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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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The GMP Regulations and the Proper Scope of FDA Rulemaking Authority.—"Guidelines are administrative recommendations and have no legal status," states *Wesley E. Forte* in the article beginning on page 532 in which he examines the Federal Drug Administration's interpretation of an opinion of the court in the *Smith Canning Case,* upon which the new Good Manufacturing Practice regulations are based. The extension of certain sections of the Food, Drug and Cosmetic Act to include a general power to make substantive regulations and the administering of such statutes containing criminal penalties is at variance, the author believes, with the power actually granted to FDA by Congress—that of interpretive regulation. On this premise he proposes a "prompt reissuance of the GMP regulations as guidelines" rather than law. Mr. Forte is an attorney for Borden, Inc. This article was originally published in the *Georgetown Law Journal.*

Latin-American Food Code.—In August 1964, the Latin-American Food Code Council published the Second Edition of the Latin-American Food Code. Beginning on page 550 of this issue of the JOURNAL, Chapter IX of the Code is reproduced. Regulations covering cereals, cereal preparations and bakery products are discussed. Included in this category also are macaroni products (termed alimentary pastes) and specialties originally peculiar to the Spanish diet, such as tortillas, pelotas and empanadas. Rules governing bakeries and macaroni factories are clearly defined.

Chapters I-V were published in the September 1965 issue of this JOURNAL; Chapters XII and XIII in the October 1965 issue; Chapter XVII in the November 1965 issue; Chapter X in the December 1965 issue; Chapter VII in the June 1966 issue; Chapter XVIII in the August 1966 issue; Chapter XVI in the May 1967 issue; Chapter VI in the August 1967 issue; Chapter XV in the October 1967 issue; and Chapter XI in the August 1968 issue. All translations have been by *Ann M. Wolf,* formerly of New York City, who has recently taken up residence in Rome, Italy.

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Journal

Have the FDA Hearing Regulations Failed Us?

By WILLIAM R. PENDERGAST

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THE RECENT SPEECH BY WILLIAM GOODRICH, giving his views on the procedural problems in handling Food and Drug Administration (FDA) administrative hearings, merits our careful study.[1] In this speech, Mr. Goodrich suggests that the hearing procedures at FDA are failing; that the hearings are too protracted; that needless formalisms are being followed; and that, as a consequence, "new methods" of conducting such hearings will have to be developed. If these assumptions are correct then every lawyer interested in Food and Drug law owes his clients and his profession a duty to seek ways to remedy the situation, to suggest alternatives, and to be careful that this failure, if any there be, is not the result of obstructionism.

It is not in the public interest to have these procedural mechanisms fail. All that could come of such a failure would surely be "new methods," born of administrative convenience, which, perhaps, would seriously limit our rights to administrative due process. The rights affected

[1] "The Food and Drug Administration's View on Procedural Rules" delivered before a Joint Meeting of the Food and Drug Committee of the Administrative Law Section and the Division of Food, Drug, and Cosmetic Law of the Corporation, Banking and Business Law Section, American Bar Association Annual Meeting in Philadelphia, Pennsylvania on August 7, 1968. 23 FOOD DRUG COSMETIC LAW JOURNAL 481 (October, 1968).

by the formal hearings are too fundamental and important to be trifled with. The affected industries must make every effort to insure that FDA's actions are exposed to the fullest possible public scrutiny —something that could be lost if the Congress, or the FDA, felt that current practices justify change.

And, of course, before we go too far in following Mr. Goodrich's lead, we must first examine his assumptions. If they are not valid then our attention to the problems must be directed elsewhere. The principal assumption, central to his entire thesis, is that the "protracted, trial-type proceedings" have strained the administrative process "almost to the breaking point by delays and by great financial expense." Is this so? Are the proceedings *unduly* protracted? Are the "trial-type" proceedings (if such there be) somehow unnecessary and do they contribute to the "undue protraction"? And, finally, does this delay (presumably in publishing final, enforceable regulations) occur during, and because of, the "hearing"?

Formal Hearings Defended

Recent experience over the last eight years suggests that not one of these assumptions is valid, that the hearing procedures have, on a broad view, been more than adequate; that the proceedings have been no longer than necessary to the subject matter and that "trial-type" proceedings[2] have worked best to protect everyone's vital interests.

Since 1960 the FDA has come to the point of holding formal hearings under the Food, Drug and Cosmetic Act on 21 separate occasions. Nine of these hearings dealt with the FDA's proposal to withdraw new drug applications or with FDA's refusal to approve new drug applications, and which clearly constitute adjudicatory hearings—the sort of hearing which all authorities and FDA agree require full, trial-type proceedings. For this reason no time need be spent on this special problem.

Ten of the hearings were rule-making hearings where FDA was establishing a standard of identity for a food product or, in one case (prescription drug advertising), establishing regulations for future conduct by the affected industry. The remaining two hearings involved the listing of two drugs as subject to the Drug Abuse Control

[2] Presumably by this characterization Mr. Goodrich refers to *inter partes* proceedings which are in the best democratic tradition and not to *ex parte* proceedings, long the anathema of our legal and legislative heritage.

Amendments Act of 1965.[3] The accompanying table demonstrates the number of days and the length of the transcript in each hearing. From a reading of these tables it is evident that most of these hearings, be they adjudicatory or rule-making, were disposed of rather quickly, with the longest completed rule-making hearing since 1960 the hearing to establish a standard of identity for peanut butter. Some review of the administrative history of this last standard is in order, in view of Mr. Goodrich's assumptions and so that the function of the "hearing" procedure in a given situation might best be understood.

HEARINGS AT FDA SINCE 1960

Products	Days*	Pages*
Diethylstilbestrol	22	3,803
Altafur tablets	21	3,185
Allergimist	4	745
Cothyrobol	4	430
Parnate	2	90
Clysrodrast	2	48
Neo Barine	10	1,198
Pro Forma	2	204
U-Series	44	6,265
Prescription drug advertising	4	138
Coal tar colors delisting	11	1,374
Jellies	2	234
Fruit Jelly	2	399
Cheddar Cheese	4	490
Orange Juice	27	3,434
Breaded Shrimp	9	1,308
Cheese Spreads	4	527
Peanut Butter	30	7,736
Orange Juice	8	874
Meprobamate	41	4,891
Librium-Valium	46	5,167

* This figure includes the pre-hearing conference as well as the hearing itself.

Procedural Method: Administrative History

FDA first proposed a standard for peanut butter on July 2, 1959,[4] and, pursuant to statute, the affected industries and consumers commented on that proposal. More than two years later, FDA acted upon these proposals and published an order establishing such a

[3] Pub. L. 89-74. One other hearing is under way—the hearing to establish standards under Sec. 401 for dietary products and Regulations under 403(j) for food for special dietary purposes. See p. 529 below.

[4] 24 F. R. 5391.

standard.[5] Objections were filed to the order and, on February 1, 1962,[6] the FDA stayed its order with no further action forthcoming from the agency until November 10, 1964, when the FDA, instead of acting on the objections, published a still further revision of its, by then, 5-year old proposal.[7]

Some eight months later, on July 8, 1965, the agency published still another order establishing a standard of identity for peanut butter.[8] Objections were filed to this order and, following more publications in the Federal Register, a hearing on these objections finally began on November 1, 1965, and continued, with interruptions, until March 15, 1966, for a total of approximately 30 days of actual hearing, and a 7,736 page transcript.

On December 6, 1967, eight months after the close of the hearing, the FDA published *tentative* findings concerning a standard for peanut butter, permitting comments to be filed until March 6, 1968,[9] the final version to become effective October 22, 1968[10] and, as of this writing, an appeal has been taken from this order to the Court of Appeals.

Thus, almost ten years elapsed from the date FDA first began administrative proceedings to establish a standard for peanut butter until a final, appealable, standard was published, surely a very long time. But, it is clear that a great deal of the time which FDA apparently needed to get this regulation in final form was spent out of the hearing with the hearing itself counting for less than 1% of the entire period of administrative action. Viewed in that light, it is manifest that if there were any administrative failures (and we don't know if this is so) the failure was internal, at FDA, and bears no relation to the conduct of a hearing. If there was no failure, then any administrative inquiry which takes ten years to comprehend surely deserves thirty days of hearing on the public record.

The peanut butter hearing is, up to now, the most egregious example of an extended, rule-making procedure, but, when it is understood in relationship to the entire process, we see that the hearing procedures themselves have not failed. This hearing was hard-fought with able counsel on both sides and now that the matter is in the Court of Appeals we should soon have a definitive judgment as to the merits of the "trial-type" record they have made.

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[5] 26 F. R. 11209, November 28, 1961.
[6] 27 F. R. 943.
[7] 29 F. R. 15173.
[8] 30 F. R. 8626.
[9] 32 F. R. 17482.
[10] See 21 CFR 46.1.

Many of the other hearings were not concluded by final order but by other action, particularly in the drug area, where the drug companies either abandoned their efforts or reached some other settlement with the agency. The other food standard hearings moved along with dispatch, so far as can be judged from their length and the records. Certainly none of them gives us reason to incriminate the entire hearing procedure. Obviously, the hearing itself does not take up much time in the FDA procedural activities, as Mr. Goodrich intimates.

Cross-Examination in Hearings

Mr. Goodrich also suggests that in such rule-making proceedings the usual "trial-type" techniques are not in order. Because of the statements he cites we assume that his criticism is directed here at the use of cross-examination in FDA hearings. Mr. Goodrich quotes at length from Davis, *Administrative Law Treatise*. In this statement, as given to us by Mr. Goodrich, Professor Davis apparently feels that a food standard hearing is not the sort of place for unlimited cross-examination and that "the method of trial has no place except when specific facts are in issue, and even then should seldom be used when the disputed facts are legislative."[11] Unfortunately, Mr. Goodrich's quotation does not reveal the examples of food standard issues which Professor Davis had in mind when he expressed his displeasure with "trials" at FDA. The Professor had earlier noted that the FDA testimony often dealt with such questions as whether "golden" should be permitted as a synonym for "yellow," whether pear halves should have a minimum weight of 4/5 ounces or 3/5 ounces, and whether tomato puree made from peelings should be labeled "trimmings" or "tomato by-products."[12] Of course, these are plainly examples of the sort of "facts" which are not amenable to sharp dispute and Professor Davis, in commenting on them, was correct in stating that unlimited cross-examination about them and other trial techniques are unsuited in such a proceeding.

But such examples are certainly not now, if they ever were, representative of the true nature of FDA rule-making hearings. A good deal of the evidence currently presented at such FDA hearings falls squarely within the exception noted by Professor Davis—for

[11] Davis, *Administrative Law Treatise*, West Publishing Co., 1958, Sec. 6.06, p. 382.

[12] See footnote 11.

such evidence *does* involve "specific facts in issue," namely, sharp factual disputes based on scientific opinion expressed by leading experts in the various disciplines of science. In the peanut butter standard hearing, for instance, there was a sharp difference of expert opinion as to whether added vitamins should be permitted as optional ingredients in peanut butter. In the two hearings to subject certain drugs to the Drug Abuse Act of 1965, experts were called by both sides to present varying, and sometimes contradictory, views on pharmacology, chemistry, therapeutics, and the practice of medicine. But, using the past as prologue, the most outstanding example of a rule-making hearing with precise and highly controverted fact issues is the currently under way hearing on dietary regulations, mentioned in an earlier footnote.[13] Almost the entire testimony to date in this hearing has consisted of expert opinion on specific fact questions such as the nutritional status of the American population, the need in the human diet of certain nutrients, and the need in human nutrition for large amounts of many vitamins and minerals.

Such fact issues are plainly far different from the ones referred to by Professor Davis in the text cited by Mr. Goodrich. Professor Davis himself clearly rejects any notion of a broad-scale removal of the right to cross-examination in administrative hearings. In commenting on a proposal to place cross-examination entirely in the discretion of the hearing examiner with such examination to be rarely granted, Professor Davis says that the "proposal is a good one for any case in which the dominant evidence is economic . . . But the . . . proposal should and will be rejected for resolving factual disputes about narrow and specific questions . . .".[14]

The holding in *Reilly v. Pinkus*[15] would indicate that opinion medical testimony is the sort of "fact dispute" discussed by Professor Davis and which requires careful cross-examination. In *Pinkus*, the Supreme Court held that it was error to exclude from a post office administrative hearing cross-examination based upon medical texts. As the Supreme Court said "It certainly is illogical, if not actually unfair, to permit witnesses to give expert opinions based on book

[13] FDC-78. This hearing is by all criteria protracted. Since it is now in session it would be inappropriate to discuss whether it is *unduly* protracted or whether the history of these Regulations reflect sound administrative policy and due dispatch.

[14] 2 Davis, *Administrative Law Treatise*, West Publishing Co., 1965 Supplement. Sec. 14, 15, p. 56

[15] 338 U. S. 269.

knowledge, and then deprive the party challenging such evidence of all opportunity to interrogate them about divergent opinions expressed in other reputable books."[16] It is obvious that the Supreme Court at least, if not the FDA, believes that expert medical opinion must be subjected to rigorous cross-examination.

It is self-evident that if scientific opinions are to be adequately tested they must be subjected to the more rigorous sort of cross-examination. In such scientific areas as the FDA regulates, every tool of trial practice must be utilized to insure that the evidence which goes into the record is precise as to nature and scope and that there be no likelihood that a given opinion is later held to justify something more than the author of that opinion intended. Following such rule-making hearings the FDA publishes findings of facts with citations to the record and, unless the scope of a witness' answer is carefully tested on cross-examination, there is no assurance that the FDA might not find that such an answer contains far more than the witness or the participants expect.

The use of cross-examination is especially important in FDA hearings where the parties do not have the power to subpoena witnesses whose testimony might conceivably rebut such expert opinion. In such a situation, extensive cross-examination might well be the only vehicle, however feeble, available to a contestant. Neither Mr. Goodrich nor Professor Davis has commented upon this factor in their discussions of the use of cross-examination in FDA rule-making proceedings, but certainly, it is a pertinent point and should be taken into account in assessing whether this "trial-type" technique is proper at FDA. Very often, experts are willing to appear on behalf of the Government but are understandably reticent about returning later on behalf of another participant. And also, many experts are unwilling to appear on behalf of companies and testify either in opposition to opinions expressed by their fellow experts or against the announced position of such an important federal agency.

I do not mean to suggest that FDA hearings are models of administrative procedure. There are, indeed, improvements to be made in the hearing regulations as well as in the conduct of the hearings themselves.

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[16] See footnote 15, page 275.

In this regard, many innovations have been considered and could well be incorporated in general hearing regulations. For instance, in the dietary hearing, the Examiner has required that a party presenting a witness serve upon all other parties, at least 10 days before the witness testifies, a summary of the witness's anticipated testimony together with his curriculum vitae and bibliography. This has proved a great help in preparing for testimony of witnesses and could well be incorporated in a general regulation. The Examiner has also required that scientific articles upon which the witness intends to rely be identified with particularity by the party offering the witness so that it will not be necessary for the other parties to search out and read every article written by the witness. Finally, oral argument on Rulings from the Bench is heard only when the Examiner requests it. Such procedures should be considered in any future hearing regulations.

Conclusion

To sum up, the facts of the last eight years would appear to contradict Mr. Goodrich's fears that the administrative hearing process is failing at FDA. Considering the broad range of products subject to FDA regulation and the broad areas of science reached by such regulations, there is no reason to believe that the few hearings held since 1960 have contributed in any measurable amount to a delay in the proposal of final, enforceable regulations. Delays there have been, but the record would seem to indicate that the delays are the result, and perhaps the necessary result, of lengthy internal deliberations at FDA.

It is clear that the great delay that occurs so often between the promulgation of proposed FDA regulations and their publication in final form is very often the result of a lamentable tendency on the part of the FDA to hastily propose unscientific, incomplete, ill-considered, "shoot-from-the-hip" regulations which, after scrutiny by the industry and, in some cases, by the hearing procedure require considerable revision and reconsideration. Perhaps more careful staff work before the hearing procedure ever begins would be a better solution to FDA's problems than any broad-scale revision of hearing procedures.

[The End]

The GMP Regulations and the Proper Scope of FDA Rulemaking Authority

By WESLEY E. FORTE

The Following Article Is Reprinted from the *Georgetown Law Journal*.* Mr. Forte, a Member of the Pennsylvania Bar, Is an Attorney with the Borden Company.

AMONG THE MOST INTERESTING AND SIGNIFICANT legal developments of the 1960's has been the expansion of the real and purported power of federal agencies to issue rules and regulations having the force and effect of law. Occasionally, this expansion has been the direct result of new federal legislation, as, for example, when Congress enacted the Fair Packaging and Labeling Act, authorizing the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) to issue substantive regulations restricting the packaging and labeling of consumer commodities.[1] More often, however, the expansion of the federal agencies' power to issue regulations having the force and effect of law has not been the result of any new legislation.[2] Instead, federal agencies have assumed this power by a new interpretation of an already existing statute. An example of this is the FTC's newly discovered power to issue trade regulation rules.[3] A temporary climax to this trend was probably reached when,

[1] See Fair Packaging and Labeling Act §§ 4-7, 15 U. S. C. §§ 1453-56 (Supp. II, 1965-1966).

[2] See, for example, FDA Dietary Food Regs., § 80, 31 Fed. Reg. 15,730 (1966). This regulation is based upon a new interpretation of § 401 of the Federal Food, Drug and Cosmetic Act, which allegedly permits the prohibition of the use of certain ingredients in all foods except those listed by the FDA. The validity of this interpretation has been challenged by industry.

[3] See FTC Trade Reg. Rules, 2 TRADE REGULATION REPORTS ¶¶ 7915-42 (1965). The basis for these rules is stated at 29 Fed. Reg. 8325, 8364-73 (1964).

in the *Federal Register* of December 15, 1967, the FDA announced a proposed new code intended to regulate the physical facilities, equipment, grounds, and operation of all plants processing foods for shipment in interstate commerce.[4]

The proposed new code, commonly called the Good Manufacturing Practice or GMP regulations, is an odd combination of generalities and specifics. It requires "adequate"[5] lighting, ventilation, and employee facilities for eating and for storage of clothes, prescribes that all doors to toilets shall be self-closing, and prohibits "excessively" dusty roads on grounds surrounding the plant. It also requires "adequate" sanitary facilities, "sufficient space" for "orderly" placement of equipment in the plant, and conformity by employees to "hygienic practices" while on duty.[6] These regulations were promulgated "to establish criteria for current good manufacturing practice (sanitation) in the manufacture, processing, packaging, or holding of human foods to effect compliance with section 402(a)(4) of the act . . . ."[7]

Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.[8] Shipment of adulterated food in interstate commerce is a criminal offense, whether or not the person responsible for the shipment intended to violate the

[4] FDA Good Manufacturing Practice Regulations for Foods, 32 Fed. Reg. 17,980 (1967) [hereinafter cited as GMP Regs.].

[5] "Adequate" is defined in the regulations as meaning in conformity with local, state, and public health requirements or recommendations, or in the absence thereof, in keeping with good public health practice. See footnote 4 at § 128.1(a).

It is difficult to understand how this definition helps the regulations. Whether a practice is "in keeping with good public health practice" is as abstruse as whether the practice is "adequate." Neither approach gives any reasonably precise definition of the offense prescribed by the Act.

Additionally, one may question the wisdom of the FDA's adoption of varying local sanitation requirements as a national code. Why should the sanitation required under national law differ because different plants have different locations? Will FDA inspectors be satisfied with proof that a sanitation practice—no matter how bad it is—conforms to local recommendations? Are all local sanitation recommendations so good that they should be incorporated in national law? How does the adoption of local standards for sanitation raise the average plant sanitation level as suggested in *Smith Canning?* See text accompanying notes 43-55 below. Are local plants presently not complying with local law? If the FDA is merely going to enforce local law, it would be easier for the federal government simply to give grants to the states and municipalities so that they might better enforce their own laws.

[6] "Hygienic practices" seems nearly as vague as "adequate," yet it is not defined at all in the regulations.

[7] GMP Regs., Introduction at 17,980.

[8] 21 U. S. C. § 342(a)(4) (1964).

law.[9] According to the FDA, compliance with the GMP regulations constitutes compliance with section 402(a) (4) of the Act.[10] Whether noncompliance with the GMP regulations in and of itself makes a food adulterated and makes all persons having a reasonable relationship to such adulteration become candidates for prison sentences is unclear. Since the FDA promulgated the GMP regulations as criteria to effect compliance with the Act, it would appear that the FDA intends these regulations to have the force and effect of law.[11] The thought of corporate managers being given a trip to the hoosegow because their plant did not meet the rather ambiguous requirements of "adequate" sanitary facilities or lighting, or because the plant premises had "excessively" dusty roads, or because an employee failed to conform to "hygienic practices" has caused predictable shudders in the business community.[12] Such vague requirements in substantive regulations promulgated under a criminal statute would also seem to raise grave doubts under the due process clause of the fifth amendment and under the sixth amendment of the Constitution.[13]

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[9] 21 U. S. C. § 333 (1964); see *United States v. Dotterweich*, 320 U. S. 277 (1943); *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008 (7th Cir. 1947), *cert. denied*, 332 U. S. 851 (1948). See also *United States v. Wiesenfeld Warehouse Co.*, 376 U. S. 86 (1964).

[10] See GMP Regs., Introduction and § 128.2, at 17,980.

[11] See footnote 10. Section 128.2 explicitly states that the criteria in the GMP regulations "shall apply" in determining whether the facilities and controls are "administered in conformity with good manufacturing practices to produce under sanitary conditions food for human consumption."

[12] Relationships between plant personnel and FDA inspectors during inspections authorized by § 704, 21 U. S. C. § 374 (1964), have been a frequent source of friction under the Federal Food, Drug and Cosmetic Act. FDA inspectors often demand information which far exceeds that which industry is obligated to furnish under the Act, and industry's refusal to give that information is not always accepted graciously. See Hutt, "Factory Inspection Authority —The Statutory Viewpoint," 22 FOOD DRUG COSMETIC LAW JOURNAL 667, 670 (December, 1967). It is inevitable that industry opposes regulations which seem to grant FDA inspectors the authority to speculate concerning whether facilities and controls are "adequate" or roads "excessively dusty."

[13] Section 402(a)(4) of the Act prohibits the manufacture, packing, and holding of food under insanitary conditions whereby it may have been contaminated with filth, and to date has been upheld as constitutional. See *Golden Grain Macaroni Co. v. United States*, 209 F. 2d 166 (9th Cir. 1953); *Berger v. United States*, 200 F. 2d 818 (8th Cir. 1952); *United States v. Gnome Bakers, Inc.*, 135 F. Supp. 273 (S. D. N. Y. 1955); *cf. United States v Wiesenfeld Warehouse Co.*, 376 U. S. 88, 91 (1964). However, the GMP regulations may well be more vague than the statute itself and may thus be unconstitutional. If the regulations are substantive and extend the prohibition beyond the express words of the statute, there is nothing incongruous about this conclusion. Even if the regulations are interpretive, their ambiguity may illustrate the vagueness of the statute and result in an overruling of prior holdings of constitutionality. Under the Federal Food, Drug and Cosmetic

(Continued on next page.)

The Fundamental Problem

The underlying question, however, is not whether the FDA's GMP regulations are good regulations or bad regulations. Their defects (including their ambiguity) only accentuate the more fundamental problem—whether the FDA, in prescribing the procedures to be followed in equipping and operating food plants, has the authority to issue regulations having the force and effect of law. The GMP regulations include a multitude of restrictions which may in general be desirable sanitary practices, but which may or may not result in a food being prepared, packed, or held under insanitary conditions in any individual case. For example, equipment may not be readily cleanable as required by the regulations, but plant personnel may invariably clean it; roads near the plant may be excessively dusty, but the plant may be so constructed that dust never enters; or doors to toilets may not be self-closing, but the employees may invariably close them. The paramount question raised by the proposed GMP regulations is thus whether the FDA must prove in each case that food was prepared, packed, or held under insanitary conditions whereby it may have been contaminated by filth, or whether the FDA has the power to prescribe legislative regulations which extend far beyond the express words of the statute and which require generally desirable sanitary practices.[14]

The asserted authority for the promulgation of the GMP regulations is Sections 402(a) (4) and 701 (a) of the Federal Food, Drug and Cosmetic Act.[15] Section 402(a)(4) does not purport to grant any regulatory authority; it merely provides that a food is adulterated if it is prepared, packed, or held under insanitary conditions.[16] Sec-

(Footnote 13 continued.)
Act (as well as other statutes), there must be fair warning and fair and effective notice of the actions prohibited by law. See *United States v. Cardiff*, 344 U. S. 174 (1952). See also *United States v. Fabro, Inc.*, 206 F. Supp. 523 (M. D. Ga. 1962).

[14] The distinction is perhaps best illustrated by the regulations, rules, and guides promulgated by the FTC. The FTC recognizes three distinct categories of administrative promulgations: trade regulation rules which are considered substantive, the violation of which is considered to be in and of itself illegal; trade practice rules which are considered interpretive, the violation of which is considered illegal only insofar as the same act may constitute a violation of the underlying statute; and guides which are considered to be administrative interpretations of the law, similar to advisory opinions of the FTC. See 16 C. F. R. §§ 1.63, 1.62, 1.55 (1967).

The GMP regulations raise the question of whether the FDA can prescribe a national sanitation code equivalent to an FTC Trade Regulation Rule or whether the FDA's rulemaking power in this area is limited to interpretive rules or guides.

[15] See GMP Regs., *Introduction* at 17,980.

[16] 21 U. S. C. § 342(a)(4) (1964).

tion 701(a), however, presents more difficult questions. It states: "The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."[17] The effect of the GMP regulations will be determined by the meaning of these words.

Enactment of the Federal Food, Drug and Cosmetic Act climaxed a five-year battle between Government and industry. The predecessor statute, the Food and Drugs Act of 1906,[18] had proved inadequate to curb the frauds perpetrated upon the public by unscrupulous manufacturers. Foremost among these frauds was economic adulteration,[19] the producing and selling of foods which look like, taste like, and are used for the same purposes as more expensive foods, but which contain (or are "economically adulterated" with) less expensive ingredients.[20] Under the 1906 Act, the FDA had to prove the standard or "proper" composition of each generic food in each case before it could prove that the cheaper food was a debased product which violated the Act.[21] The lack of a generally established composition for commonly debased foods hampered enforcement of the 1906 Act, and when

[17] 21 U. S. C. § 371(a) (1964).

[18] Act of June 30, 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

[19] See O. Anderson, *The Health of a Nation* 69 (1958); Hart, "Food Adulteration in the Early Twentieth Century," 7 FOOD DRUG COSMETIC LAW JOURNAL 485 (August, 1952). See also Anderson, "Pioneer Statute: The Pure Food and Drugs Act of 1906," 13 J. Pub. L. 189 (1964).

[20] See, for example, *Union Dairy Co. v. United States*, 250 F. 231 (7th Cir. 1918) (milk diluted by water); *William Henning & Co. v. United States*, 193 F. 52 (5th Cir. 1912) (catsup diluted by pumpkin); *Frank v. United States*, 192 F. 864 (6th Cir. 1911) (pepper diluted by corn); *United States v. Frank*, 189 F. 195 (S. D. Ohio 1911) (lemon extract diluted by alcohol and water).

The most prominent example was a product known as "Bred Spred," which lacked much of the expensive element (fruit) usually contained in jam. The three *Bred Spred* cases ended unhappily for the Government. See *United States v. Ten Cases of Bred Spred*, 49 F. 2d 87 (8th Cir. 1931); *United States v. Fifteen Cases of Bred Spred*, 35 F. 2d 183 (7th Cir. 1929); *United States v. 49½ Cases of Bred Spred*, M. White & O. Gates, *Decisions of Courts in Cases Under the Federal Food and Drugs Act* 1204 (1934) (E. D. Mich. 1904). The *Bred Spred* cases are credited with furnishing much of the impetus for the Federal Food, Drug and Cosmetic Act. See *62 Cases of Jam v. United States*, 340 U. S. 593 (1951); *United States v. Thirty Cases of Leader Brand Strawberry Fruit Spread*, 93 F. Supp. 764 (S. D. Iowa 1950).

[21] Under the 1906 Food and Drugs Act, the FDA did not have the authority to promulgate regulations having the force and effect of law describing the composition of foods. See Crawford, "Ten Years of Food Standardization," 3 FOOD DRUG COSMETIC LAW JOURNAL 243, 244-45 (June, 1948). Interpretive regulations were issued defining some foods, but these regulations were usually not given any weight. See, for example, *United States v. Swift & Co.*, M. White & O. Gates, below note 20, at 1146 (D. Ore. 1925); *United States v. St. Louis Coffee & Spice Mills*, 189 F. 191 (E. D. Mo. 1909). But see *United States v. Frank*, 189 F. 195 (S. D. Ohio 1911).

a revision was proposed, the FDA argued that it should be given the power to promulgate definitions and standards of identity which were not merely advisory but which would have the force and effect of law.[22]

A Schizophrenic Statute

The proposal to permit the FDA to define foods in regulations having the force and effect of law divided Congress.[23] Questions were raised concerning both the advisability of such regulations and the procedural safeguards necessary to prevent their arbitrary promulgation.[24] Congress, in the Federal Food, Drug and Cosmetic Act of 1938, finally authorized the FDA to issue definitions and standards of identity and certain other regulations having the force and effect of law, but circumscribed this authority with the strictest procedural limitations.[25] These limitations, contained in section 701 of the Act, require a public hearing on proposed regulations and detailed findings of fact based upon substantial evidence developed in the record of the hearing.[26] The statute also provides for judicial review of the regulations by a United States court of appeals on the petition of any person adversely affected by the regulations.[27]

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[22] Walter Campbell, then Commissioner of Food and Drugs, regarded the provision for standards of identity as one of the most important provisions in the Federal Food, Drug and Cosmetic Act. See *Federal Security Adm'r v. Quaker Oats Co.*, 318 U. S. 218, 231 n. 7 (1943).

[23] Commissioner Campbell, remarking on S. 5, the bill which ultimately became the Federal Food, Drug and Cosmetic Act, stated: "The most popular criticism directed at this bill is that it confers unusual and unnecessary authority upon the administrative officer. It is asserted that it is a mere skeleton of legislation with accompanying warrant to the Secretary to fill in its needed provisions. . . . It is extremely difficult, if not impossible, to formulate a legislative measure which will provide for adequate protection of the consuming public in the regulation of a subject as complex and varied as production and traffic in foods, drugs, and cosmetics. It is necessary, after a clear indication of the legislative purpose, to delegate to the executive branch the task of fact-finding as a preliminary to the formulation of regulations for the purpose of giving effect to the expressed legislative intent." C. Dunn, *Federal Food, Drug & Cosmetic Act* 1230 (1938). He then went on to discuss many of the provisions authorizing regulations having the force and effect of law, at 1230-32. See also *S. Wilson, Food and Drug Regulation* 97-99, 105-07 (1942), Kleinfeld, "Legislative History of the Federal Food, Drug & Cosmetic Act," 1 FOOD DRUG COSMETIC LAW JOURNAL 532, 539-40, 544-45 (December, 1946).

[24] Fuchs, "Formulation and Review of Regulations Under the Federal Food, Drug & Cosmetic Act," 5 *Law & Contemp. Prob.* 43, 46-48 (1939).

[25] See 21 U. S. C. §§ 371(e)-(g) (1964).

[26] 21 U. S. C. § 371(e) (1964). The Federal Food, Drug and Cosmetic Act is almost unique in requiring hearings prior to the issuance of rules of general applicability. See Attorney General, *Manual on the Administrative Procedure Act* 32-33 (1947).

[27] 21 U. S. C. § 371(f) (1964).

Section 701 of the Federal Food, Drug and Cosmetic Act is a schizophrenic statute. Section 701(a) authorizes the promulgation of regulations "for the efficient enforcement" of the Act, but sections 701(e), (f), and (g) set forth a detailed procedure for public hearing and judicial review of regulations promulgated only under sections of the statute *other* than section 701(a).[28] Regulations subject to the procedural provisions of sections 701(e), (f), and (g) clearly have the force and effect of law.[29] The question is whether section 701(a) regulations, lacking such procedural safeguards, also have that effect, or whether they are merely interpretive regulations.

In contrast to the great debate on the provisions for a public hearing and judicial review in sections 701(e), (f), and (g), section 701(a) attracted almost no attention. The absence of this attention is in itself significant. Congress in 1938 was deeply divided on the question of whether the FDA should be able to promulgate definitions and standards of identity for foods and other regulations having the force and effect of law and ultimately granted this authority only with the strictest procedural safeguards.[30] None of these procedural lim-

[28] Section 701(e) and (f) procedures are made explicitly applicable to the promulgation of standards of identity for foods, labeling requirements for special dietary foods, regulations providing for issuance of permits to govern processing of foods which may be contaminated with micro-organisms, regulations establishing tolerances for poisonous or deleterious substances added to foods, regulations fixing methods determining strength or purity of drugs, and regulations describing those drugs which must bear labeling indicating that they are habit-forming. See 21 U. S. C. §§ 371(e)-(f), 341, 343(j), 344(a), 346, 351(b), 352(d) & 352(h) (1964).

[29] Standards of identity are given the force and effect of law by § 403(g), and dietary food regulations by § 403(j). 21 U. S. C. §§ 343(g) & (j) (1964). Permits for packing food which may be contaminated with micro-organisms are in effect exemptions from § 402(a)-(4). 21 U. S. C. § 342(a)(4) (1964). Regulations granting tolerances for poisonous and deleterious substances are in effect exemptions from § 402(a)(1). 21 U. S. C. § 342(a)(1) (1964). These exemptions by their very nature have the effect of law. Both regulations providing for tests for establishing purity of drugs and regulations designating those drugs which must bear warnings that they are habit-forming are given the force and effect of law by the sections of the Act which authorize the promulgation of such regulations. 21 U. S. C. §§ 352(b) & (d) (1964).

There is, however, no specific provision in the Federal Food, Drug and Cosmetic Act which provides that a violation of a § 701(a) regulation is a violation of the Act. This omission is probably due to the fact that Congress intended § 701(a) to authorize interpretive, not substantive, regulations.

[30] One commentator regarded the dispute over judicial review of the FDA's regulations as the last major battle of the campaign for new legislation. See Cavers, "The Food, Drug & Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions," *6 Law & Contemp. Prob.* 2, 20 (1939). This battle was caused mainly by the apple growers, who feared that the FDA would unreasonably restrict their use of pesticides under the new Act. See pages 15, 20-21. This last dispute, however, was merely one aspect of the many

(Continued on next page.)

itations was applicable to section 701(a) regulations. It seems inconceivable that Congress, after five years of debate on the procedural limitations to be placed on the promulgation of some substantive regulations, would authorize the issuance of other regulations having the force and effect of law without debate and without any procedural safeguards. The possibility that this occurred is further diminished by the fact that if section 701(a) does authorize issuance of regulations having the force and effect of law, the sole limitation on this power is that the regulations further the "efficient enforcement of the Act," a limitation which is so general that it is virtually nonexistent.[31] If section 701(a) regulations are substantive, Congress gave the FDA a grant of power so broad that it literally swallows every other authority in the Act to issue regulations, including the much debated authority to issue definitions and standards of identity for foods.[32] It strains credulity to suggest that a Congress which carefully circumscribed authority to issue substantive regulations with substantive and procedural limitations also delegated a rulemaking power to the FDA encompassing all of the specific rulemaking authority without providing any substantive or procedural limitations.[33]

It is not necessary to depend solely upon inference to demonstrate that Congress did not intend to make section 701(a) regulations legally binding. The same conclusion is clear from Senate and House reports during the legislative history of the Federal Food, Drug and Cosmetic Act. For example, the 1935 Senate bill contained two separate

(Footnote 30 continued.)

objections to the FDA's power to issue rules and regulations having the force and effect of law. See page 9.

[31] Presumably, all regulations issued by the FDA further efficient enforcement of the Act.

[32] Since there are no procedural limitations on § 701(a) regulations, and no substantive limitations save that they must further efficient enforcement of the Act, the Secretary could, if these regulations have the force of law, disregard all specific rulemaking authority in the Act and rely solely upon § 701(a), thereby circumventing the §§ 701(e)-(g) requirements of notice, hearing, and judicial review. 21 U. S. C. §§ 371-(a), (e)-(g) (1964).

[33] The proposed GMP regulations are an example of the unlimited power which the FDA finds in § 701(a) of the statute. The regulations were published in the *Federal Register* and industry was permitted to make written comments on them. However, presumably there will be no right to a public hearing, no requirement that the regulations be based upon detailed findings of fact, and no judicial review through the § 701(f) procedure, since §§ 701(e)-(g) are inapplicable to §701(a) regulations. The FDA is asserting the right to issue regulations having the force and effect of law which regulate the facilities and operations of all interstate sellers of foods without giving these sellers the benefit of the procedural limitations which would apply if the FDA were attempting to issue a standard of identity for the least important food in the United States. 21 U. S. C. §§ 371(a), (e)-(g) (1964).

provisions for rulemaking power. Section 701(a) provided that the authority to promulgate regulations for the efficient enforcement of the Act was vested in the Secretary[34] and was identical to section 701(a) as ultimately adopted.[35] Section 703, however, provided for the promulgation of certain definitional and public health regulations under strict procedural safeguards.[36] In referring to this section, the 1935 Senate report listed the specified regulations and stated: "While other regulations are authorized for the purpose of making exemptions or for purely administrative operations, the only regulations imposing positive requirements are those listed above."[37] Thus, it was clear as early as 1935 that the language which ultimately became section 701(a) of the Act was not intended to confer substantive rulemaking authority on the FDA.

The same conclusion is apparent from the House report on the bill which ultimately was enacted as the Federal Food, Drug and Cosmetic Act. The House Report said:

> Section 701 relates generally to regulations. In the case of regulations, the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given and that adequate time shall be given after the promulgation of a regulation before it becomes effective.
>
> Section 701(e), (f), and (g) of the committee amendment set forth the procedure governing the formulation and judicial review of certain regulations to be issued by the Secretary. . . .
>
> Such regulations are not merely interpretive. They have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported.[38]

Dichotomy of Section 701

The House therefore intended to make a sharp dichotomy between two very different types of regulations: Those under sections 701(e), (f), and (g) have the force and effect of law; those under section 701(a), which are not subject to the procedural limitations of sections 701(e), (f), and (g), are merely interpretive.[39]

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[34] S. 5, 74th Cong., 1st Sess., as reported by the Senate Commerce Comm., March 13, 1935.

[35] Compare footnote 34 § 701(a) *with* 21 U. S. C. § 371(a) (1964).

[36] S. 5, 74th Cong., 1st Sess. § 703, as reported by the Senate Commerce Comm., March 13, 1935.

[37] S. Rep. No. 361, 74th Cong., 1st Sess. 23-24 (1935); S. Rep. No. 646, 74th Cong., 1st Sess. 10 (1935).

[38] H. R. Rep. No. 2139, 75th Cong., 2d Sess. 9-10 (1938).

[39] For the argument that only regulations issued under §§ 701(e)-(g) can implement the law, see Citizens Advisory Committee, "Report on Food and Drug Administration," 10 Food Drug Cosmetic Law Journal 470-71 (August, 1955).

The status of section 701(a) regulations was apparently clear when the Federal Food, Drug and Cosmetic Act was enacted. In the leading symposium analyzing the Act, one commentator observed:

> The procedural and review provisions of the new Food, Drug and Cosmetic Act apply to those regulations, enumerated in the procedural section, which operate with regulatory effect in the sense that they must be observed by private enterprises in production or marketing which is subject to the Act . . . [O]ther regulations, which do not directly control private activity, are not subject to the same procedural and review provisions.[40]

Section 701(a) was cited as authorizing regulations not directly controlling private activity.[41] Paradoxically, it would be difficult to cite any FDA regulations which more directly control private activity than the GMP regulations now promulgated under that section.[42]

Although the FDA considered the possibility of GMP regulations during the early years of the Act,[43] it was apparently the *Smith Canning* case[44] which gave the greatest impetus to their issuance. In that case the FDA, on the basis of its inspection of a processing plant, seized shipments of tomato paste as adulterated, alleging that it had been prepared under insanitary conditions whereby it might have been contaminated with filth. The company contested the seizure. FDA inspectors testified that there was a migratory labor camp on the canning company's premises and introduced photographs of piles of trash, pools of water, and dirty inoperative rest rooms in and around the camp.[45] They also testified that there were unscreened openings permitting flies to get into the plant and that there was dried and rotting tomato on machinery used for processing food. Other witnesses testified to the contrary.[46] The district court granted a judgment in favor of the Smith Canning Company[47] and the Government appealed.

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[40] Fuchs, "The Formulation and Review of Regulations Under the Food, Drug and Cosmetic Act," 6 *Law & Contemp. Prob.* 43, 44 (1939).

[41] See footnote 40 at 44 n. 18.

[42] The regulations prescribing the nature and use of food processing facilities probably control private activity more directly than any heretofore issued under the Act. Perhaps the next most direct are §§ 409 and 706 concerning food and color additives. 21 U. S. C. §§ 348, 376 (1964).

[43] Barnard, "Good Manufacturing Practices Regulations in the Food Industry," 22 FOOD DRUG COSMETIC LAW JOURNAL 511-12 (September, 1967).

[44] *United States v. 1500 Cases of Tomato Paste*, 236 F. 2d 208 (7th Cir. 1956).

[45] See footnote 44 at 212.

[46] A Utah state food inspector testified that the fly problem was nil and employees testified that the machinery and equipment was cleaned daily. See footnote 44 at 213. The trial court apparently accepted this testimony.

[47] *United States v. 1500 Cases of Tomato Paste*, No. 54 C 1754 (N. D. Ill., Aug. 12, 1955), V. Kleinfeld & C. Dunn, *Federal Food, Drug and Cosmetic Act: Judicial and Administrative Record*, 1953-1957, at 62 (1958), affirmed in part, reversed in part, 236 F. 2d 208 (7th Cir. 1956).

The Seventh Circuit affirmed, holding that the Government had failed to prove that the labor camp was close enough to the plant to affect the conditions under which the tomato paste was prepared, packed, or held and that in view of the conflicting evidence, the trial court had not clearly erred in rejecting the FDA inspectors' testimony that there were flies in the plant and dried tomato on the machinery.[48] Thus, the judgment in *Smith Canning* turned upon the Government's failure to prove facts indicating the insanitary conditions prohibited by section 402(a)(4) of the Act. In reviewing the law applicable to the case, however, the court said:

> Section 342(a)(4) provides that food is adulterated if it is "packed, or held under insanitary conditions whereby it may have been contaminated with filth." Whether or not a given factory is insanitary under this subsection is, of course, a question of fact, but the standard is so expressed, perhaps unavoidably, that the decision is likely to be highly subjective. Therefore, when we are dealing, as here, with products that, admittedly, will not affect the public health or sensitivities, we have a natural tendency to equate the standard with the average condition of canneries throughout the country. *If the Federal Food and Drug Administration desires to improve that average, it would be more likely to receive the support of the courts if it promulgated regulations which provided detailed standards as to cleaning procedures, screens, hygienic facilities, etc., publishing them to food packers as the requisites for complying with 21 U.S.C.A. § 342(a)(4), and* then *seizing food packed in plants not meeting the specific standards set.*[49]

Misinterpretation Basis for New Proposals

In analyzing this language, which is credited with inspiring the issuance of the proposed GMP regulations, there are three significant points:

(1) The court did not recommend that the FDA attempt to improve the average condition of plants by promulgating GMP regulations; it merely said that if the FDA desired to improve the average, it would be more likely to receive judicial support if it issued such regulations.[50] Whether the sanitary conditions in the average plant needed improvement was a judgment to be made by the FDA, and presumably, the FDA could, in the absence of GMP regulations, force below average plants to improve their condition. The FDA apparently

[48] 236 F. 2d at 213-14. The appellate court, however, reversed a holding of the trial judge that other cases of tomato paste were not adulterated because of mold. See footnote 48 at 215.

[49] See footnote 48 at 212 (emphasis added).

[50] See footnote 48. The problem of imprecise standards dominated *Smith Canning*. An example of this is the court's treatment of canned tomato paste seized because it contained filthy material. Noting that some rot or mold exists in all food, the court gave the force of law to an FDA administrative tolerance of 40% under the Howard Mold Count method of measurement. See footnote 48 at 210-12. A standards problem was also raised by testimony that the Smith cannery was better than most in regard to flies. See footnote 48 at 213.

erred in *Smith Canning* by not trying to prove that the Smith plant was below average.[51]

(2) The court did not review the FDA's power to promulgate substantive regulations governing plant sanitation. In its dicta, the court simply assumed that the FDA had the authority to promulgate standards for sanitation and opined that the FDA would receive more support from the courts in raising the average sanitation levels if it first promulgated such standards.[52] *Smith Canning* thus supports the view that it would be desirable to have GMP regulations if the FDA is trying to improve sanitation practices. It offers no authority, however, for the issuance of these regulations and, more particularly, no assistance in determining whether such regulations, if issued, are substantive or interpretive.

(3) The type of standards which the court considered helpful in raising sanitation levels were "detailed standards as to cleaning procedures, screens, hygienic facilities, etc."[53] The proposed GMP regulations provide that "equipment shall be maintained in a sanitary condition through cleaning as frequently as necessary to prevent contamination," that plants shall have "adequate screening," and that employees shall "conform to hygienic practices while on duty."[54] These are not the "detailed standards" or "specific standards" contemplated by the court in *Smith Canning*. The presently proposed regulations are so abstruse that they are not standards at all, and, while they may have merit as guidelines or platitudes, they find no legitimate parentage in *Smith Canning*.

Despite *Smith Canning*, there are indications that the FDA never has considered itself to have the authority to issue GMP regulations

[51] Paradoxically, under the GMP regulations, the FDA adopts local standards to determine what constitutes "adequate" compliance with federal law. See GMP Regs. § 128.1, at 17,980. Since presumably local plants obey local laws, it would seem that the FDA now thinks the average cannery is adequately sanitary. See footnote 5 and accompanying text.

[52] 236 F. 2d at 212.

[53] See footnote 52. As for mold tolerances, the court felt it was not the proper body to define broad standards applicable in particular cases since courts know neither what is necessary for the public health nor what can reasonably be expected from the canning industry. The court further said that the standard should not be determined individually in each case but that there should be definite standards. See footnote 52 at 211. Yet the GMP regulations are so vague that in each new case courts would have to determine what was necessary for the public health, what reasonably could be expected from industry, and what standard should be applied. How else could the court determine whether a road was "excessively dusty," or whether employees followed "hygienic practices"?

[54] GMP Regs. §§ 128.6(c), 128.3(b)-(6), 128.8(b)(1), at 17,980-82. It is submitted that these regulations do no more than identify the same general areas identified by the *Smith Canning* court as needing standards.

having the force and effect of law. William W. Goodrich, Assistant General Counsel for Food and Drugs in the Department of Health, Education, and Welfare, reviewed the *Smith Canning* case in 1957 as follows:

> The *Smith Canning Company* case, decided by the Seventh Circuit in July, is a significant food case. . . . We were told that if we wish to improve this national average, we should do so by promulgating regulations specifying the sanitary measures to be taken. Once such regulations were promulgated, the court indicated, they likely would be given the force of law. . . .
>
> *It is difficult for one to find in the statute authority to promulgate a code of sanitation,* but if the national-average rule is followed and it should become necessary in simple filth cases to establish on a case-to-case basis what those average conditions are, we shall have to consider further the court's suggestion about the code.[55]

There have been no relevant amendments to the statute since 1957, and there is no reason to believe that it would be any easier today to find support for these regulations than it would have been in 1957.[56]

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[55] Goodrich, "Judicial Progress in 1956," 12 FOOD DRUG COSMETIC LAW JOURNAL 81, 87 (February, 1957) (emphasis added). See also Goding, "The Impact of the Administrative Procedure Act on the Administration of the Federal Food, Drug and Cosmetic Act," 2 FOOD DRUG COSMETIC LAW QUARTERLY 139, 144 (June, 1947).

[56] Indeed, it may be considerably more difficult to get a court to hold that the FDA has such power since Congress in 1962 explicitly provided that drugs must be manufactured in conformity with "current good manufacturing practice" and regulations adopted defining this phrase are merely interpretive. See 21 U. S. C. § 351(a)(2)-(B) (Supp. II, 1965-1966). See also 30 Fed. Reg. 932-33 (1965); Pendergast & McMurray, "The Constitutionality of the Good Manufacturing Practices Provision of the Federal Food, Drug and Cosmetic Act," 23 *Bus. Law* 445, 449 (1968); Crowley, "Current Good Manufacturing Practice," 21 FOOD DRUG COSMETIC LAW JOURNAL 137, 141 (March, 1966). When the FDA is limited to interpretive regulations under a statute requiring current good manufacturing practices for drugs, it would seem unlikely that the FDA could promulgate substantive GMP regulations for foods in the absence of such a statute.

One other recent development should be mentioned because some apparently find it relevant. The recent Supreme Court decisions, *Toilet Goods Ass'n v. Gardner*, 387 U. S. 158 (1967), and *Abbott Labs. v. Gardner*, 387 U. S. 136 (1967), have been cited as indicating both that interpretive GMP regulations may have the force of law and that they do not have the force of law. Compare Barnard, "Good Manufacturing Practices Regulations in the Food Industry," 22 FOOD DRUG COSMETIC LAW JOURNAL 511, 513-14 (September, 1967), with Pendergast & McMurray, cited above. Both conclusions seem erroneous. The Supreme Court never passed upon the effect of the regulations, but merely said that they "purport to be directly authorized by the statute" and "purport to give an authoritative interpretation" of the statute. See *Abbott Labs. v. Gardner*, cited above at 151, 152. This was enough to place the plaintiffs in danger and give them a justiciable issue under the Declaratory Judgment Act; they did not have to violate the regulations and offer themselves as potential criminals to get judicial review. Thus, the Supreme Court held only that the action was properly brought and remanded the case to the circuit court to review the case on its merits.

If any further proof were needed that the FDA has no authority to issue GMP regulations having the force and effect of law under Section 701(a) of the Federal Food, Drug and Cosmetic Act, that proof is inherent in the testimony of FDA witnesses during the recent Fair Packaging and Labeling Hearings. These hearings began with an investigation in 1961-1962 into current food packaging and labeling practices.[57] The investigation indicated that some food products did not have their net weight and other information required by law printed prominently and conspicuously on their principal display panels.[58] A basic question was whether the FDA had the authority to issue substantive regulations prescribing the type size and location necessary to make the net contents statements prominent and conspicuous as required by the Federal Food, Drug and Cosmetic Act.[59] The key witness on this point was Mr. Goodrich; during his testimony he engaged in an exchange with one of the committee counsel on this question:

MR. GOODRICH: What we should do is promulgate a regulation interpretive of section 403 of the conspicuousness requiring a certain point of placement. We are going to get a big legal argument on that, but we are prepared to take that step all the way down the street here [to the Supreme Court], if necessary, and we are confident that we can make at least some of that stick...

MR. COHEN: You were talking about interpretive regulations in answer to some of Mr. Raitt's questions. I understand from that, that you do not have the authority under the sections which are applicable to the packaging and labeling of these items to issue legislative regulations; is that correct?

MR. GOODRICH: In terms of the net weight and a statement of the ingredients, no, but we have a Supreme Court case, *United States v. Antikamnia Chemical Company* which was decided some years ago, which holds that where you issue one of these interpretive regulations carrying out the purposes of the law it will be given the effect of law... I have confidence that we can make those regulations stick.

MR. COHEN: If you had the authority to issue legislative regulations you would not have to worry about that.

MR. GOODRICH: We would not—we would not.

MR. COHEN: If legislative regulations could be promulgated, would it not be a more effective way of handling this situation than interpretive regulations?

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[57] See generally *Hearings Pursuant to S. Res. 52 Before the Subcomm. on Antitrust and Monopoly of the Senate Judiciary Comm.*, 87th Cong., 1st Sess. (1961-1962).

[58] For a summary of the conclusions reached during the 1962-1963 Senate Hearings, see *Report on S. 387 by the Subcomm. on Antitrust and Monopoly of the Senate Judiciary Comm.*, 88th Cong., 2d Sess. 7-11 (1964).

[59] The primary argument raised by industry against the new legislation was that existing law was adequate. See Hart, "Can Federal Legislation Affecting Consumers' Economic Interests Be Enacted?," 64 *Mich. L. Rev.* 1255, 1264 (1966).

MR. GOODRICH: They would be surer of standing up in court, although I have, as I have indicated, been thoroughly confident of our present abilities."[60]

It was thus Mr. Goodrich's position in 1962 that the FDA did not have the power to promulgate substantive regulations which would define the minimum standards necessary to prevent labeling from violating the misbranding sections of the Federal Food, Drug and Cosmetic Act. Precisely the same issue is presented when the FDA asserts it has the authority to prescribe minimum standards necessary to prevent sanitary practices from violating the adulteration sections of the Act.[61]

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[60] See *Hearings Pursuant to S. Res. 258 Before the Subcomm. on Antitrust and Monopoly of the Senate Judiciary Comm.*, 87th Cong., 2d Sess. 807-08 (1962).

The case referred to by Mr. Goodrich, *Antikamnia Chemical Co.*, 231 U. S. 654 (1914), involved a drug which was labeled as containing no acetanilid but which contained acetphenetidin, a derivative of acetanilid. The 1906 Food and Drugs Act required acetanilid and its derivatives to be declared on the labels of drugs, and an FDA regulation stated that acetphenetidin had to be designated on the label both by name and as a derivative of acetanilid. A key issue was the validity of this regulation.

The Supreme Court began by stating that the power to issue regulations was an administrative power only and not a power to alter or add to the Act. The Court then held that it was administrative and not additive of the Act to require the labeling prescribed by the regulation. In dictum, the Court indicated that a regulation which fulfills the purpose of the law does not add to it and is therefore valid. See pages 666-68. It is this dictum which was relied upon by Mr. Goodrich.

While it might be possible to give the *Antikamnia* case in isolation the broad interpretation adopted by Mr. Goodrich, that interpretation becomes patently invalid when it is analyzed in the context of the history of food and drug law. It is not true that every regulation which fulfills the purpose of the Act is valid. For example, under the 1906 Food and Drugs Act, the FDA promulgated certain standards for foods which prescribed their composition. These standards fulfilled the purposes of the Act, since they made it possible to determine when foods were economically adulterated. However, these regulations were not given the force and effect of law. See 1 A. Herrick, "Food Regulation and Compliance" 304-08 (1944); Callaway, "Current Problems in Formulating Food Standards," 2 FOOD DRUG COSMETIC LAW QUARTERLY 124-27 (June, 1947); note 21 cited above. It was therefore necessary for the FDA to go to Congress in the 1930's, more than twenty years after the *Antikamnia* case, and ask for authority to make substantive regulations prescribing the composition of foods. See, for example, *Hearings Before a Subcomm. of the House Comm. on Interstate and For. Commerce*, 74th Cong., 1st Sess. 50-51 (1935) (remarks of W. Campbell, Comm'r of Food and Drugs); FDA, 1933 Report 14-15; FDA, 1931 Report 4-5.

[61] If § 701(a) contains a substantive rulemaking authority at all, it is to promulgate regulations for the efficient enforcement of the Act. 21 U. S. C. § 371(a) (1964). It would have aided the efficient enforcement of the Act to define the type sizes and package locations which would give the mandatory net contents statement the conspicuousness required by § 403(f). 21 U. S. C. § 343(e)-(f) (1964). However, Mr. Goodrich said that the FDA did not have such power. How then can the FDA now say that it has the power under

(Continued on next page.)

Other FDA witnesses at the Fair Packaging and Labeling Hearings also made it plain that the FDA had no power to issue substantive regulations for the general enforcement of the Federal Food, Drug and Cosmetic Act.[62] Indeed, the testimony of the FDA witnesses was so clear that the Senate Subcommittee on Antitrust and Monopoly reported to the Senate Commerce Committee that "neither act [FTC or FDA] authorizes the agency involved to draft substantive regulations that would give meaning to these vague concepts by establishing guides for the manufacturer to follow."[63]

It is thus clear that Congress has not granted the FDA a general power to make substantive regulations under section 701(a) of the Act and that the FDA itself has construed that section as authorizing only interpretive regulations.

Conclusion

The FDA has no authority to issue GMP regulations for foods having the force and effect of law, and the proposed regulations which purport to establish criteria for compliance with section 402-(a)(4) of the Act are invalid. If the FDA desires to issue GMP regulations, they must be either interpretive regulations or guidelines. Interpretive regulations may be given the force and effect of law in individual cases if the regulations do not alter or add to the Act and if the court agrees with the agency's interpretation of the statute.[64] Guidelines are administrative recommendations and have no legal status.[65]

The proposed GMP regulations now contain many requirements which far exceed the simple statutory command that food must not be prepared, packed, or held under insanitary conditions.[66] The regula-

(Footnote 61 continued.)
§ 701(a) to promulgate the minimum sanitation requirements for compliance with § 402(a)(4)?

[62] For example, George Larrick, then Commissioner of Food and Drugs, testified that the improvement which would result from the enactment of the Fair Packaging and Labeling Act was that it would give the force and effect of law to the FDA's regulations on labeling. *Hearings on S. 387 Before the Subcomm. on Antitrust and Monopoly of the Senate Judiciary Comm.*, 88th Cong., 1st Sess. 352-56 (1963).

[63] *Report of the Subcomm. on Antitrust and Monopoly of the Senate Judiciary Comm. Pursuant to S. Res. 262*, 88th Cong., 2d Sess. 11 (1964).

[64] See *United States v. Antikamnia Co.*, 231 U. S. 654 (1914). See also 1 K. Davis, *Administrative Law Treatise* § 5.03 (1958).

[65] See footnote 14.

[66] For example:

(1) Unused equipment that may constitute an attractant to insects cannot be kept within the immediate vicinity of the plant. GMP Regs. § 128.3(1). But if, in fact, the equipment has not attracted insects, it is not an insanitary condition.

(Continued on next page.)

tions attempt to control plant areas other than those where food is prepared, packed, or held.[67] Many of the prohibitions and requirements of the regulations regulate practices which may or may not affect the conditions under which food is prepared, packed, or held, depending upon other conditions and practices in the individual plant.[68] The GMP regulations are thus not a proper interpretation of the statute; they instead extend the Act by prescribing generic sanitation requirements and, therefore, could not be made valid by reissuance in interpretive form without extensive redrafting.[69]

(Footnote 66 continued.)

(2) Plants and facilities must be of a suitable size, construction, and location to facilitate maintenance. § 128.3-(b). If, however, plants and facilities do not meet this standard but still are kept clean, there is no insanitary condition.

(3) Plant equipment and utensils must be readily cleanable. § 128.4. If, however, the not readily cleanable equipment and facilities are in fact kept clean, there is no insanitary condition.

(4) Plant records must be kept for two years. § 128.7(i). However, this may have no effect at all on sanitation.

(5) Plant personnel must have proper education or training. § 128.8(c). However, a man with neither could be running a sanitary plant.

See also text accompanying footnote 14.

The FDA regulations insofar as they are definite do, in general, recommend desirable sanitary practices. However, there is no doubt that these regulations exceed a mere interpretation of the Act. Indeed, they do not even purport to be an interpretation of the Act; they purport to be legislative regulations.

[67] The regulations now extend to the location and grounds of the plant, although food may not be prepared, packed, or held anywhere except in the plant and although these surrounding conditions may have no effect upon conditions inside the plant. GMP Regs. § 128.3.

[68] See footnote 66. In general, the GMP regulations describe the most satisfactory conditions and equipment rather than those required by law. In their present form, therefore, they are more guidelines than legal requirements. Indeed, despite *Smith Canning*, it would seem that issuing guidelines is generally a more appropriate method of improving average sanitation practices than is attempting to legislate them out of existence. Query whether Congress really intended to describe the average plant as insanitary under the Federal Food, Drug and Cosmetic Act? If not, can the FDA interpret the statute as outlawing average sanitation practices when the Supreme Court has said that the FDA cannot alter or add to the statute? See *United States v. Antikamnia Co.*, 231 U. S. 654, 666 (1914).

[69] *Cf. Toilet Goods Ass'n v. Gardner*, CCH Food Drug Cosmetic Law Reports, ¶ 40,285 (S. D. N. Y., Jan. 8, 1968). The court here rejected the FDA's theory that every regulation which carries out the purposes of the Federal Food, Drug and Cosmetic Act is valid, making it clear that the FDA's authority to make regulations must be determined in the light of the legislative history of the Act and its amendments and in the light of the FDA's own prior interpretations of the Act. This decision, unless reversed, is an authoritative answer to the FDA contention that every interpretive regulation which furthers consumer protection and the other purposes of the Act is valid. See footnote 60.

When an agency administers a statute which contains criminal penalties, it should be particularly careful to remain within the scope of the authority delegated by Congress. Prompt reissuance of the GMP regulations as guidelines would be in the interest of the Government, industry and the consumer.[70] **[The End]**

[70] Confusion about the presently proposed GMP regulations seems to extend to the FDA itself. In a recent article, an FDA official describes the regulations as providing both an "objective standard" and "clear cut regulations which everyone understands," although one of the principal problems of the regulations is that they are so vague that they provide a purely subjective standard. Barnard, "The Need for Formal GMP Guidelines in the Food Industry," 23 FOOD DRUG COSMETIC LAW JOURNAL, 4, 6, 7 (January, 1968); see text accompanying footnotes 5-13. The same official feels that a federal standard will help guide local officials. Barnard, footnote 7. Yet it seems that varying local standards are in many instances being adopted by the FDA. See footnote 5.

All of us have an interest in improving sanitation practices in the food industry. Industry lawyers would welcome *guidelines* on sanitation to help improve their present practices. Guidelines should, however, be labeled and written as such and should be made as specific as possible if they are to achieve their intended purpose.

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION (Act of October 23, 1962; Section 4369, Title 39, United States Code)

1. Date of filing: Oct. 1, 1968. 2. Title of publication: Food Drug Cosmetic Law Journal. 3. Frequency of issue: Monthly.

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8. Known bondholders, mortgagees, and other security holders owning or holding 1 percent or more of total amount of bonds, mortgages or other securities: None.

9. For completion by nonprofit organizations authorized to mail at special rates: Not applicable.

10. Extent and nature of circulation.

	Average no. copies each issue during preceding 12 months	Actual number of copies of single issue published nearest to filing date
A. Total no. copies printed (*Net Press Run*)	1,431	1,500
B. Paid circulation		
1. Sales through dealers and carriers, street vendors and counter sales	0	0
2. Mail subscriptions	1,025	1,014
C. Total paid circulation	1,025	1,014
D. Free distribution (*including samples*) by mail, carrier or other means	24	24
E. Total distribution (*Sum of C and D*)	1,049	1,038
F. Office use, left-over, unaccounted, spoiled after printing	382	462
G. Total (*Sum of E & F—should equal net press run shown in A*)	1,431	1,500

I certify that the statements made by me above are correct and complete:

(Signed) Allen E. Schechter

Latin-American Food Code 1964 Edition

In August, 1964, the Latin-American Food Code Council Published the Second Edition of the Latin-American Food Code. Information Concerning the Code and the Table of Contents of the New Edition Appeared in the April 1965 Issue of the Food Drug Cosmetic Law Journal (Vol. 20, page 238). The First Five Chapters Were Published in the September 1965 Issue; Chapters XII and XIII in the October 1965 Issue; Chapter XVII in the November 1965 Issue; Chapter X in the December 1965 Issue; Chapter VII in the June 1966 Issue; Chapter XVIII in the August 1966 Issue; Chapter XVI in the May 1967 Issue; Chapter VI in the August 1967 Issue; Chapter XV in the October 1967 Issue; and Chapter XI in the August 1968 Issue. Chapter IX Appears Below. The Translation Is by Ann M. Wolf of New York City.

Chapter IX: Cereals, Cereal Preparation and Bakery Products

Cereals, Flours and Similar Products

Article 253.—The term "Cereal" means the edible seeds or grains of the family Gramineae: rice, oats, barley, rye, corn, wheat, etc. Cereals intended for human consumption must be free from impurities, foreign matter, dust, dirt and parasites; they must be in a perfect state of preservation and not spoiled, damaged or fermented. They may in general not contain water in a proportion of more than 15 percent.

Hulled cereals (rice, barley, etc.) may be polished, shined, coated or glazed with glucose or talc, provided always that the weight increase caused by this process does not exceed 0.5 percent. They may be bleached with sulfur dioxide, up to 40 centigrams of which may be tolerated in one kilo of cereal.

Polishing with dragon's blood or resins is prohibited.

Article 254.—*Puffed Cereals* are obtained by way of several industrial processes which break the endosperm and cause the kernels to swell.

Article 255.—*Rolled Cereals* are prepared from clean grains from which the outer integument may have been removed and which have been rolled by way of a suitable process.

Article 256.—*Cereal Flakes* are prepared from clean grains, from which the integument has been removed mechanically or by way of an alkaline treatment, and which have been cooked together with malt extract, sucrose syrup, dextrose and salt, or other permitted additives, dried, rolled and toasted.

Article 257.—*Shredded Cereals* are prepared from whole flours or cereal grits and malt extract, with or without the addition of other permitted products. After shredding, they are baked as necessary.

Article 258.—*Rice* (the fruit of *Oryza sativa L.*) shall be sold with an indication of its geographic origin. The kernels must be whole, uniform, hard, dry, without black spots or perforations, white or slightly yellowish, and shall be sold free from dust, grubs, other parasites, or foreign matter, in a perfect state of preservation. Rice may not contain sulfur dioxide in a proportion of more than 0.04 percent or talc in a proportion of more than 0.05 percent. Average percentage composition: water 13; protein 7; fat 0.3; assimilable carbohydrates 78; crude fiber 0.2; ash 0.6.

The various rice products and by-products of rice shall meet the following requirements:

1. *Whole Rice:* The hulled grain (without glumes or spikelets).

2. *Puffed Rice:* Rice cleaned and treated as described in Article 254. Average percentage composition: water 13; protein 7; fat 0.4; assimilable carbohydrates 79; crude fiber 0.2; ash 0.4.

3. *Polished or Coated Rice:* The hulled kernel from which the pericarp and the aleurone have been removed and which has been polished by rubbing with the addition of glucose and talc.

4. *Crushed Rice:* The kernels crushed by any process.

5. *Carolina or American-type Rice:* Long-grain rice varieties which are smooth, hard, translucent and very shiny. Depending upon their size of homogeneousness, they are identified by the numbers 000, 0000 and 00000, as shown in the table hereinafter.

6. *Coated Milled Rice:* Varieties of short-grain and medium-grain rice, less translucent and shiny, but thicker than Carolina-type rice. They are graded into classes B, AA and AAA, depending upon the percentage of defective kernels. To

grade Carolina and coated milled rice, the following defects of the kernels shall be taken into consideration:

Grooved kernels: kernels with a red groove;

Chalky or dead kernels: kernels which look starchy, opaque and are generally small in size;

White-spotted kernels: kernels half or more of which is covered by a white or starchy spot, which does not cover them entirely, however;

Spotted kernels: kernels with black or dark spots;

Amber kernels: kernels with a more or less pronounced amber color;

Broken kernels: kernels fractured to less than half their normal size.

The percentage of defective kernels in Carolina-type rices sold under the names Five Zeros or Four Zeros may not exceed the following proportions:

Kernels	00000 Type %	0000 Type %
Grooved	5	10
Chalky	2	4
Spotted and amber	1	4
White spotted	4	7
Broken	15	25

Coated rice sold under the designations Triple A and Double A may not contain defective kernels in a percentage exceeding the following proportions:

Kernels	AAA Type %	AA Type %
Grooved kernels	5	10
Chalky kernels	2	4
Spotted and amber kernels	1	4
White spotted kernels	4	7
Broken kernels	15	25

7. *Parboiled Milled Rice:* Rice with the hull, subjected to a soak and steam treatment. Average percentage composition: water 13; protein 7; fat 0.7; assimilable carbohydrates 78.3; crude fiber 0.2; ash 0.8.

8. *Valencia-type Rice:* Varieties of dull, short-grain kernels.

9. *"Arrozín" or "Arrocín":* The fragments (tips) and albumen flour that separate when rice is cleaned or polished.

10. *Rice Flakes:* The product prepared as set forth in Article 256. Average percentage composition: water 12; protein 7.8; fat 0.1; assimilable carbohydrates (sugars 2.5) 78.9; crude fiber 0.2; ash 0.4.

11. *Rice Flour:* The product obtained by grinding one or several of the rice varieties defined in this article.

Article 259.—*Rolled Oats* are oats from the grains of *Avena sativa L.* prepared as described in Article 255. They shall not contain water in a proportion of more than 13 percent; not more than 2.7 percent of crude fiber and 2.5 percent of ash, and their nitrogen content shall not be less than 2.24 percent.

Article 260.—The name *"Oatmeal"* means the product obtained by grinding hulled oats *(Avena sativa L.)*. It shall not contain ash in a proportion of more than 2.2 percent, crude fiber in a proportion of more than 1.5 percent, nitrogen in a proportion of less than 2.24 percent and fatty matter or ether-soluble products in a proportion of less than 5 percent, an amount of 2.5 percent of flours from other grains being permitted.

Article 261.—The term *"Rye Flour"* means the product obtained by grinding hulled rye *(Secale Cereale L.)*. It shall not contain ash in a proportion of more than 2 percent. Average percentage composition: water 11; protein 11.5; fat 1; assimilable carbohydrates 73; crude fiber 1.5; ash 1.8.

The term *"Whole Rye Flour"* means the product obtained by grinding rye grains still in their hulls. Average percentage composition: water 10; protein 11; fat 1.5; assimilable carbohydrates 72; crude fiber 2; ash 2.5.

Article 262.—The name *"Hulled Barley"* means the whole, clean, well preserved grains of barley *(Hordeum vulgare L.)* from which the integuments have been removed. It may not contain ash in a proportion of more than 3.5 percent.

The term *"Pearl Barley"* means the grains of hulled barley rounded by repeated rubbing in special machines. It may not contain ash in a proportion of more than 3 percent. Average percentage composition: water 12; protein 9; fat 1.5; assimilable carbohydrates 74; crude fiber 1; ash 2.3.

The term "*Roasted Barley*" means hulled barley which has undergone a roasting process. When this has been done with the addition of dextrose or sucrose, (the only sweeteners permitted) in a proportion of not more than 10 percent, the product shall be named "barley roasted with sugar," and the proportion of sweetener used shall be declared in the labeling.

Article 263.—The name "*Malt*" means dried germinated barley grains. Malts made from other cereals shall be named according to their origin: Wheat Malt, Corn Malt, etc.

The name "Roasted Malt" means roasted malted barley grains. The name "Sweetened Malt" means the same product roasted with sucrose or dextrose (the only sweeteners permitted) in a proportion of up to 10 percent, the presence of which shall be declared in the labeling.

These products are prohibited from being named "Malt Coffee."

Article 264.—The name "*Chaquepa*"* means ground roasted barley. Average percentage composition: water 9; protein 8; fat 0.5; assimilable carbohydrates 78; crude fiber 3.5; ash 2.

Article 265.—The name "*Corn*" (maize) means the grains of *Zea mais L.* Corn may not contain ash in a proportion of more than 5 percent. Average percentage composition (green ears): water 70; protein 3.5; fat 1; assimilable carbohydrates 23; crude fiber 1.2; ash 0.8; ascorbic acid 8 mg. (dried ears): water 10; protein 10; fat 6; assimilable carbohydrates 70; crude fiber 2; ash 1.8; ascorbic acid 0 mg.

1. The name "*Popcorn*" means properly roasted small-grain white popping corn, with or without the addition of sugar. Average percentage composition (unsweetened popcorn): water 4; protein 11; fat 5.5; assimilable carbohydrates 75; crude fiber 1.7; ash 2.3.

2. Fine corn grits, generally named "*Corn Meal,*" shall meet the following requirements: its moisture content may not exceed 15.5 percent; its acidity, expressed as SO_3, may not exceed 0.2 percent; its nitrogen content may not be less than 1.12 percent; it shall not contain ash in a proportion of more than 1.6 percent; it shall leave no residue when passed through a sieve with 40 meshes per square centimeter and may not contain flour from other cereals, foreign matter, insects, etc.

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* Note of the Translator: A Latin-American product without an English equivalent.

3. The term *"Roasted Corn Meal"* ("Gofio") means the product obtained by roasting corn meal as defined in the preceding paragraph (See Article 328, paragraph 8).

4. *Corn Flakes* shall be prepared as set forth in Article 265. They shall be made from clean, polished white or yellow corn. Average percentage composition: water 11; protein 7; fat 0.3; assimilable carbohydrates (sugars 3) 79; crude fiber 0.5; ash 3.

5. The names *"Chococa," "Chochuco"* and *"Chuchuca"** mean very ripe, fresh white corn which has been cooked briefly in a small amount of water and then dried. Average percentage composition: water 15; protein 6; fat 2.5; carbohydrates 72; crude fiber 3; ash 1.3.

6. Products sold as derivatives of *Corn Gluten* shall consist of the part of commercial corn in the hull which remains after the starch and the germ have been partially extracted in the preparation of corn syrup. The protein content shall be declared in the labeling.

7. The name *"Kjora"* means dried germinated red corn. Average percentage composition: water 15; protein 6.5; fat 3.6; carbohydrates 72; crude fiber 0.3; ash 1.8.

8. The names *"skinned, shelled* or *hulled Corn"* (Hominy grits) mean maize kernels from which the hulls have been removed by means of a suitable alkaline process, after which they are washed, cooked until tender, and dried.

9. The name *"Mazamorra"* (corn crumbs) means coarsely ground fresh or dried corn intended in general for "mazamorra" (a thick corn soup), "locro" (stew), etc. which must not be mistaken for quick grits which consists of kernels fractured by machine.

10. Corn paste treated with lime (Nixtamal): means yellow or white corn which has been soaked in lime water, with or without ash, and cooked, whereafter the hulls are removed, and the grains are washed and ground to prepare the dough (Nixtamal). This treatment increases the calcium content by 800 percent; for instance, in 100 grams of corn, from 9 mg. to more than 70 mg. Average percentage composition; water 62; protein 3.5; fat 1.5; carbohydrates 32.5; crude fiber 0.5; ash 0.5.

Article 266.—*Corn Grits,* as grits from other cereals prepared for use as human food or in the manufacture of foods and beverages, shall be sold and marketed under their Spanish name "Semola," always followed† by the name of the cereal used in it: such as "Corn Semola," "Oats Semola," "Barley Semola," etc.

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* Note of the Translator: A Latin-American product.

† Note of the Translator: In English the name precedes.

Article 267.—The name "*Wheat*" means the grains of *Triticum sativum Lam.*

1. The name "*Rolled Wheat*" means wheat prepared in accordance with Article 255. Average percentage composition: water 10; protein 10; fat 1.7; assimilable carbohydrates 75; crude fiber 1; ash 1.6.

2. The term "*Puffed Wheat*" means wheat grains prepared as described in Article 254. Average percentage composition: water 12; protein 10; fat 1.8; assimilable carbohydrates 73; crude fiber 1; ash 1.8.

3. The term "*Washed Whole Wheat*" or simply "*Washed Wheat*" means wheat grains which have been washed to remove the surface dirt and the waxy outer layer.

4. The terms "*Crushed*" or "*Coarse ground Wheat*" mean clean wheat grains (after removal of the cellulose covering, aleurone and germ which have been crushed or ground). Average percentage composition: water 9; protein 10.5; fat 1.4; assimilable carbohydrates 76; crude fiber 1.7; ash 1.2.

5. The term "*Hulled Wheat*" means washed wheat from which the cellulose wall (epicarp, mesocarp, endocarp, testa and part of the endopleura) has been removed while preserving the aleurone layer and the germ. Average percentage composition: water 13; protein 12.4; fat 2; assimilable carbohydrates 70; crude fiber 0.7; ash 1.

6. The term "*Wheat Flakes*" means wheat processed in accordance with Article 256. Average percentage composition: water 11; protein 10; fat 1.1; assimilable carbohydrates (sugars 2.5) 75; crude fiber 1.1; ash 1.7.

7. The term "*Wheat 'Gofio'*" means the product obtained by roasting wheat flour.

8. The term "*Whole Bran*" means the product prepared from wheat bran in accordance with Article 257. Average percentage composition: water 5; protein 14; fat 4.5; assimilable carbohydrates 65; crude fiber 6; ash 5.

9. The product commercially known as "*Wheat Germ*" shall meet the following specifications: water, 8 to 18 percent; assimilable carbohydrates, 30 to 48 percent; protein, not less than 23 percent; fat, not less than 7 percent; crude fiber, not more than 4 percent and ash, not more than 5 percent.

Article 268.—The term *"Flour,"* without any other qualification, means the product obtained by milling wheat which meets the requirements laid down in Article 253. Flours made from other cereals, leguminous plants, etc. shall be named after the product from which they were obtained: Corn flour, lentil flour, etc. No flour sold in commerce may contain more than 100,000 non-pathogenic bacteria per gram.

To regulate fermentation in bread-making, sodium or potassium bromate may be added to wheat flour in a proportion not exceeding 75 p.p.m., which addition must be declared in the labeling and business papers used in connection with the product. Wheat flours intended for the preparation of cookies may also be treated with sulfur dioxide in a proportion of not more than 80 p.p.m., which treatment must be stated in the labeling. Average percentage composition: water 12; protein 11; fat 1; assimilable carbohydrates 74; crude fiber 0.4; ash 0.8.

Article 269.—The terms *"Whole Wheat Flour"* and *"Graham Flour"* mean the entire product obtained by milling wheat. Whole flours of other cereals, leguminous plants etc. shall be designated by names indicating their origin.

Three types of Graham Flour are permitted, which are distinguished from one another by the size of their particles and shall be named by the following names: Coarse Graham Flour, Medium Graham Flour, and Fine Graham Flour. None of these types is permitted to contain moisture in a proportion exceeding 15.5 percent determined at 130°C., or ash in a proportion exceeding 2.20 percent, calculated on the dry residue at 920°C., a tolerance of plus 3 percent being permitted. Average percentage composition: water 12; protein 12; fat 2; assimilable carbohydrates 70; crude fiber 1.8; ash 1.6.

Article 270.—Wheat flours graded commercially by the names: Four Zeros (0000), Triple Zero (000), Double Zero (00), Zero (0), Half Zero (½-0) and Standard are the whitest types of flour with the smallest percentage of wheat bran fragments, obtained by gradual methodical milling and yielding between 70 and 90 percent of the weight of clean grain (first grade flour).

The analytical data of these flours shall be within the limits shown in the table hereinafter, with a tolerance of plus 3 percent for ash and minus 3 percent for color specifications.

DATA

First Grade Flours	Moisture at 130°C. Maximum	Ash at 920°C. (on the Dry Substance) Maximum	Color ("Lovibond" Tintometer)
Four Zero	14.5	0.48	95
Triple Zero	14.5	0.40 to 0.54	94 to 92
Double Zero	14.5	0.55 to 0.67	91 to 90
Zero	14.5	0.68 to 0.87	89 to 86
Half Zero	14.5	0.88 to 1.35	86
Standard	14.5	1.36 to 2.00	—

In addition, flours intended for bread—not those intended for pastry and macaroni products—shall meet the following requirements to be suitable for bread-making:

DATA

First Grade Flours	Water Absorption %	Volume of Bread on 100 grams of flour, Minimum	Specific Volume of Bread
Four Zero	56-62	550 ml.	4.20
Triple Zero	57-63	520 ml.	4.00
Double Zero	60-66	500 ml.	3.80
Zero	62.5	475 ml.	3.20

Article 271.—Flours classified in commerce as *"Second Grade Flour"* are obtained by gradual reduction of the wheat remaining after the 20 percent used for First Grade Flour has been bolted, yielding an amount of about 40 percent of the weight of the clean grain. They shall be white, with a slightly yellowish tinge, and may have tiny yellowish specks caused by the milling of the bran.

Article 272.—The term *"Third Grade Flour"* is used to designate the product obtained by gradual reduction of the wheat left over after the first and second grade flours have been bolted. Its weight may vary between 12 and 14 percent of that of the clean grain. Its color may be more or less dark yellowish, but must never be bluish or grey, and any specks or spots must come from fragments of the bran.

Article 273.—Other products obtained by milling wheat are:

a. *Bran:* the milling residue consisting of the pericarp of the grain mixed with the outer part of the endosperm and perisperm.

b. *Light Bran:* bran ground more finely than bran and coming from the deeper layers of the pericarp, with part of the endosperm and perisperm.

c. *"Rebacillo"**: the mill product which tails over the last fine sieve in the mill after the flour has been extracted. When obtained from an identical type of wheat, "Rebacillo" contains approximately 63 percent of nitrogen-free extract, whereas Light Bran contains 59 and Bran 56 percent.

d. *"Semitin"* is milled more finely than *"Rebacillo"* and contains a larger amount of endosperm and perisperm.

e. *"Semita"* or *"Asemita":* a mixture of "Semitin" and Second Grade Flour usually sold with a labeling that states the flour content, such as "30 or 40 percent Semita."

f. *"Groats":* the endosperm and perisperm of more or less coarsely ground grain obtained when the grain is passed through the first milling sieves (about 190 openings per square centimeter).

g. *"Semolina":* the same product as described at f., but more finely grained (about 640 openings per square centimeter), the middling between groats and flour.

In conducting analyses, it must be considered that with time, the particles of groats and semolina may disintegrate, thus producing a certain amount of flour.

Article 274.—The name *"Starch,"* preceded by the name of the vegetable from which it has been obtained (such as corn starch, wheat starch, rice starch, etc.), may be used only to designate the starchy substances found in the aerial organs of plants.

The name *"Faecula,"* preceded by the name of the vegetable from which it has been obtained, may be used only to designate the starchy substances from subterranean parts of plants (roots, tubercles, rhizomes). Thus: Potato, manioc, salep faecula, etc.

In both starches and faeculae, the ash content, calculated on the dry residue, may not exceed 1.5 percent and the water content may not exceed 15 percent, with the exception of potato faecula, in which it may amount to up to 18 percent.

Starches and faeculae intended for use in canned products must be free from thermophilic bacteria.

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* Note of the Translator: A Latin-American product.

Article 275.—The name *"Arrowroot"* means the faecula extracted from the rhizomes of various plants of the genus Maranta (*Maranta arundinacea, nobilis,* etc.). Average percentage composition: water 13; protein 0.3; fat 0.1; assimilable carbohydrates 86; crude fiber 0.05; ash 0.2.

Article 276.—The name *"Sago"* means the starch extracted from various species of palm trees (*Metroxylon sagu*, etc.). Pearl sago prepared from potato faecula must be labeled "Potato sago." Average percentage composition: water 12 to 15; protein 0.1 to 0.8; fat 0.1 to 0.2; assimilable carbohydrates 78 to 84; crude fiber 0.1 to 0.4; ash 0.1 to 0.7.

Article 277.— The name *"Salep"* means the starch extracted from the tubers of various orchids (*Mascula militares, morio, latifolio*, etc.). Average percentage composition: water 11; protein 5; fat 0.2; carbohydrates (gum 48; starch 27; sugar 1) 81; crude fiber 0.6; ash 1.5.

Article 278.—The name *"Tapioca"* means the product obtained by heating moistened, granulated and partially gelatinized cassava starch. The granulation usually takes the form of seeds, pearls, or flakes. Tapioca prepared from potato faecula or other starchy substances shall be designated by the name of the substance from which it was made: "Potato tapioca," "sago tapioca," etc. Average percentage composition: water 12 to 15; protein 0.4 to 0.9; fat 0.1 to 0.2; assimilable carbohydrates 82 to 88; crude fiber 0.1 to 0.3; ash 0.1 to 0.3.

Article 279.—The name *"Manioc rind"* means the product obtained by rasping and drying cassava from which the radical CN has been removed. Manioc rind meal must contain starch in a proportion of not less than 70 percent and its ash content may not exceed 2 percent.

The names *"Manioc meal"* and *"Tapioca meal"* mean sweet cassava (*Manihot palmata Müll*) and bitter cassava (*Manihot utilissima Pohl* and varieties thereof) peeled, washed, freed from the radical CN, rasped and lightly roasted. Its color must be white or yellowish, and it shall not leave any residue when passed through a sieve with 36 openings per square centimeter. It shall not contain any foreign matter, larvae, mites, etc. and shall be in a perfect state of preservation. Its moisture content may not exceed 15 percent; its ash shall not exceed 2 percent; its acidity may not be more than 0.2 percent

expressed as sulfuric acid, and its starch content shall not be less than 60 percent. Manioc meal submitted to a second roasting process shall be named "Roasted manioc meal." Average percentage composition: water 13; protein 9; fat 0.5; assimilable carbohydrates 74.5; crude fiber 1.5; ash 1.

Article 280.—The name *"Carob meal"* means the ground seeds of white carobs (*Prosopis alba Griseb*). Average percentage composition: water 12; protein 8; fat 0.8; assimilable carbohydrates 66; crude fiber 10; ash 2.7.

Article 281.—The name *"Banana flour"* means the product obtained by drying and pulverizing the fruits of various kinds of banana trees (especially *Musa paradisiaca*). Its color must be slightly greyish, its taste acid and astringent, and it must not cake. The addition of sweeteners must be declared in the labeling. Percentage composition (which varies depending upon the ripeness of the fruit): water 3 to 12; protein 3.5 to 5; fat 0.6 to 4; assimilable carbohydrates (sugars 4 to 48) 77 to 81; crude fiber 1.4 to 2.5; ash 2.3 to 3.5.

The name *"Banana starch"* means the product obtained by rasping peeled green bananas whose pulp has been properly washed. It must have the appearance of a brightly white fine powder which, when pressed with the fingers, creaks like potato faecula. Average percentage composition: water 10; protein 10; fat 0.5; assimilable carbohydrates 69; crude fiber 8; ash 2.8.

Article 282.—The name *"Kafir"* means the grains of *Sorghum cafrorum Beaur* and varieties thereof, whose flour is used in breadmaking, to which end it may be mixed with wheat flour. Average percentage composition: water 12; protein 12; fat 3.5; assimilable carbohydrates (sugars 9) 68; crude fiber 2; ash 1.2.

Article 283.—*Vegetable flours* must be labeled and advertised stating the name of the vegetable used, and in case of mixtures, their components. Average percentage composition: (Green peas): water 11; protein 23; fat 1.5; assimilable carbohydrates 60; crude fiber 2.1; ash 2.3. (Chickpeas): water 12; protein 18; fat 3.8; assimilable carbohydrates 60; crude fiber 3.3; ash 3. (Lentils): water 11; protein 22; fat 1.2; assimilable carbohydrates 59; crude fiber 3.7; ash 2.7. (Beans): water 12; protein 25; fat 1.4; assimilable carbohydrates 55; crude fiber 3.8; ash 2.6.

Article 284.—The name "*Vegetable grits*" (peas, beans, chickpeas, etc.) means products consisting of a mixture of vegetable flours and wheat semolina. Average percentage composition: water 8 to 15; protein 8 to 15; fat 0.5 to 1; assimilable carbohydrates 40 to 60; crude fiber 0.9 to 2; ash 1 to 2.

Article 285.—The name "*Soup and purée mix*" designates single or mixed cereal and vegetable flours, to which meat extracts, vegetable extracts, powdered milk and permitted condiments may have been added. Their composition must be declared in labeling and advertising.

Article 286.—The name "*Potato flour*" means the product obtained by grinding the dried tubers of *Solanum tuberosum L.* Average percentage composition: water 12; protein 6.5; fat 0.2; assimilable carbohydrates 75; crude fiber 2; ash 3.8.

The name "*Potato faecula*" means the starch extracted from the tubers of *Solanum tuberosum L.* Percentage composition: water 13 to 18; protein 0.05 to 1; fat 0.01 to 0.07; assimilable carbohydrates 76 to 86; crude fiber 0.02 to 0.14; ash 0.2 to 0.5.

Cornstarch may be named "Corn flour." Average percentage composition: water 12; protein 0.3; fat 0.1; assimilable carbohydrates 87; ash 0.3.

Article 287.—The name "*Quinoa* Flour*" means a flour obtained by grinding the dried seeds of *Chenopodium quinoa Willd.*, from which the teguments have been removed mechanically or by an alkaline process. It must not be confused with flour of "Inca Wheat" (*Amarantus edules Speg.*). Average percentage composition: water 15; protein 10; fat 3; assimilable carbohydrates (sugar 3) 68; crude fiber 2; ash 1.5.

Article 288.—The name "*Soybean flour*" means the flour obtained by grinding the dried seeds of Glycine soja and varieties thereof.

Depending on its grade, soybean flour is classified into "0", "00" and "000." Average percentage composition: (Normal flour) water 8; protein 45; fat 21; assimilable carbohydrates 18; crude fiber 1.8; ash 4. (Defatted flour): water 8; protein 58; fat 2.5; assimilable carbohydrates 23; crude fiber 2; ash 4.5.

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* Note of the Translator: A goosefoot variety.

Article 289.—Cereal flours and vegetable flours may be mixed, provided always that in labeling and advertising such mixtures, the names of their components be stated clearly in the order of their proportion.

Article 290.—The word "Cream" may not be used to distinguish high quality or special flours, starches or faeculae.

Article 291.—The name *"Pancake Mix"* means a mixture of cereal flours to which powered milk, chemical leavening, salt and/or sugar have been added and which may contain permitted flavors.

Article 292.—The name *"Edible dextrine"* means the product obtained by the incomplete hydrolysis of starch. Edible dextrine may not contain reducing sugars in a proportion of more than 13 percent, calculated as dextrose on the moisture-free substance, or ash in a proportion of more than 1 percent.

Alimentary Pastes

Article 293.—The names *"Noodle Factory," "Maccroni plant,"* etc. mean plants at which noodles and macaroni products (alimentary pastes) are being manufactured. Such plants shall meet the general standards and in addition have rooms in which to store raw materials and finished products, a manufacturing room and a packing room with a flat ceiling, waterproof floors and wainscots waterproofed up to a height of 1.80 m. The work tables shall have a smooth surface made of tiles, cement, marble, hardwood or another suitable material. The entire manufacturing process shall be mechanical, except for the mixing of the dough which may be either mechanical or manual. The drying shall take place in driers with cold or hot, dry or moist air, depending upon the product and the process used. Long-goods may be dried over odorless wooden rails or stainless metal sticks. All stretchers, sifters and trays shall consist of a frame lined with a stainless metal sheet coated with rust-proof paint approved by the health authority, with plastic screens, and shall be covered with pieces of burlap, jute or cotton. The boxes or trays shall also be so constructed that when stacked on top of each other, they form a tight ensemble with continuous side walls. The finished products shall be placed on tables, racks, stands, in boxes, barrels, burlap or cotton bags, or on racks with legs, separated from the floor and protected from atmospheric contamination, insects, mites and rodents. Alimentary pastes may not be manufactured in cellars, basements and other unsuitable places.

Article 294.—The names *"Fresh Alimentary Paste Plant," "Noodle and Ravioli Plant,"* and similar names mean plants at which noodles, ravioli and similar products intended for immediate sale are prepared. Such plants must meet the general requirements and have storage facilities for raw materials, a processing room with waterproof floor and a wainscot waterproofed up to a height of 1.80 m., and a refrigerator in which to keep easily perishable products.

If a manufacturer so desires, he may combine the processing and sales rooms in one, always provided that it is protected from outside contamination and, if necessary, is provided with exhaust fans.

Under no circumstances may the fillings used in the preparation of fresh alimentary pastes (ravioli, capelletti, tortellini, etc.) or the pastes containing them be kept for more than 24 hours from their preparation.

Article 295.—The term *"Soup pastes"* means unfermented products obtained by mechanically mixing and kneading with potable water farina, semolina or gluten-rich durum flours or flours used in bread-making or mixtures thereof. Pastes made from other groats or flours or containing eggs, saffron, turmeric, vegetables, authorized colors, wheat germ or other permitted additives shall be labeled accordingly. To accelerate cooking, sodium phosphate may be added in a proportion of up to 0.5 grams per 100 without a declaration.

Article 296.—Alimentary pastes are classified according to their shapes into: Long-goods (Macaroni, spaghetti, vermicelli, ribbons, etc.); short-goods (elbows, shells, bow-knots, etc.); pastina: (rings, stars, birdshot, etc.) and Threaded Pastes: (Angel's hair, spaghettini, etc.) and depending on their consistency, into fresh and dried pastes. Fresh pastes must be sold within 24 hours from their preparation and may contain water in a proportion of up to 35 percent; dry pastes may not contain more than 14 percent of water. In both, the acidity may not be more than 0.45 percent, expressed as lactic acid.

Pastes which are being sold as "Extra," "Super Extra," etc. may not have an acidity of more than 0.10 percent, expressed as lactic acid, or contain ash in a proportion of more than 0.65 percent calculated on the moisture-free substance.

Moreover, alimentary pastes must be able to withstand boiling until they are ready for serving without disintegrating and without

clouding or coloring the liquid in which they are cooked. Fresh pastes prepared with vegetables are excepted from this last requirement. Their hardness shall be determined by their cooking time in an amount of water ten times their weight (50 grams of paste in 500 ml. of potable water to which 2.50 grams of kitchen salt has been added), which shall fluctuate between seven and three minutes for fresh pastes and between two and thirty-five minutes for dry ones.

Article 297.—Noodles prepared with flours or crushed noodles are prohibited from being named "Groat Noodles."

Article 298.—Dry egg noodles, also named "Egg noodles," shall contain eggs in a proportion of not less than two eggs per kilogram of flour and their cholesterol content, calculated on the moisture-free substance, must be not less than 0.04 grams per 100 grams. Unfilled fresh noodles, ribbons, etc. which are called "egg noodles" must contain at least three egg yolks per kilogram of dough and for this reason have a cholesterol content of not less than 0.06 grams per 100, calculated on the moisture-free substance. Their color may not be reinforced with any kind of dye.

Article 299.—Dry alimentary pastes may be colored with (natural or synthetic) substances of vegetable origin authorized by this Code and the competent health authority, but such coloring must be stated on the label in a clearly visible manner that does not allow any confusion or deception. Fresh pastes may be colored as follows without a declaration in the labeling: 1. Yellow pastes: with eggs; 2. Green pastes: with vegetables, spinach, chard, etc.; 3. Red pastes: with peppers and/or tomatoes and pepper and tomato preserves.

Article 300.—Alimentary pastes prepared with pastes left over from previous batches, not fit for human consumption or for some reason in conflict with the provisions of this Code shall be considered unsuitable for human consumption.

Bakery Products

Article 301.—The name *"White Bread,"* or simply *"Bread,"* without any further definition, means the product obtained by baking a dough made of a mixture of wheat flour, potable water and salt, fermented by the addition of a sour or yeast (brewers' yeast, cereal yeast, synthetic yeast). The kneading of bread dough must be done mechanically.

The water content of bread may not exceed 40 percent, and its total ash content, calculated on a moisture-free basis, may not exceed 3.25 percent.

Bread made from flours other than wheat flour, or from wheat flour to which rice flour was added in a proportion of 30% (Venezuelan bread), or bread which contains other food substances (milk, eggs, sugars, etc.) must be labeled according to its composition as "rye, barley, wheat and rice or Venezuelan Bread, milk bread," etc.

To correct and favor fermentation sodium or potassium bromate may without a declaration be used in bread manufacture in amounts not exceeding 5 grams per 70 kilograms of flour, always provided that the flour contains neither of these additives. In the preparation of rye bread, the addition of citric acid (of the necessary purity) is permitted in a proportion of 0.35 grams per 100 grams of flour. This acid, when intended for bread-making, must be marketed and sold already mixed with rye flour. The addition of calcium or sodium propionate in a proportion of up to 3,000 p.p.m. and of potassium sorbate in a porportion of up to 5,000 p.p.m. is likewise permitted to inhibit the action of microorganisms of the *B. mesentericus* strain which causes bread to become "ropy" or slimy.

Article 302.—The name *"French Bread"* or "French-type bread" means bread prepared in the same manner as explained in the preceding article, with or without sours, that is cut lengthwise before baking and which has a shiny crust.

French bread must meet the following principal characteristics; it must be porous and light, its soft part must be elastic and uniform, and its taste and smell must be pleasant. Its water content may not be more than 35 percent by weight of the whole bread and its total ash content on a moisture-free basis may not be more than 3.25 percent. Average percentage composition: water 31; protein 9; fat 0.16; assimilable carbohydrates 58; crude fiber 0.2; ash (sodium chloride 0.8) 1.5.

French bread is marketed in different shapes and weights under various distinctive names.

Article 303.—The name *"Creole Bread"* means loaves of a special shape. Creole bread may not contain water in a proportion of more than 40 percent by weight of the whole bread or more than 3.25 percent of total ash. Average percentage composition: water 25; protein 9; fat 0.4; assimilable carbohydrates 54; crude fiber 0.3; ash (sodium chloride 0.3) 1.

When fat has been added to the dough of Creole Bread in a proportion of not less than 4 percent, it shall be sold as "bread with fat," "miriñaque" or "cannon bread," which can have various shapes: a cross, horn, etc.

Article 304.—The name *"German Bread"* means bread prepared with brewers' yeast or cereal yeast in whose dough part of the water has been replaced by beer. It has a shiny crust. Average percentage composition: water 35; protein 9; fat 0.2; assimilable carbohydrates 54; crude fiber 0.2; ash (sodium chloride 0.3) 0.9.

Article 305.—The name *"Vienna Bread"* means bread prepared with brewers' or cereal yeasts and milk. During baking the upper part is sprayed with a mixture of faecula and water. Average percentage composition: water 25; protein 10; fat 1.8; assimilable carbohydrates 61; crude fiber 0.2; ash (sodium chloride 0.5) 1.

Article 306.—The names *"Sandwich Bread"* and *"English Bread"* mean bread made by placing the dough in a greased form which, put into the oven, produces a short loaf with a large soft crumb. English Tomato Bread is prepared with tomato extract in a proportion of 10 per thousand and English Spinach Bread is prepared with 10 percent of spinach leaves.

Article 307.—The name *"Graham Bread"* means bread made from whole wheat flour and water, to which no yeast or salt has been added. The dough is left to ferment for several hours (with the yeast originally present in the whole wheat grain) and then baked in tin moulds. Graham bread shall not contain water in a proportion of more than 40 percent by weight of the whole loaf and not more than 2 percent of ash. The selling as Graham Bread of dark or whole wheat bread prepared with yeast and salt shall be considered a fraud. Average percentage composition: water 35; protein 9.5; fat 0.8; assimilable carbohydrates 51; crude fiber 1.7; ash (sodium chloride 0.1) 1.5.

Article 308.—Dark bread or whole wheat bread is bread prepared with equal parts of whole wheat flour and triple-zero grade flour, compressed yeast or sours, and various additives intended to improve the flavor: butter or another fat, malt extract, rye flour, etc. It is generally baked in pans. It may not contain water in a proportion of more than 40 percent by weight of

the whole loaf and not more than 3.5 percent of ash, including the salt. Average percentage composition: (Dark bread with a sour): water 32; protein 8.5; fat 0.5; assimilable carbohydrates 56; crude fiber 0.9; ash (sodium chloride 0.3) 1.4. (Dark bread with compressed yeast): water 36; protein 10; fat 3; assimilable carbohydrates 47; crude fiber 1.8; ash (sodium chloride 0.5) 1.6.

The names "Simons, Sanitas, Growitt, Steinmetz, Finker, Schlueter" bread mean breads with a base of whole wheat flour prepared according to special processes.

Article 309.—The name *"Grissini"* means long, thin, crispy breadsticks prepared without yeast with wheat flour, butter or another shortening, water and salt. Average percentage composition: water 10; protein 12.5; fat 0.2; assimilable carbohydrates 75; crude fiber 0.1; ash (sodium chloride 0.9) 1.6.

Malted "Grissini" must contain not less than 8 percent of malt extract; Groat "Grissini" equal amounts of wheat flour and groats, and Whole Wheat "Grissini" a 50:50 mixture of white and whole wheat flour.

Article 310.—The name *"Cracker"* means various products prepared with flour, little, or very little, yeast and potable water. Crackers are found in commerce in the following types:

1. Moulded Crackers: so named because the dough is cut before baking with a round iron of varying diameters. Their surface is pierced to prevent the formation of blisters.

This type of cracker includes the so-called "water crackers," "honey crackers," "biscuits," "malt crackers," "whole wheat crackers," etc., which are distinguished from each other by their ingredients.

Moulded crackers may not contain water in a proportion of more than 12 percent by weight of the whole product.

2. Plain or hand-cut Crackers: so called because they are cut by hand. They are usually sold as small biscuits of various sizes, which are dark on the outside, white on the inside. They include the so-called "Field crackers." They shall not contain water in a proportion of more than 30 percent by weight of the whole cracker and not more than 2.3 percent of ash.

3. Multi-layer crackers: crackers made by placing a layer of dough about 2 centimeters thick on top of another layer of equal thickness and then cutting the whole to size. Average percentage

composition: (Water Crackers): water 11; protein 12; fat 0.8; assimilable carbohydrates 75; crude fiber 0.2; ash (traces of sodium chloride) 0.6.—(Field Crackers): water 25; protein 10; fat 1; assimilable carbohydrates 62; crude fiber 0.2; ash (sodium chloride 0.5) 1.2.

Article 311.—The name *"Easter Rusk"* means a product made with a base of flour, milk, butter or another shortening, and eggs, flavored with natural essences, which is sold as a twisted roll decorated with granulated sugar and whole hard-boiled eggs. Usually, a little gift is put inside that is supposed to bring luck to the finder.

Article 312.—The name *"Unleavened Bread"* means the product prepared by quickly heating a dough prepared with water and fine flour or starch between two metal sheets or in moulds.

Article 313.—Bread Crumbs may be prepared only at bakeries or plants engaged specifically in this business. Only whole loaves in good condition may be used for the purpose.

Bread crumbs shall be sold in containers sealed with cellophane or another moisture-proof material and shall have the respective labeling.

Article 314.—The generic names "baked goods" and/or "pastry" identify sweet or salted products of various shapes and sizes, prepared with flour, potable water, yeast, butter or another shortening, sugars, salt, milk, eggs, egg white, sweet and bitter almonds, and pine nuts, with or without the addition of permitted flavors.

The maximum hydrocyanic acid content of products containing almonds shall be 40 p.p.m.

These products are being sold under names such as: *Half Moons, Health Bread, "Palmeras," macaroons, Madeleines, scones, tarts, black and white cakes, vanilla wafers,* etc.

Article 315.—The name *"Patay"** means a product prepared by kneading carob (*Prosopis algarrobo*) flour and water into a dough that before baking is shaped into small bricks. Percentage composition: water, from 10 to 12; protein, from 4 to 6; fat, from 0.8 to 1.5; assimilable carbohydrates (starch from 8 to 12) from 55 to 65; crude fiber, from 5 to 6; ash, from 5 to 8.

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* Note of the Translator: A Latin-American type of cookie.

A similar dough prepared with jujube (*Zizyphus mistol*) flour is called "jujube Patay."

Article 316.—The generic names *"Cookies"* and *"Biscuits"* distinguish many products which have a base of wheat flour or other flours and are prepared with or without the addition of yeast, butter or another shortening, milk, cheese, sugars, magnesium carbonate in a proportion of up to 0.5 grams per 100 grams (rolled wafers), condiments and flavors, and are given fancy shapes before they are placed in the oven. Average percentage composition (Water-type cookies): water 5; protein 12; fat 7; assimilable carbohydrates 71; ash 4.5. (Cream cookies, sandwich-type cookies): water 5; protein 12; fat 10; assimilable carbohydrates 68; ash 4. (Graham crackers): water 5; protein 10; fat 10; assimilable carbohydrates 69; crude fiber 0.8; ash 4.5 (Wafer type cookies): water 6; protein 6; fat 14; assimilable carbohydrates 71; ash 2.5.

Article 317.—*"Pretzels"* shall be prepared with flour, water, salt, butter or another shortening, and yeast. The dough is left to ferment, shaped into sticks which are then bent to form an 8 etc., cooked in an alkaline bath, baked, salted and returned to the oven for a few minutes. Average percentage composition: water 10; protein 9.5; fat 3.8; assimilable carbohydrates 72; ash 4.

"Wheat Flake Biscuits" are prepared with the flakes mentioned in Article 265, numeral 4, which, prior to baking, are pressed into biscuits.

Cones are prepared with flour, sugars, water, eggs and butter or another shortening; the dough is shaped into wafers which are then rolled into cones or cornucopias.

"Butter Cookies" are prepared with flour, a generous quantity of butter or another shortening, sugars, eggs, wine and other authorized products. The whipped batter is placed in paper moulds of different shapes and baked. When done they are sprinkled with sugar. "Polvorones" (a scone variety) are made from a similar batter and, when done, sprinkled with sugar and cinnamon.

There exist many similar products in different shapes prepared with different processes: *Cat's Tongues, Madeleines, Scones, Vanilla wafers,* etc.

Article 318.—As a general rule, the various types of bread, pastry and other bakery products shall be sold under names

which clearly indicate their nature. Any products whose composition differs from the one implied by their name shall be considered misbranded unless the purchaser is notified of their composition in a clear and unmistakable manner.

Article 319.—Bread, crackers, cakes and other baked goods are prohibited from being circulated, held and sold if they are poorly prepared or baked, if dyes have been used instead of eggs, if they contain foreign substances, are contaminated by cryptogamic diseases or animal parasites, are damaged or adulterated, or if their acidity, in the case of white bread, is over 0.54 percent calculated as lactic acid, and in the case of dark bread (whole wheat, rye, etc.), over 0.72 percent calculated as lactic acid. Such poorly prepared and baked, burned, damaged or adulterated bread or bakery goods shall be seized summarily by the inspection authorities without prejudice to such other proceedings as may be applicable.

Article 320.—Bread, pastry and other bakery goods are prohibited from being circulated, held and sold if they have a poor appearance or smell, are not fresh, perfectly preserved and free from contamination by pathogenic bacteria, or if they contain harmful substances and extraneous or prohibited products.

Article 321.—The name "*Bread Bakery*" (Panadería") means any establishment at which bread, crackers and similar products are prepared; the names *"Pastry Shop"* ("Pastelería") or "*Dough and Cake Bakery*" ("Fábrica de Masas y Pasteles") mean the establishment at which these and similar products are prepared, and the name "Cookie Bakery" ("Fábrica de Galletas") the establishment which produces this type of baked goods.

All these plants shall meet not only the general requirements, but also the following requisites:

1. The rooms used to store flours and other supplies shall meet all conditions required for the purpose; they shall be clean and well ventilated and protected from harmful animals, rodents, insects, etc.

2. The manufacturing rooms shall be large, have a flat ceiling, a waterproof floor and a waterproof wainscot 1.80 m. high, which may consist of flagstone, glazed tiles, small slabs or another material which, in the opinion of the health authorities, is equally hygienic. When cake batters or other pastry products are prepared in bread bakeries, a special room shall be required therefor.

3. Doughs and batters containing eggs or butter shall be worked on marble tables and may not come into contact with copper vessels unless they are lined with tin plate. If it is necessary to wet the surface of bakery products, this shall be done by means of a mechanical sprayer. All machinery and equipment used shall always be kept perfectly clean and in good working order.

4. Expectorating and smoking shall be prohibited in the manufacturing rooms, and signs to that effect shall be posted and cuspidors with disinfectants be provided. In bathrooms and toilets, signs shall be posted stating that one must wash one's hands each time one leaves the room, for which purpose wash-basins shall be provided near-by. Special care shall be taken to assure compliance with these provisions.

5. Whenever bread, crackers, cakes and other products of bread and pastry manufacture are found to have been contaminated by microorganisms, all working utensils shall be sterilized.

6. Baking ovens shall be at least 50 centimeters distant from the next partition, and their chimney must likewise be at least 50 centimeters distant from the partition and be equipped with a soot-catching device.

7. Drying chambers and ceilings must be whitewashed; walls must be plastered and whitewashed, and floors must be waterproof.

8. The sales rooms shall be staffed with employees whose only duty is selling. Bread may be sold loose, in pieces and unwrapped only at bakeries or bread shops. In all other outlets, bread may be sold only in its original wrapper (as packed at the bread bakery).

9. Bread bakeries, pastry shops, cookie factories and similar establishments may not be installed in garages or basements, are not permitted to do business in apartment buildings, to communicate directly with such buildings or with any dangerous, disturbing or unsanitary industrial plants, or to be close to dairies, stables, tanneries or slaughterhouses.

Article 322.—The selling and shipping of bakery products shall meet the following requirements:

1. Unpackaged products shall be kept at outlets engaged in their sale exclusively on shelves or in showcases protected by glass, fine metal mesh, plastic or a suitable type of gauze which shall be kept perfectly clean.

2. In any locality officially considered a city and in population centers expected to develop into cities, bakery products may be sold only by outlets that sell this type of product exclusively.

3. In all other centers of population, groceries and other stores shall be permitted to sell bakery products, but only in their original wrapper (as packed at the bakery), always provided that the goods are kept at suitable places, as provided for by Articles 21 and 23 of this Code.

4. Unpackaged bakery products may be shipped only in closed cars and vehicles safe from contamination.

Empanadas (meat pastry), Tortillas (pancakes), Arepas (griddle cakes), Churros (fritters), Pizzas, Sandwiches and Similar Foods

Article 323.—Establishments which prepare meat pastry, pancakes, griddle cakes, tamales, fritters, pizzas, sandwiches, snacks, canapés and/or similar products, separately or combined with another business, shall, as a minimum requirement, have for the purpose a work room with running water and a sink directly connected with the municipal sewers; a storage room for the raw materials, and a sales room that meets the requirements fixed in this Code. Both the work and the sales rooms must have a flat ceiling, and be wainscotted up to a height of 1.80 m., with glazed tiles, flagstone or another similar material; their counters and tables shall be of marble or another similar material approved by the health authorities. Such establishments are not permitted to do business in garages, basements or apartment buildings, nor may they directly communicate with such places or any dangerous, disturbing or unsanitary industrial establishment, or be close to dairies or stables.

When the goods are prepared in sight of the public, the work room may on the aforesaid conditions be combined with the sales room provided that the operation of the stoves, ovens and chimneys do not cause annoyance to the public, affect the sanitary condition of the goods or the safety of the establishment and the staff. The cooking oven must be at least 50 centimeters distant from the adjoining walls.

Both the employees and the premises of such establishments and any equipment used (pans, cutlery, meat slicers, etc.) shall not only meet the provisions hereof, but shall also appeal to the public by their attractive and spotless appearance. The finished goods shall be placed on trays or platters made of china or ceramics, stainless metal or another authorized material which permits the fat to run off. The public shall be requested by signs to dispose of used napkins in cans provided for the purpose.

The firms shall have refrigerators in which to keep raw materials, sandwiches, canapés and snacks requiring refrigeration.

Article 324.—In places at which meat pastries, griddle cakes, pancakes, sandwiches, pizzas, snacks, canapés, etc. are consumed (tea rooms, cafés, luncheonettes, milk bars, pizzerias, griddle bars, etc.) products may be returned free of charge only if they were sold protected by paper and safety closures (metal staples); goods not meeting these conditions when returned by the patron who ordered them must be destroyed summarily, even when they have not been paid for. The waiter and the owner of the establishment shall be liable jointly for failure to comply with this provision. The health authorities shall fix the time for which each of these products may be kept.

Article 325.—The general name "*Pizzeria Products*" is used for: Pizza, "Fugazza," "Fainá," "Ricotta Pizza" and shortcake.

Pizza:—a product prepared with flour, yeast, water and salt, which is generally round and flat and garnished on the top with oil, tomatoes, anchovies; it has to ferment for some time and is then baked in the oven.

"Fugazza":—a pizza garnished with oil and onions cut into strips or rings.

"Fainá":—a product prepared with chickpea flour, water, salt and oil and baked in the oven in a flat circular pan.

Shortcake:—a pastry made of a biscuit-dough consisting of flour, milk, egg yolks, sugar, butter or another shortening and baking powder, filled with fruit in syrup and covered with a lattice-work of the same dough; baked in the oven.

Ricotta Pizza:—a shortcake filled with cottage cheese or ricotta, sugars and glazed fruit.

Article 326.—Sandwiches may be covered or open.

Covered sandwiches, also called "emparedados," consist of various foods put between two or three slices of (English, German or black) bread, which may be plain or toasted, cold or hot. Open sandwiches, also called "canapés," consist of tiny slices of (English, German or black) bread, plain, fried or toasted, on which the foods which one wishes to serve are arranged.

Dry sandwiches (with cold cuts, cheeses, meats, etc.) may be kept under a glass bell at room temperature for up to 12 hours, but moist sandwiches (with salads, tomatoes, pickles, etc.) shall be kept in refrigerators or ice-boxes.

Article 327.—The term *"cocktail snacks"* means various types of special pastry and tidbits, such as timbales, canapés, tartlets, shells, chips, small cakes, meat-filled pastry, sausages, cocktail sausages, kidneys, meat balls, croquettes, etc. of small size and varied composition served cold or hot together with drinks.

Article 328.—The names listed hereinafter designate various products typical of certain countries, which are usually sold by street-vendors or at special outlets:*

1. Alfandoque: a cake made of sugar syrup, cheese, and anise or ginger, cut into strips. The name applies also to a type of sugar paste prepared with almonds (See Article 354, numeral 1).

2. Arepa (Corn griddle cakes): the hull of corn is removed in a pounding trough (hulled corn) or by means of lye or lime (skinned corn); after hulling or skinning, the corn is boiled until it is tender, then the soft dough is whipped, salt and fat is added and the whole is baked over a clay or iron griddle. Arepas are kept hot in a coal stove or oven. Percentage composition: water 48 to 60; protein 3.7 to 5.5; fat 0.3 to 2; assimilable carbohydrates 34 to 44; crude fiber 0.3 to 1.6; ash 0.7 to 1.6. Arepas are sometimes decorated with cheese, ham, crisp bacon, etc.

3. Cachapa (a Venezuelan corn bread with sugar): a cake prepared with tender corn, raw sugar and salt. It can be fried over a griddle (fried Cachapa) or be wrapped in a corn leaf and then cooked in boiling water (leaf Cachapa).

4. Catalina: a cake prepared from wheat flour and raw sugar syrup.

5. Casabe or Cazabe: a cake made of manioc flour.

6. Churro: a fritter or cruller made with a dough of flour, water and salt, which is pressed through an orifice that gives it its characteristic cucumber-shape. It is fried in deep fat or oil and then left to drain in a basin or tray of suitable material.

7. Empanada (Meat Pie): a pastry that consists of a rolled dough cut into rounds, on one end of which a piece of filling is placed (these fillings can be of different types and have a base of meat, corn, vegetables, fish, shellfish or cheese, etc.). The pastry is closed by folding

* Note of the Translator: Most of the names listed here designate regional specialties found only in Latin America, for which reason there do not exist equivalent terms in the English language. Wherever possible, I added an approximate equivalent.

the dough like a half-moon; then an edging is put on and the product is fried in fat or hot oil, or baked in the oven.

8. Gofio: a pastry prepared from roasted corn flour and raw sugar syrup. After drying it is sprinkled with the same flour and cut into rectangular pieces (See Article 265, numeral 3).

9. Hallaca or Hayaca: a tidbit prepared with hulled corn (see Arepa) to which pieces of meat, raisins, olives or other ingredients may have been added. It is wrapped in a plantain leaf and cooked in boiling water.

10. Hallaquita: prepared with hulled corn; the dough is wrapped in a green corn husk and boiled with water and salt.

11. Humita: the same as Hallaca, but prepared with skinned corn, peppers, tomatoes, etc.; the mixture is wrapped in a green corn husk and then cooked in boiling water or a water bath.

12. Manjarete, Atol, Atole: a gruel of corn, sugar, milk and cinnamon (See Article 516, numeral 2).

13. Mazamorra: a preparation similar to Manjarete, but made of crushed or hulled white corn, milk and sugar, to which orange peel, cinnamon etc. is usually added.

14. Pelota: a preparation made of hulled corn (see Arepa), which is soaked in water for 3 or 4 days until it begins to acidify; then syrup or sugar and a few orange slices are added and the liquid is concentrated under heat. When ready, it is wrapped in a plantain leaf.

15. Tamale: a dish similar to Hallaca, but made with skinned corn, with or without other ingredients, chicken, ham, sugar, etc. It is wrapped in a plantain leaf and then baked on a clay griddle or in boiling water.

16. Tortilla (Pancake): the so-called "Mexican tortilla" is prepared with hulled corn, which means corn from which the hull has been removed by cooking it with lime and ash (Nixtamal), which is then cleaned, crushed, kneaded and shaped in form of a cake and baked on a clay griddle called "comal." Percentage composition: water 45 to 51; protein 3.3 to 4.4; fat 1.2 to 3; assimilable carbohydrates 42 to 45; crude fiber 0.6 to 0.8; ash 0.7 to 1.8.

Guatemalan tortillas are likewise prepared by cooking corn in an alkaline medium, but using unhulled grains.

The name "Nixtamal" is used for corn cooked in water with lime and ash. "Nixtamalina" is dried powdered "Nixtamal." **[The End]**

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