed in the preceding section.

[51] Law 18284, Article 3. Regulatory Decree, Article 3, *in fine*. Code, Article 2.

[52] Regulatory Decree, Article 3.

[53] *Ibid.* Article 2.

as is the possibility that a manufacturing plant or other establishment be located therein.

The application must be filed by the person or entity having title to the foodstuff[54] (who needs not be the owner of the manufacturing plant or other establishment).

The whole system of registration must be uniform. In that sense, the Law and the Regulation require:

(i) that the applications be filed on specific forms approved by the Federal Authority;[55]

(ii) that the Federal Authority supervise the registers run by the local authorities, which must follow the pattern set by the Federal Register.[56]

According to the letter of the Code, once a foodstuff has been registered with the corresponding local authorities, the registration is communicated to the Federal Register, which assigns, to that registration, a special number in its computer system, and then relays information on the registration to all other Registers in the country.[57]

Hence, the main effect of the registration system is that the foodstuff registered with one jurisdiction may be marketed, transported and sold *throughout the country*. (Only one registration per product is required.)[58]

The control of the local Health Authorities over manufacturing plants and other establishments located within their jurisdiction, entails particular consequences regarding the federal registration of a foodstuff, in case there is more than one plant or establishment. Those authorities are entitled to verify that the plants and other establishments are fit to manufacture, produce or subdivide *the foodstuff as registered*. If it were found that the plant or establishment is fit to manufacture, produce or subdivide a foodstuff that differs from the registered foodstuff, an amendment to the original registration would be involved, and, hence, the prior approval by the original registration authority would be needed.[59]

The registration of the foodstuff does not, furthermore, affect the powers of on-the-spot verification by the local authorities of foodstuffs on the market. This task usually will be performed by the mu-

[54] *Ibid.* Article 3.
[55] *Ibid.* Article 3, *in fine*.
[56] *Ibid.* Articles 6 and 7.
[57] *Ibid.* Article 7.
[58] Law 18284, Article 3. Regulatory Decree, Article 3.
[59] Regulatory Decree, Article 3, *in fine*.

nicipal authorities which, save for the Municipality of the City of Buenos Aires, are not in charge of registration.[60]

2.7.2. *Re-registration of Foodstuffs*

The Bromatopeia, enacted by Law 18284, is no other than the old Reglamento Alimentario Nacional (Decree 141/53). Hence, those foodstuffs registered pursuant to the provisions of the Reglamento were granted a special status.[61] They could be re-registered at simple request of the interested party, without undergoing the standard substantial analysis and approval to which the new foodstuffs are subject.

A term of 60 days was initially set for re-registration purposes, which, in turn, was successively extended through an Executive Decree and resolutions by the Secretariat.[62] All terms have now expired, quite inconsequentially, in view of the failure of the system.

The only condition for a foodstuff to qualify for re-registration was that it should have been registered pursuant to the terms of the Reglamento Alimentario. (Decree 141/53.) Though neither the Law nor the regulation deal with the problem, it must be assumed that for re-registration purposes it could not suffice that the jurisdiction with which the original registration was filed had formally adopted the Reglamento at some point in time. It seems necessary that the Reglamento was indeed effective when the registration was granted, and that such registration was granted pursuant to the terms of the Reglamento. This, of course, entails the necessity of a careful consideration of each re-registration application.

Re-registration applications had to be filed with the authorities with jurisdiction over the plant or other establishment where the foodstuffs were manufactured, produced or subdivided, and in the case of several plants, with each authority with jurisdiction over each plant.[63] It is not clear why the single registration system provided for in case of new foodstuffs has not been followed.

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[60] Law 18284, Article 3.

[61] Law 18284, Article 8. Regulatory Decree, Article 8.

[62] Regulatory Decree, Article 8. The power to extend the re-registration term was granted to the Ministry of Social Welfare, through Decree 897 of the Federal Executive. (February 18, 1972/Published in Anales de Legislación Argentina, Rev Jur La Ley, 1972 Volume at 413). The Ministry of Social Welfare passed Resolution 1116 (April 11, 1972/Boletín del día, Ministry of Social Welfare, April 25, 1972) and Resolution 2097 (June 13, 1972/Boletín del dia, Ministry of Social Welfare, July 3, 1972) extending the term to its final deadline of August 30, 1972.

[63] Law 18284, Article 8. Regulatory Decree, Article 8.

The procedure was slightly different in case the original registration had been granted by the Federal Authority, since, in this instance, the re-registration application had to be filed with the same authority. The Federal Authority would communicate the re-registration of the foodstuff to each authority with jurisdiction over plants or other establishments and thus the single re-registration would suffice.[64]

2.7.3. *Registration of Foodstuffs for Exportation or Importation*

Registration and on-the-spot vertification of foodstuffs imported or exported is reserved to the Federal Authority. A special Register will be carried for the first purpose.[65]

Foodstuffs to be imported must meet the requirements of the Argentine Food Code. The corresponding permits of importation must be applied for with the Federal Authorities, according to regulations that provide for the submittal of the same information required for registration of local foodstuffs. The Federal Authority might deem prior on-the-spot verification necessary, and the permit will not be issued until a laboratory analysis is carried out.

Foodstuffs to be exported may either:

(i) meet the requirements of the Argentine Food Code; or

(ii) fail to meet those requirements, but (a) be especially authorized by the Federal Authorities; (b) meet the legal requirements of the country of destination; (c) state the foregoing in their labels.

The corresponding exportation permits will be issued by the Federal Authorities. Emergency permits for foodstuffs still undergoing laboratory analysis will be issued, conditional upon the final outcome of such analysis.

2.7.4. *Registration of Manufacturing Plants and Other Establishments*

Every manufacturing plant and establishment producing or subdividing foodstuffs, must be registered with the local Health Authorities with jurisdiction over the place of their location. Thus, for a single product, there will be as many registrations as establishments.[66]

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[64] *Ibid.* This provision, of course, has never been applied for reasons examined elsewhere.

[65] Law 18284, Articles 4 and 7. Regulatory Decree, Article 4.

[66] There is only a fleeting reference to a uniform centralized system for registration of establishments. See Law 18284, Article 7.

Each local registration will be communicated to the Federal Authority, in the same way local registrations for foodstuffs are communicated. The Federal Authority will carry the corresponding register.

The text of the Bromatopeia might cause some confusion in this respect.[67] It seems to require registration under the Federal system of every type of establishment including commercial outlets. This is not so. Only establishments engaged in the manufacture, production or subdivision of foodstuffs are subject to local registration pursuant to the federal regulations, and have an entry in the pertinent Federal Register.

Commercial outlets, storage facilities, and other establishments may be subject to local authorization and to inspection by the municipal authorities as a matter of municipal law, but not as a matter of Federal Law.

2.8. Infringement of the Food Code

Infringements of the Food Code may be of two types:

(i) formal infringements; or

(ii) substantive infringements.

Formal infringements will occur whenever particular foodstuffs or establishments have not been registered with the corresponding Health Authorities, irrespective of the fact that the foodstuff might comply with the standards set forth in the Bromatopeia.

Substantive infringements will occur, on the other hand, whenever a particular foodstuff does not comply with the standards or labeling requirements set forth in the Bromatopeia, irrespective of the fact that the foodstuff or the establishment might have been properly registered.

A foodstuff that complies in every respect with the provisions of the Bromatopeia will be regarded as "genuine or normal."[68] Conversely, if it does not, it will be deemed either "altered,"[69] "contami-

[67] Argentine Food Code, Articles 12 through 16, inclusive.

[68] *Ibid.* Article 6, paragraph 4. The definition reads: "(O)ne which, complying with all the regulations, does not contain non authorized substances nor additives which might constitute an adulteration, and is marketed under the legal denomination and labeling, without statements, signs or drawings that might deceive as to its source, nature or quality...."

[69] *Ibid.* Article 6, paragraph 5: "(O)ne which, through natural causes derived from technological processing—be they physical, chemical or biological, acting separately or combined—has undergone a deterioration in its organoleptic characteristics or in its intrinsic composition, or in its nutritional values."

nated,"[70] "adulterated,"[71] or "falsified."[72] The common element of the latter four types is their noncompliance with the Code and, hence, the existence of a substantive infringement.

The determination that an infringement (whether formal or substantive) exists, will usually result from inspections carried out by the Health Authorities. Though inspection of retail outlets will be generally a task for the municipal authorities, and inspection of all kinds of establishments within provincial jurisdiction is generally within the scope of action of the provincial authorities, the Federal Secretariat of Public Health is always empowered to preemptive action[73] as regards all establishments that manufacture, produce, distribute, subdivide, store or sell foodstuffs, wherever located.

The procedure outlined for the carrying out of federal inspections is concerned primarily with the determination that the establishment and the foodstuffs manufactured, stored or sold therein have been registered (verification of whether a formal infringement exists). In case of nonregistered products, the federal inspectors are empowered to seize them and to obtain samples for laboratory analysis.[74] Such analysis, though, will not be material for purposes of establishing the existence of an infringement in the case of formal ones (nonregistration). The analysis may prove, however, the existence of violations of the Bromatopeia and other legal bodies (i. e., the Penal Code).

For the most part, inspectors will be concerned with substantive infringements, either as they regard the establishment involved, or the foodstuffs manufactured, produced, stored or sold therein.

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[70] *Ibid.* Article 6, paragraph 6: "(O)ne which contains either:

(a) Living agents (virus, microorganisms or parasites unsafe for human health), chemical, mineral or organic substances extraneous to its normal composition, irrespective of their being repulsive or toxic; or

(b) Natural toxic components in a higher ratio of concentration than the one allowed by regulations."

[71] *Ibid.* Article 6, paragraph 7: "(O)ne which has been totally or partially deprived of its useful or characteristic elements, whether they have been replaced or not by other alien or inert substances; or to which non authorized additives have been added, or which has been subject to processes of any kind to hide or dissemble alterations, deficiencies in the qualities of the raw materials used or defects in the manufacturing process."

[72] *Ibid.* Article 6, paragraph 8: "(O)ne which presents the appearance and characteristics of a legitimate product, whether or not protected by a registered trademark, and bears the denomination corresponding to such product without actually being such, or has not been manufactured or produced by its authentic manufacturers or within the known and/or declared area of production."

[73] Regulatory Decree, Article 14.

[74] *Ibid.* Article 14, paragraph (e).

For purposes of ascertaining the existence of such violations, inspectors have broad powers. They may have access to all premises of the establishments themselves or of the administrative offices, provided the inspection be carried out during working days and working hours. In so doing, they may also examine the books and documents related to the business. They may carry out the preventive seizure of *prima facie* infringing products and request search warrants from the Courts. The preventive seizure may later on be confirmed through a sanction of attachment of the infringing products imposed by the Health Authority.[75]

After the inspection has been carried out, a memorandum of record will be drawn, and subsequently signed by all intervening parties (inspectors and those acting on behalf of the establishment). The memorandum will be the basis of the ensuing administrative proceedings.

Samples obtained for purposes of laboratory analysis will be identified in a separate document—three such samples must be obtained from each particular food product.[76] Within three days after the carrying out of the analysis, the establishment involved will be notified of the results. In case the analysis shows the existence of an infringement, there will be a term of three days running from such notification for the establishment to submit an objection to the analysis carried out by the agency involved, and to request that another analysis be carried out, with intervention of private experts. In case the establishment does not object to the results of the analysis, such inaction will be construed as an admission and the result will be deemed full evidence of infringement and liability at the ensuing administrative proceedings.

Infringement proceedings will be carried out before the Health Authority with jurisdiction over the place where the infringement has occurred.[77] It seems that, according to administrative practice, whenever the infringement has been determined through a federal inspection, the Federal Health Authority will, in all probability, decide on the case. Each administrative jurisdiction will have its own administrative procedures, but such procedures must give the infringers full opportunity to be heard and to present evidence on their behalf.

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[75] Law 18284, Articles 14 and 9.

[76] The first sample will remain in the establishment, the second will be subject to laboratory analysis by the agency involved, and the third will be reserved in case further analysis proves necessary (i.e. as a result of the objection raised by an interested party).

[77] Law 18284, Article 11.

Infringers might, however, be duly precluded from presenting evidence in their favor, whenever the conclusions of the above-mentioned memorandum of record have not been objected to at the time of its signature. The infringer will have forfeited his rights through inaction, and thus the memorandum will constitute full evidence of liability (akin to the similar situation in case of nonobjected laboratory analysis).

The proceedings are regulated in Decree 2126/71. After specific charges have been notified to the purported infringer, there is a term of five working days for submittal of a defense statement and documentary evidence. After the evidence has been examined, an administrative decision will be passed within ten days. Such decision might be appealed to the Federal Court with jurisdiction in the case, within five working days after notification of the administrative decision.[78] An appeal can be filed with the same Health Authority which in its turn will forward it to the corresponding federal court.

The Administrative Authorities have broad discretion as to the application of sanctions for infringements of the Food Code. Those sanctions may be:

(i) fines, within a certain range, which might be increased tenfold according to the circumstances;

(ii) attachment of the infringing foodstuffs;

(iii) temporary closing, either partial or total, of the corresponding establishment;

(iv) suspension or cancellation of the authorization to manufacture, market or sell the infringing foodstuff; in case this sanction is imposed, there are two possible variants:

(a) If the infringing foodstuff can be connected to a specific source, the suspension or cancellation order will only apply to the specific plant or establishment where such foodstuff has been manufactured, produced or subdivided. Marketing and sales of the foodstuff will, nonetheless, be suspended or cancelled throughout the country;

(b) If the infringing foodstuff cannot be traced to a specific source, the suspension or cancellation of the authorization will apply to establishments throughout the territory. From a practical viewpoint, this elaborate distinction

[78] *Ibid.* Article 12. This provision is consistent with the constitutional principle that calls for an open appeal to the judiciary in every administrative proceeding.

does not seem to serve any purpose, since, even if other plants of the same manufacturer are allowed to continue manufacturing the foodstuff, the suspension or cancellation of all marketing or sales thereof makes continuation of manufacturing or other activities useless.

(v) publication of the decision imposing any of the sanctions above.

It must be noted at this point that even though local authorities may follow their own administrative procedures in case of infringements, they must apply the above-mentioned sanctions as determined by Law 18284.[79]

All infringements of the Food Code have a statute of limitations of two years.[80]

Aside from the infringement proceedings examined above, the Federal Health Authority is empowered to issue a restraining order (of the injunctive type) suspending for a term of not more than 30 days, the authorization to market and sell a particular foodstuff, irrespective of the authority that has granted it. This restraining order may only be issued in case of serious danger to the health of the population at large. After the term of suspension elapses, the authority must in all cases publish the result of the inspections carried out, whether administrative proceedings and sanctions have ensued or not.[81]

The determination of the existence of an infringement of the Food Code may also show *a priori* evidence of the existence of a crime (violation of the Penal Code, which is applied throughout the country). In that case, the Health Authority will submit all evidence and administrative documents to the corresponding criminal courts.

The Penal Code has regulated crimes against public health, by establishing that "anyone who poisons, contaminates or adulterates, rendering them hazardous to health, drinking water, foodstuffs or medicinal substances, destined to be used by the public or to consumption by a human community, will be subject to a term of imprisonment ranging from three to ten years. In case of ensuing death, the sanction will range from ten to twenty-five years of imprisonment or reclusion." The crime has to be intentional.[82]

[79] *Ibid.* Article 9.
[80] *Ibid.* Article 10.
[81] *Ibid.* Article 5. Regulatory Decree, Article 5.
[82] Argentine Criminal Code, Article 200.

The sanctions will, nevertheless, be applied to anyone who sells, offers for sale, gives away or distributes, medicines or commodities hazardous to health, without disclosing their deleterious character.[83]

Those who commit any of the acts described above through negligence, carelessness, or unskillfulness in an activity or profession, or lack of compliance with regulations or legal provisions, will have the lesser punishment of a fine in case no human disease or death has ensued. The sanction will be imprisonment, ranging from six months to two years, in case human disease or death has followed.[84]

Section 3. Commercial Identification

The labeling of foodstuffs is subject to a double set of provisions:

(i) as goods in commerce, the Law and regulations on Commodity Identification apply;[85] and

(ii) as foodstuffs proper, the corresponding articles of the Argentine Food Code apply.[86]

3.1. Commodity Identification in General

Foodstuffs are a particular kind of commodity, and the general law regulating commodities applies to them, insofar as it does not contradict the special provision on foodstuff identification.[87]

Commodities are deemed manufactured in Argentina, whenever there is a modification in their nature (that is, some industrial value added), whether the raw materials or products used are foreign or national in any proportion. Such commodities must bear on their labels the phrase "Argentine Industry."[88] If the commodities in question were natural produce or fruits, the corresponding phrase would be "Argentine Produce."

All Argentine commodities, in the sense stated in the paragraph above, must bear labels in the national language (Spanish), and the measure units therein must comply with the national system of weights and measures (metric system).[89] The obligation extends to foreign commodities subdivided in the country.

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[83] *Ibid.* Article 201.

[84] *Ibid.* Article 203.

[85] Law 19982 (November 29, 1972/ Boletín Oficial, December 5, 1972); Regulatory Decree 8454 (same dates).

[86] Arge. tine Food Code, Title V, Articles 220 through 246 inclusive; also Law 18284 and Regulatory Decree, Article 19 in both cases.

[87] See Argentine Food Code, Article 1412.

[88] Law 19982, Article 1.

[89] *Ibid.* Articles 4 and 5.

Duly protected trademarks which might be (i) misleading as to the origin of the commodity or (ii) have a meaning in any foreign language, but which are manufactured or produced in Argentina, must bear the legends stating the origin in the same letter size as the trademark in question.[90]

Argentine commodities destined for exportation may:

(i) bear all legends in foreign language and measure units; or

(ii) bear an additional translation of the indication of origin.

These commodities are subject to special regulations to be passed on the matter by the Federal Executive.[91]

The scope of the Law is federal in an orthodox sense. The Federal Agency in charge of application of the same is the Secretariat of Internal Commerce, a division of the Ministry of Commerce.[92]

Compliance with the law on commodity labeling does not require prior registration of the labels to be used. In this sense, the Law provides for an *ex post facto* registration, within a period of time after commencement of use of the label.[93] Naturally, the Authorities will intervene whenever some label is found to violate any of the provisions of the Law. In case of doubt, interested parties might seek an opinion of the Secretariat before starting to use the label by voluntarily submitting such label for approval.[94]

The Executive Power is entitled to regulate a procedure of prior registration of all labels, if such procedure were deemed essential for purposes of attaining the goals of the legislation.[95] So far, that has not been the case.

Responsible for compliance with the Law and regulations are:[96]

(i) manufacturers of domestic commodities;

(ii) importers of foreign products or raw materials;

(iii) packagers of domestic fruits and produce;

(iv) principals in all agencies involving packaging and manufacturing activities;

(v) retail merchants; and

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[90] *Ibid.* Article 7.

[91] *Ibid.* Articles 5, 1 and 10, paragraph (d).

[92] Regulatory Decree 8454.

[93] Law 19582, Articles 9 and 19.

[94] *Ibid.* Article 11, paragraph (a).

[95] *Ibid.* Article 10, paragraph (e) and (i).

[96] *Ibid.* Articles 6 and 12 (Retail merchants must request to be furnished by manufacturers with the corresponding labeling and correlative materials, and keep them at all times at their outlets).

(vi) directors, officers, managers, or agents of commercial or civil entities carrying out the activities implied above.

The Authority having jurisdiction (Federal Secretariat of Internal Commerce) has extensive preventive powers of action:

(i) It may at any time obtain samples of commodities, and proceed to carry out chemical, physical or other types of analysis.

(ii) It may seize commodities infringing the Law and regulations, or commodities as to which there is an *a priori* evidence of infringement, provided that there is reasonable risk that the evidence might be effaced through action of the responsible party or of the third parties, in case the seizure is not carried out.

(iii) It may compel the responsible parties to include the indications of origin of the commodities as required by the Law and regulations in their labeling, advertising campaigns, etc.

(iv) It may issue a restraining order (injunctive proceeding) to cease using labels or advertising that infringe the provisions of the Law and regulations. This type of action might also be resorted to at any stage of the administrative proceedings resulting from an infringement.

Infringement of any of the provisions of the Law and regulations, noncompliance with a restraining order to cease an infringing activity, or using the labeling, advertising, etc., inaccuracies, exaggerations, concealments, etc. able to cause error, deceit or confusion regarding the quality, quantity, composition, or purity of the commodity in question, or the manufacturing or marketing technology applied to it, entails several sanctions.

Those sanctions are:

(i) a fine ranging from (approximately) $75 to $75,000 (United States currency);

(ii) a double fine in case of a second offense;

(iii) an ancillary declaration of disability to carry out commercial activities, for serious infringements of the Law and regulations (extending from one to six years); and

(iv) cancellation of the Charter of Incorporation and, hence, forced dissolution of artificial entities as such.

This extremely harsh penalty imposed upon artificial entities (corporations, etc.) seems exaggerated when compared to that of temporary disability for individuals. (See above.) This may be an

oversight of the legislators or a recognition of the fact that an artificial entity might always be reorganized and registered under a different name, with different membership, etc.[97]

All sanctions imposed by the authorities having jurisdiction may be appealed to the Federal Court of Appeals with jurisdiction (or to the National Court of Appeals on Economic Crimes, where appropriate).

The statute of limitations for all infringements is three years.

3.2. Foodstuff Identification Proper

Any label to be used on a foodstuff, or any prospectus, instruction, or item of advertising, is subject to prior registration and approval by the Health Authorities, and thus to compliance with the corresponding provisions of the Food Code.[98]

Approval of foodstuff labels and similar material by the Secretariat of Public Health will be concomitant with the approval of the foodstuff itself and, hence, will usually precede the submittal of the labels to the Commercial Authorities. The labels corresponding to all foodstuffs, condiments, beverages, food additives and their raw materials, must carry the following declarations:

(i) the denomination of the product and its composition. This requirement is closely connected with the particular standard of identity set by the Bromatopeia for the foodstuff in question;

(ii) net weight and volume of each unit to be sold to the public;

(iii) name and domicile of the manufacturer, producer or concern engaged in subdivision;

(iv) the phrase "Argentine Industry" for products manufactured totally or partially in the country; (The alternative use of the phrase "Argentine Produce" might be considered legal in view of the provisions of Law 19982);

(v) the numbers of registration of both the foodstuff and the manufacturing establishment; and

(vi) all other requirements of the Food Code and of effective law. In this last sense, Article 1412 of the Food Code states that compliance with the Identification of Foodstuffs provisions set forth in Title V does not preclude further compliance with the provisions on Commodity Identification in general. This

[97] *Ibid.* Article 12.

[98] Argentine Food Code, Article 222.

reference can only be understood as limited to Commodity Identification general provisions which do not contradict the specific provisions of the Food Code; otherwise, the rationale for the existence of a particular regulation of foodstuff labeling would disappear, since any successive Commodity Identification Law could presumably supersede the whole Title V by legislating differently.

One interesting example of such contradiction is that of imported foodstuffs subdivided in Argentina. Compliance with the Food Code labeling provisions would require that only the indication that the subdivision has been carried out in the country be translated into Spanish. The labels for such foodstuffs, thus, would be approved by the Health Authority even though they were all in a foreign language, save for the specific indication that the subdivision has taken place in the country. It is conceivable that, upon receiving communication of the use of such label, the Commercial Authority would deem them as infringing Article 5 of Law 19982, which requires "all statements" to be in the national language. The outcome in case of such a conflict is uncertain.

There are two prohibitions set forth by the Food Code which have a general interest:

(i) The use of the following adjectives in the labeling of foodstuffs is forbidden: "cream, pure, fresh, first, recommended, homemade, fine, superfine, insuperable, irreplaceable, strengthening, or similar expressions," when that in the judgment of the Health Authority would imply the attachment of a special quality to the product, whatever the spelling, if the phonetics of the same were similar to that of the forbidden words. Only those exceptions expressly referred to within the Code are admitted.

(ii) Artificial products may not carry in their labeling symbols or drawings that represent natural raw materials.[99]

Mere possession of foodstuffs labels in places other than manufacturing or subdivision establishments, is also forbidden.[100]

Infringement of the labeling provisions of the Food Code is subject to the general sanctions and administrative proceedings set forth by the Law and its regulations.[101]

[99] *Ibid.* Articles 232 and 233.
[100] *Ibid.* Article 243.
[101] Law 18284, Articles 9 and following. Regulatory Decree, Article 9.

Section 4. Food Law Matters Regulated Elsewhere

4.1. Wines and Other Alcoholic Beverages

Wines and some alcoholic beverages continue to be regulated by the Law on Wines.[102]

The Law on Wines provides for administrative application through a federal government instrumentality, the Instituto Nacional de Vitivinicultura (National Viticulture Institute), and is effective throughout the Argentine territory. (Curiously, its constitutionality has not been questioned.)

The overlapping articles of the Argentine Food Code will be applicable only insofar as there is a gap in the specific legislation.[103] It is to be noted, though, that the articles of the Food Code do not especially regulate wines and their types, but only define alcoholic beverages in general, and some of their types in particular (i.e., brandy, whiskey, etc.).

The Argentine Food Code provides that the provisions in the Law on Wines and its amendments and regulations will be revised for eventual incorporation into the Code itself.[104]

4.2. Products, Subproducts and Derivatives of Animal Source

All manufacturing establishments or storage facilities for products, subproducts and derivatives of animal source, are under the control and inspection powers of the Direccion General de Sanidad Animal (General Direction of Animal Sanitation), dependent from the Federal Ministry of Agriculture. Included are cattle, seafood, and poultry slaughterhouses, markets and cold storage facilities. The matter has been regulated by the Law on Animal Sanitary Control, its amendments and regulations.[105]

Proceeding upon its powers as granted by the same Law, the Federal Executive has regulated the inspection procedure to be followed regarding the establishments referred to above.[106]

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[102] Regulatory Decree 2126/72, Article 2, paragraph 4. Law on Wines—14878 (October 28, 1959/Boletín Oficial, November 25, 1959). As amended through Law 17848 (August 9, 1968/Boletín Oficial August 20, 1968) and through Law 17849 (same dates).

[103] Argentine Food Code, Article 1108 and following.

[104] *Ibid.* Article 1411.

[105] Law 3959 (Animal Sanitary Control, November 1900), amended through Law 17160 (February 2, 1967/Boletín Oficial, February 15, 1967), also amended through Decree, Federal Executive No. 2872/58.

[106] Decree 4238, Federal Executive (July 19, 1968/Boletín Oficial, August 26, 1968), Inspection regulations on products, subproducts and derivatives of animal source. Also Law 18811 (October 13, 1970/Boletín Oficial, November 2, 1970). Regulation of meat products. Law 18811 was regulated and supplemented by Decree, Federal Executive No. 1600/70.

The administrative control to be carried out by the above-mentioned Federal Agency is to be coordinated with the action of the Federal Sanitary Authority (Secretariat of Public Health) in its application of the Argentine Food Code.[107]

Though the Argentine Food Code makes its own provisions supplemental in this case, the fact that the Law on Animal Sanitary Control, its amendments and regulations, do not define standards of identity for foodstuffs of animal source, would suggest that the application of the Code will be mandatory in most cases.[108]

Establishments engaged in the manufacture, storage or distribution of products, subproducts and derivatives of animal source, provided they are foodstuffs under the Food Code, must:

(i) request an authorization of the establishment and the products according to the provisions of the Law on Animal Sanitary Control, either from the provincial authorities or from the Direccion Nacional de Sanidad Animal (General Direction of Animal Sanitation); and

(ii) apply for registration of both the establishment and the products according to the provisions of the Argentine Food Code, either with the provincial authorities or with the Federal Secretariat of Public Health (this authority will also approve the corresponding labeling).

It seems that the Law on Animal Sanitary Control, its amendments and regulations will only apply in case of orthodox federal jurisdiction (either territorial or involving the commerce clause of the Constitution). On the other hand, the Inspection Regulations passed by the Federal Executive are applicable throughout the country, either by the federal or provincial authorities.

The Food Code further provides for revision of the Law on Animal Sanitary Control and related legislation for eventual incorporation to the Code text.[109]

Infringements of the Law on Animal Sanitary Control may be sanctioned by:

(i) fines ranging from approximately $10 to $10,000 (United States currency);

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[107] Argentine Food Code, Article 1410. Regulatory Decree, Law 18284, Article 2, paragraph 5.

[108] *Ibid.* Article 247 and following.

[109] *Ibid.* Article 1411.

(ii) suspension or cancellation of the pertinent authorization.[110]

The sanctions imposed by the administrative authority may be appealed to the Federal Courts with jurisdiction over the place of occurrence of the infringements.

4.3. Pesticide Chemicals and Residue of Pesticide Chemicals

The specific legislation on the matter deals with:

(i) manufacture, use, marketing, transportation and storage of pesticide chemicals *per se;* and

(ii) use of pesticide chemicals in the slaughter of animals, or in the manufacture or storage of products, subproducts or derivatives of animal source. In this last sense, tables attached to the Law and regulations determine the maximum levels of pesticide chemical residue in products, subproducts and derivatives of animal source. Those tables may be amended by the Federal Executive.[111]

The Application Authorities are, jointly, the Federal Secretariat of Public Health, and the Federal Ministry of Agriculture.

The pesticide chemicals to be used must be listed as authorized substances and the residuary levels in foodstuffs must meet with the requirements of the corresponding tables. Both the list and the tables will be kept updated by the application authorities, though it seems that their powers would only be advisory since a Decree of the Federal Executive is, nevertheless, required.

This legislation applies throughout the country.

Section 5. Argentine Food Law and International Harmonization

5.1. General Observations

As has been outlined in Section 1 of this paper, the complex constitutional and political system prevailing in Argentina and reflected in several layers of federal, provincial and municipal food

[110] Law 17160. (See footnote 105 *supra.*)

[111] Law 18073 (January 20, 1969/Boletín Oficial, January 27, 1969), Prohibition of substances deleterious to human or animal health. Law 18073 was amended through Law 18796 (October 2, 1970/Boletín Oficial, October 8, 1970) with respect to pesticide chemicals. Law 18073 was regulated by Decree, Federal Executive No. 2678 (May 26, 1969/Boletín Oficial, June 10, 1969). This Regulatory Decree was subject to minor amendments through Decree, Federal Executive No. 1417/70.

legislation, prompted early attempts to achieve "internal" harmonization by the development of uniform provincial laws and regulations and/or the introduction of "national" food legislation. This trend gained particularly strong momentum in Argentina through the leadership of Dr. Carlos A. Grau, a food chemist, pharmacologist and pioneer of modern food law. He was the author of the first comprehensive "Codex Alimentarius" of the Province of Buenos Aires (1928), the first such code ever promulgated in Latin America. This Code was greatly enlarged and improved in three subsequent editions—1937, 1944 and 1949—and it served as a model for the federal "Reglamento Alimentario" (Decree 141 of January 8, 1953).

5.2. Latin American Food Code

With this background, it was not surprising that the Sixth Latin American Chemical Congress held in Caracas in 1955 commissioned Dr. Carlos A. Grau of Argentina to draft a "Latin American Food Code" which he did with the active cooperation of experts from 16 Latin American countries. The first completed draft of this Code was approved by the Seventh Latin American Congress in Mexico City in 1959, and published in book form in Buenos Aires in 1960. It was a comprehensive piece of work consisting of 19 Chapters and 798 Articles and covering general principles, rules for the general treatment of foods, labeling and individual standards of identity for all types of foods and articles for domestic use. The Second Revised Edition was published in 1964.[112] Dr. Grau was working on the Third Edition when he died in 1972. This Code exerted a considerable influence on the recent food legislation of many Latin American countries. In fact, the Inter-American Bar Association (IABA), at its XIV Conference in San Juan, Puerto Rico, in 1965, adopted a recommendation (No. 33) "that the Latin American Food Code be adopted as the sole legal instrument to regulate the negotiations carried out among the member countries of the Latin American Free Trade Association (LAFTA)."[113] However, in spite of wide official sponsorship the Latin American Food Code has not

[112] Many chapters of the Latin American Food Code (both 1960 and 1964 Editions) have been translated into English and published in the FOOD DRUG COSMETIC LAW JOURNAL. See Bibliography by J. G. Zimmerman, 26 FOOD DRUG COSMETIC LAW JOURNAL 303, 315 (July 1971).

[113] Zimmerman, J. G., "Harmonization of Food Laws and Food Standards in Latin America," 27 FOOD DRUG COSMETIC LAW JOURNAL 645 (October 1972); Bledel, Enrique E., "Food Regulation in Latin America," 28 FOOD DRUG COSMETIC LAW JOURNAL 585 (September 1973).

been adopted in its entirety by any country except Ecuador in 1963, and that only on a temporary basis.

The IABA, at its conference in Buenos Aires in November 1957, formed a special "Food, Drug and Cosmetic Law Section" (later transformed into Committee XIX) and has consistently supported the idea of international harmonization of food law. This is also true of all the Latin American Regional Groupings which have been formed in recent years to promote economic integration.

5.3. Latin American Economic Groupings

The LAFTA was set up by the Treaty of Montevideo in 1961 by Argentina, Brazil, Chile, Mexico, Paraguay, Peru and Uruguay. The basic purpose of the Treaty was to gradually eliminate all restrictions hindering the exchange of goods produced in the contracting countries, including, of course, food products which were affected not only by customs duties but also by the diversity of local food and labeling laws. As a matter of positive policy the first Executive Secretary of LAFTA, Dr. Alberto Sola, mentioned the necessity of establishing uniform legislation and regulations on food matters, but an initiative to adopt a uniform Food Code and common metrological labeling regulations based on the text of the Latin American Food Code was never formally adopted. However, as a practical matter, several committees within LAFTA used the Latin American Food Code to facilitate negotiations dealing with food law problems because of the diversity of terminology and nomenclature in their national laws.[114]

There are two other subregional Free Trade Associations in Latin America in which Argentina is not a member, namely the so-called Andean Group established within the framework of LAFTA in 1969 (Bolivia, Chile, Colombia, Ecuador, Peru and Venezuela), and the Caribbean Free Trade Association (CARIFTA), established in 1968, but so far they have not as yet produced any uniform food legislation.

The only successful attempt in this field has been in the Central American Common Market which was created by the Treaty of Managua in 1960 by Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua and with Panama as an associate member. These six countries enlisted the help of the Pan American Health Organization

[114] Bledel, *supra*, at 587; also "The Latin American Common Market and Food Legislation," 22 FOOD DRUG COSMETIC LAW JOURNAL 402 (July 1967).

(PAHO) and its Pan American Sanitary Bureau in Washington (PASB), the Regional Office of WHO for the Western Hemisphere. This organization agreed to sponsor the project and delegated the task of drafting food standards to the late Dr. Ariosto Bueller-Souto, Director of the "Instituto Adolfo Lutz" in Sao Paulo, the largest bromatological institute in Latin America. By 1965, Dr. Bueller-Souto and his associates had drafted about 380 food standards including analytical methods and lists of permitted additives, which were somewhat revised by the Conference of Health Ministers of the six countries and then published in three volumes (1967/1968) by PAHO in Washington under the title "Normas Sanitarias de Alimentos." These standards contain many features which originated in the Latin American Food Code, in the elaboration of which Dr. Bueller-Souto, likewise, cooperated. Furthermore, there is a close relationship to the Food and Agriculture Organization of the United Nations and the World Health Organization (Joint FAO/WHO Food Standards Programme) which has in recent years taken over the world leadership in harmonizing food standards both on a worldwide and regional basis, including Latin America.[115]

5.4. Joint FAO/WHO Codex Alimentarius Commission

The task of developing worldwide food standards is now primarily concentrated in the Joint FAO/WHO Codex Alimentarius Commission, the organization and functions of which are described in a Procedural Manual (fourth edition, 1975) published by the Commission. At the time of its first session in 1963, it had some 30 members, mostly developed countries. By 1976, its membership had increased to 114 countries—of which more than two-thirds are developing countries. Altogether the Commission had eleven sessions, the last one in March 1976. Detailed reports of each session are published with a summary of the activities of its various committees. Among its subsidiary bodies are six Worldwide Codex General Subject Committees, eleven Worldwide Codex Commodity Committees and four geographically limited Coordinating Committees for Africa, Asia, Europe and Latin America.

The procedure for the elaboration of worldwide and regional Codex Standards provides for eleven steps in accordance with the Procedural Manual. Step nine is the "recommended standard" which is sent to all member states and associate members of FAO and

[115] Olszyna-Marzys, A. E., "Food and Drug Legislation in Central America and Panama," 23 FOOD DRUG COSMETIC LAW JOURNAL 253 (May 1968).

WHO for acceptance in accordance with the procedure laid down under the General Principles of the Codex Alimentarius which provides for three options: (i) full acceptance; (ii) target acceptance; and (iii) acceptance with specific deviations.

By the end of 1975, about 70 international standards had been finalized and sent to governments for acceptance. An additional 40 international standards for milk and milk products have been elaborated and adopted by the Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning milk and milk products, a subsidiary body of the Commission, and sent to governments for acceptance. Acceptances have been and continue to be forthcoming.[116]

5.5. Participation of Latin America in the Codex Project

At the First Session of the Codex Alimentarius Commission in 1963, 32 countries were represented as participants or observers, including Argentina and the Dominican Republic. At the Second Session, the Latin American Group attending the session represented Argentina (Dr. Carlos A. Grau, Chief Coordinator of the Latin American Food Code), Brazil, Cuba, Nicaragua and Trinidad/Tobago. Subsequently a "formal" membership was established in the Codex Alimentarius Commission and the listing in 1974 at the time of the Tenth Session included 21 members from Latin America as follows: Argentina, Barbados, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Guatemala, Guyana, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Trinidad/Tobago, Uruguay and Venezuela.

The Report of the Tenth Session (Rome, July 1—11, 1974) mentions the establishment of a Coordinating Committee for Latin America as follows:

"33. Having received the strong support of delegations from Latin America during the course of the Commission's session, the Commission agreed to establish a Coordinating Committee for Latin America with the following membership and terms of reference:

Membership

"Membership of the Committee is open to all Member Nations and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission within the geographic location of Latin America.

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[116] Report by G. E. Kermode, Chief of the FAO/WHO Food Standards Programme for the European Food Law Association (EFLA) Conference in Parma, Italy (September 1975), reported by Zimmerman, J. G., "Food Law—International," 31 FOOD DRUG COSMETIC LAW JOURNAL 218 (April 1976).

Functions:

"The Committee exercises general coordination in the preparation of standards relating to the region of Latin America and exercises such other functions as may be entrusted to it by the Codex Alimentarius Commission."

The Commission also noted with appreciation the kind offer of the Government of Mexico to host at its own expense an FAO/WHO Food Standards Regional Conference for Latin America in 1977.[117]

The First Session of the Coordinating Committee for Latin America took place in Rome (March 25—26, 1976 (ALINORM 76/17)). It was attended by 15 participants from 8 countries, namely: Argentina, Brazil, Chile, Cuba, France, Mexico, Uruguay and Venezuela, and by observers from the Netherlands and Switzerland. The Committee elected Dr. E. R. Méndez of Mexico Chairman of the Committee as well as Coordinator for Latin America to serve from the end of the Eleventh Session of the Codex Alimentarius Commission (Rome, March 29—April 9, 1976) to the end of the Twelfth Session. Inasmuch as the Joint FAO/WHO Food Standards Conference for Latin America has been scheduled to take place in Mexico early in 1977, it was decided to postpone the Second Session of the Committee until 1978 and to continue the initiated work within the framework of the Conference.

The Coordinating Committee was informed that only four countries had replied so far to the questionnaire (CX 3/15(Q)) which had been distributed to members of the Region of Latin America in October 1974 and which sought to collect background information and data about existing food legislation in each country. The Committee requested the Coordinator to encourage replies to this questionnaire.

The Committee was also informed of the endorsement by the Coordinating Committee for Africa (September 1975) and the Food Standards Conference for Asia (December 1975) of a model food law prepared by the Secretariat and intended for member countries to compare with their existing food laws. This would improve the harmonization of food laws on a regional or worldwide level. Consideration of a similar model food law had been proposed for the Latin American Food Standards Conference.

The Committee agreed that the following points might be given priority after consideration by the Regional Conference:

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[117] Codex Alimentarius Commission, Report of the Tenth Session (Rome, July 1—11, 1974) paragraphs 13, 32—34, and Appendix II ALINORM 74/44—Report of the 20th Session of the Executive Committee of the Codex Alimentarius Commission, Rome, June 28, 1974, paragraphs 10—12.

(1) Harmonization of Food Legislation:

(a) examination of Codex work on a worldwide basis in the light of the particular conditions prevailing in the region of Latin America;

(b) the consideration of standards and other regulations for foods of particular interest to the region of Latin America, including the establishment, where appropriate, of regional standards.

(2) Promoting adequacy and uniformity of Food Inspection Services.

(3) Promoting adequacy and uniformity of Food Legislation, including the consideration of a model food law.

(4) Specific consideration of questions of contaminants (pesticide residues, mycotoxins and other chemical residues in food) as well as the use of food additives; the establishment of Codes of Hygienic Practice and Microbiological Specifications for foods.

In this connection, it is of interest that the delegation of Argentina stressed the need to develop worldwide rather than regional standards. This as well as the other developments mentioned above seem to indicate that most, if not all, progress in "harmonizing" food laws, regulations and standards can be expected to occur within the framework of the Codex Alimentarius Commission setup.

[The End]

CYCLAMATE PETITION DENIED

A petition to remarket the artificial sweetener cyclamate has been formally denied by the Food and Drug Administration, after the petitioner, Abbott Laboratories, declined to heed the FDA's advice to withdraw the petition. The agency stated that extensive study of the petition and other information, including a report by the Temporary Committee for the Review of Data on Carcinogenicity of Cyclamate empaneled by the National Cancer Institute, failed to establish the safety of cyclamic acid, calcium cyclamate, and sodium cyclamate as sweetening agents in food or for technological purposes other than caloric reduction.

In a concurrently issued FDA *Talk Paper*, the agency cited the following as options now available to Abbott if it wants to pursue its efforts to remarket cyclamate: (1) requesting a hearing before an administrative law judge, (2) requesting that the FDA convene a public board of inquiry at which independent experts review the scientific evidence, or (3) conducting a well-designed, long-term study as suggested by the National Cancer Institute's Committee.

Any person adversely affected by the FDA's order may, on or before November 3, 1976, file written objections and request a public hearing.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,725

WITHDRAWAL OF APPROVAL PROPOSED FOR CERTAIN ESTROGENIC DRUGS

In conjunction with its review of estrogenic drug products for general use, the Food and Drug Administration has reclassified as "lacking substantial evidence of effectiveness" the "probably" and "possibly effective" indications for certain preparations for vaginal use; for certain estrogen-androgen combination drugs, and for certain estrogen-containing drugs for oral or parenteral use. The agency has proposed to withdraw approval of the new drug applications for the drugs that provide for such uses and has given interested persons until October 29, 1976 to request a hearing and until November 29, 1976 to submit data to justify a hearing.

The agency has also set out the conditions for marketing the drugs for the indications for which they continue to be regarded as effective. As previously announced, the FDA has proposed that patient labeling be required for certain estrogen drugs and has issued examples of revised physician labeling and proposed patient labeling for the drugs.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,718—41,721 and 45,411

CONSUMER REPRESENTATION PLAN PUBLISHED

The Department of Health, Education, and Welfare has issued a Consumer Representation Plan intended to assure that persons affected by HEW regulations, policies, and decisions are informed of those actions and have an opportunity to comment on them. The CRP, published at 41 *Federal Register* 42796, September 28, 1976, requires that each notice, guideline, etc. contain the name, address, and telephone number of the person responsible for responding to citizen inquiry. The Primary Consumer Contact for the Department of HEW is: HEW Consumer Representation Coordinator, Office of Consumer Affairs, Department of Health, Education and Welfare, 330 Independence Ave., SW, Washington, D. C. 20201; (202) 245-1957.

The CRP provides that, where important policy issues are involved, a Notice of Intent be published and public comment invited before beginning the drafting of regulations. The Department of HEW will take affirmative action to encourage maximum consumer participation at public hearings. Time allowed for public comment will be longer than is now customary.

The Food and Drug Administration, as part of its CRP, will seek permission to train and use volunteers to gather consumer points of view on major issues. The Department of HEW has developed a comprehensive body of new policies and procedures for the issuance of regulations. These new policies and procedures will apply to FDA regulations, but will not apply to those regulations for which a Notice of Proposed Rule Making was transmitted to the Office of the Secretary prior to July 25, 1976.

REPORT SUGGESTS MERGER OF FDA WITH OTHER AGENCIES

Merging the Food and Drug Administration, the Consumer Product Safety Commission, and some programs of the National Highway Traffic Safety Administration into a single agency was one of several recommendations in a wide-ranging Congressional report on federal regulatory agencies and regulatory reform. The report, which is the product of nearly two years of investigation by the Oversight and Investigations Subcommittee of the House Committee on Interstate and Foreign Commerce, proposes the implementation of comprehensive reforms aimed at modernizing and improving Federal regulation. Other significant recommendations contained in the report include: establishing more consumer participation in the agencies, strengthening Congressional oversight, reorganizing energy regulation, and increasing regulatory agency independence from Executive Branch interference.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,727

CCH Reporting on Strict New
Medical Device Safety/Efficacy Rules . . .

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