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Food Drug Cosmetic Law JOURNAL

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

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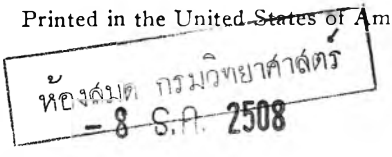

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Role of Government in the Field of Cosmetics.—*Vincent A. Kleinfeld,* author of this paper, is an attorney in Washington, D. C. In this article, beginning on page 480, he discusses the problems the cosmetics market raises. Virtually every cosmetic causes an unforeseeable reaction to a limited number of persons. Therefore, each new preparation must be subjected to tests designed by experts. The majority of cosmetic manufacturers conduct these tests, but some have not observed the necessary precautions and the result has been the enactment of regulatory legislation. In the 1938 Federal Food, Drug and Cosmetic Act, Congress set forth the circumstances under which a cosmetic shall be deemed adulterated and misbranded, and severe penalties for violations were provided. Still, injuries occurred and new legislation appears inevitable. How far the government can go in affording additional protection to the consumer is the question the author discusses in his article.

Food, Beverages, and Their Containers.—*Harvey L. Hensel,* author of this article, is the head of the Commercial Division of the Law Department of Swift & Company in Chicago. In this article, beginning on page 486, he discusses the area of products liability under the general headings of "Theories of Recovery" and "Questions of Proof." The first heading deals with the right to recover under the implied warranty theory, the effect of lack of privity, the right to recover under express warranty theory and under negligence theory, the doctrine of *res ipsa loquitur* and the right to recover under violation of statute theory. Who manufactured the product involved, was the product contaminated, when did the product become contaminated, did the food in question cause the plaintiff's illness, proof of contributory negligence and evidence of due care are topics discussed under the second heading, "Questions of Proof."

Latin-American Food Code.—Beginning on page 505, the first five chapters of the *Latin-American Food Code* are reproduced. Other chapters will be published later. This Second Edition of the Latin-American Food Code was first published in Spanish in August, 1964 by the Latin-American Food Code Council, and was translated by *Ann M. Wolf* of New York.

The first chapter includes general provisions and definitions in the Code which affect any person, commercial firm or establishment that manufactures, packs, holds, transports, sells, exhibits or handles food or household articles or raw materials used in such products.

The second chapter deals with general requirements for food factories and food outlets. Storing, preservation and processing of foods are covered by regulations in the third chapter.

Chapter IV concerns utensils, receptacles, containers, wrappers, machinery, and accessories. Regulations governing use of the above in preparation and packaging of foods are included.

Labeling is the topic of Articles 78—86 in Chapter V. The designation of the product and its nature, and the measure or weight of each unit are among items regulated here.

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The Role of Government in the Field of Cosmetics

By VINCENT A. KLEINFELD

Mr. Kleinfeld Is an Attorney in Washington, D.C. The Following Article Is Reprinted Here by Special Permission of *The Journal of the Society of Cosmetic Chemists.*

THERE IS NO DOUBT THAT SERIOUS PROBLEMS are always involved in the marketing of cosmetic preparations. The normal human skin may be injured in several ways as a result of cosmetic application, and there is probably no ingredient which can be used with impunity by every human being. In the case of virtually every cosmetic, some limited number of persons may experience an unforeseeable reaction, although all others may suffer no ill effects.

Unfortunately, it is not feasible to specify a rigid series of tests, satisfactory for all cosmetics, which will be adequate to disclose the possible incidence of local contact dermatitis, or loss of hair, or eye injury. Each newly introduced preparation must be subjected to specific tests designed by experts, which take into consideration the types of ingredients, the intended manner of use of the product, and its estimated potentialities for producing particular kinds of irritation.

This is essentially the procedure employed by the responsible cosmetic manufacturers who comprise the bulk of the industry. Thus, former President Roosevelt pointed out to the Congress of the United States, when the bills leading to the enactment of the Federal Food, Drug and Cosmetic Act of 1938 were under consideration, that the great majority of those engaged in the food, drug and cosmetic

industries do not need regulation—that "they observe the spirit as well as the letter of existing law."

The attempts of organized society to regulate the commerce in foods and drugs are by no means a recent development. Early Greece and Rome had wine inspectors to guard against adulteration. Sanitary regulations concerning food are found in the Rabbinical laws. During the time of William the Conqueror, brewers were heavily fined for adulterating their product and were drawn around in carts to receive the jibes and execrations of an outraged citizenry. During the eleventh century, regulations were enforced in several European cities forbidding the adulteration of wine and beer. In 1202, the "Assize of Bread" was passed in England, and in 1266 a law was enacted forbidding the sale of unwholesome wine and meat. The Magna Carta contained a provision dealing with weights and measures. A pharmacopeia was published in England by the College of Physicians as far back as 1613.

It was the development of analytical chemistry, with the creation of methods for detecting adulterants, which stimulated an increased interest in legislation directed against sophistication. An indication of the fact that the adulteration or misbranding of cosmetics was not taken too seriously was the fact that, when the first national Food and Drugs Act was enacted by the United States in 1906, there was no attempt to include cosmetics in the protection offered to the consuming public. There were a number of incidents, however, some quite serious in nature, which soon revealed that protection against abuses in the distribution of cosmetics was necessary. For example, a product named "Lash Lure" caused irreversible blindness to a few women who were particularly susceptible to the *p*-phenylenediamine which it contained. A depilatory, "Koremlu," caused thallium poisoning in some women, resulting in symptoms such as abdominal pain, nausea, loss of hair, and blindness. Thus, when the Federal Food, Drug and Cosmetic Act of 1938 was enacted, Congress set forth the specific circumstances under which a cosmetic shall be deemed to be adulterated or misbranded, and severe penalties were provided for those distributors or manufacturers who marketed products which could cause injury or whose labeling made false or misleading claims.

1938 Act Included Cosmetics Regulation

The injuries resulting from the use of improperly tested cosmetics were primarily responsible for the inclusion of cosmetics in the law which prior to 1938 had concerned itself solely with the marketing of

foods and drugs. There is no question but that the regulation of cosmetics in the 1938 Federal Food, Drug and Cosmetic Act greatly decreased the incidence of harm caused by cosmetics. But, despite the fact that there have been very few serious injuries since the passage of the 1938 statute, instances involving some injury to some consumers have occurred. For example, there was an outbreak of dermatitis as the result of the substitution by a manufacturer of synthetic resin for shellac in the manufacture of a hair lacquer very popular at the time. A number of years ago, two hair shampoos were marketed which, when inadvertently introduced into the eyes by users while shampooing their hair, produced opacity of the cornea which impaired vision for a period of time. There have been other instances of harm—from hair dyes, hair straighteners, depilatories, deodorants, and other cosmetics. Among the injuries resulting from the use of such cosmetics were skin eruptions, itching, and brittleness and temporary loss of hair.

The fact that the 1938 Federal Food, Drug and Cosmetic Act specifically provided that new drugs must be demonstrated to be safe for their intended use before they are marketed certainly did not prevent a number of side effects, some of them quite serious, as well as deaths from new drugs which had obtained prior governmental clearance. This is not to say that regulation is not needed or that the new drug provisions of the statute do not serve an extremely useful purpose. The point is that it is virtually impossible to have an absolute assurance that some few persons may not suffer some side effects, occasioned by the use of a particular drug or cosmetic, unless such drastic legislation is enacted. Thus legislation would probably result in a collapse of the drug and cosmetic industries, or at least the removal from our economy of large numbers of safe and useful products.

The fact remains, nevertheless, that literally hundreds of chemicals are utilized in cosmetics and that the number of chemicals entering the cosmetic market of the world increases each year. Many millions of men, women and children use cosmetics every day in one form or another. Since 1938, the percentage of injuries caused by the many millions of units of cosmetics marketed is quite small. As pointed out, nevertheless, injuries have occurred. There is a strong popular demand for increased consumer protection. These considerations appear to make it inevitable that the state will enter into the cosmetic picture in a stronger fashion than before. But what kind of legislation

do we need, and how much power do we wish to give to the state because of these factors?

The important question at this time is how far we wish to go in affording additional protection to the consumer. This depends in large part on one's theory of government. As indicated, one can devise a statute which will vest such authority in the state and require such testing and safeguards that most old cosmetics will be regulated out of existence, and virtually no new ones will appear. In addition, one can cause such increase in the cost of cosmetics as to create a serious financial burden upon many millions of consumers. We can over-legislate and over-regulate so that the small businessman who may be considered to be a bulwark of the economy of many nations is driven from the market place.

Taking everything into consideration, it would seem to be advisable to provide, as far as the United States is concerned, for approval of the safety of a new cosmetic by the Food and Drug Administration before it is permitted to enter the channels of commerce. But it would appear that, particularly in this area, there is no necessity for a complicated and burdensome statute which, for example, provides that investigations must be conducted which will "include adequate tests by all methods reasonably applicable to show whether or not" the cosmetic is not only safe for its intended use but for "other reasonably foreseeable uses." Again, is any vital purpose served (other than to create a greater labyrinth of governmental regulation) by declaring that a cosmetic will be deemed unsafe not only if its intended use, but also if "any reasonably foreseeable use," will or may result in ingestion and is found by the government to be carcinogenic in some amount, to some strain or species of animal, under some circumstances, when applied in some manner, and at some stage of development? And concerned as we all are with respect to cancer, is it realistic to provide, in addition, that a cosmetic shall be deemed unsafe not only if its intended use, but again if "any reasonably foreseeable use," will not result in ingestion, and "after tests which are appropriate for the evaluation of the safety of cosmetics for any such use, or after other relevant exposure of man or animal to such cosmetic" is found by the government to induce cancer "in man or animal?" Is there any necessity for requiring a cosmetic manufacturer to demonstrate in advance, to the satisfaction of the government, that his labeling is not false or misleading? What does that have to do with safety?

A bill introduced in Congress also provides that a cosmetic shall be deemed unsafe if its composition is such that it is not generally

recognized among experts qualified by scientific training and experience to evaluate the safety of cosmetics, as having been adequately shown, through scientific investigations, to be safe. . . ." The author certainly has no quarrel with a provision of this character, as far as it goes, or with the opinions of learned experts. But the provision completely ignores, in connection with cosmetics which may have been on the market for many years, what is in the author's view the most authoritative criterion—actual experience.

The problem presented by the scope of proposed social and economic legislation is frequently the same. There are always certain inevitable conditions encountered in the enactment of such legislation. There is the influence of that group which has a real concern for the public welfare but which possesses, in addition, interests which cause it to seek precautions against abuses in the administrative process. There is the element which, when any regulation is attempted, commences by declaring that it is for effective legislation and then seeks to emasculate it by a multitude of weakening amendments. There is a small, selfish element that is opposed to any regulation at all, no matter how essential it may be. And lastly there are the doctrinaire consumer groups, backed by the more sophisticated agencies concerned, who take the opportunity offered by a need for some remedial legislation to add unnecessary restraints and licensing provisions. These countering crosspulls are always present, and all should be scrutinized.

In any event, if a strait jacket type of cosmetic legislation is to be enacted, is it not advisable to have a check on the particular reviewing governmental official by providing for a review by some committee of qualified scientists? As indicated, also, it would appear that those cosmetics which have been on the market and have not caused injury, other than perhaps an occasional allergic reaction, should not be placed in the precise category of a "new cosmetic." Has not such a cosmetic been shown to be safe by the very fact that it has been used for an appreciable period of time without a real incidence of injury?

In addition, it is vital to comprehend the importance of semantics as far as the law of this country is involved. The Federal Food, Drug and Cosmetic Act of 1938 specifically defines "drug," "new drug," and "cosmetic." Frequently, a few words may convert a product which is essentially a "cosmetic" into a "drug" or "new drug." Thus, an article offered to provide a woman with a rich tan will be considered to be a cosmetic, the labeling of which need not declare the ingredients. The same product may be converted into a drug if it is marketed to

afford relief from sunburn. A face cream is a cosmetic, but it may become a drug, in addition, if it is held out for the removal of wrinkles and crow's feet. A tooth powder will be a cosmetic if offered to keep teeth clean and breath fresh, but it may fall into the drug category if its labeling or advertising claims that it will prevent decay. I point out this factor to indicate that legislation in the United States, attempting to regulate more stringently the marketing of cosmetics, should take into account the fact that the definitions in existing law of "drug" and "new drug" are so comprehensive as to encompass (with the attendant strict controls presently in existence for these products) many articles which are fundamentally cosmetics but which employ active ingredients and make representations which are somewhat therapeutic in nature.

Summary

In summary, there appears to be a need for greater regulation in the area of cosmetics. In the United States, new food additives, new drugs, antibiotics, and colors must be shown to be safe before they are introduced into interstate commerce, and there is a strong demand for a similar requirement with respect to cosmetic preparations. In view of these considerations, it would seem inadvisable to resist the passage of reasonable legislation requiring that new cosmetics, or their ingredients, be demonstrated to be safe before they are marketed. Balancing all the pertinent policy considerations, however, the creation of unnecessary restrictions, even if they may seem at first glance to afford the consumer greater protection, would be ill-advised. **[The End]**

REGISTRATION UNDER 1965 DRUG ABUSE AMENDMENTS

Registration procedure for those subject to the Drug Abuse Control Amendments of 1965 has been announced by FDA Commissioner George P. Larrick. The new law requires registration by owners or operators of establishments which distribute, job, or wholesale stimulant and depressant drugs including barbiturates, amphetamines and other psychotoxic drugs having a potential for abuse because of their depressant or stimulant effects on the central nervous system or because of their hallucinogenic effects. Previously only establishments associated with manufacturing and distributing drugs in general were covered.

Initial registration by Form FD-1597, "Registration of Drug Establishment," must be effected no later than February 1, 1966. Firms currently registered as producers who also are covered by the Amendments may register simultaneously at the time of annual registration beginning November 15, 1965.

The text of Department of Health, Education, and Welfare Release, HEW-WO2-4171, is reproduced in FOOD DRUG COSMETIC LAW REPORTS ¶ 80,106.

Food, Beverages, and Their Containers

By HARVEY L. HENSEL

Mr. Hensel Is Head of the Commercial Division of Swift & Company Law Department in Chicago. This Article Is Reprinted from the University of Illinois *Law Forum*, Products Liability: Vol. 1964, Winter Number, Pages 705—724.

IN THE AREA OF PRODUCTS LIABILITY, developments in food and beverage cases have traditionally led the field. In fact, food cases have been so far ahead of other product cases that it is common to talk about the "food exception" to the usual rules of recovery. It is the writer's opinion, however, that the present day developments in the products liability field are to a large extent developments by which other products are catching up with food products.

While the products liability field appears to have a rather large general interest at the present time, an article of this type should have the most practical significance to an Illinois lawyer about to file or defend a food product liability case. This article was written with this viewpoint in mind.

Since with few exceptions food and beverages have been treated alike by the courts, the term "food" will generally be used here as including beverages. For the purpose of this article the Illinois food products liability cases have been discussed under the general headings of "Theories of Recovery" and "Questions of Proof." Separate sections will deal with a few special food and beverage problems and with the subject of their containers.

I. Theories of Recovery

A. Right to Recover Under the Implied Warranty Theory

The Illinois courts have clearly held that in a sale of food there is an implied warranty that the food is wholesome and fit for consumption. The situations in which Illinois courts have upheld actions

based on implied warranty in food cases are (1) consumer versus manufacturer (nonsealed container);[1] (2) consumer versus manufacturer (sealed container);[2] (3) consumer versus retailer (nonsealed container);[3] (4) consumer versus retailer (sealed container);[4] and (5) consumer versus restaurant.[5]

The courts' holdings in these situations are briefly summarized in a recent Illinois Supreme Court case:

> By furnishing food to the general public, the manufacturer and retailer both impliedly warrant that the product is fit for human consumption at the time it leaves their respective control, and where the food proves to be deleterious, either or both may be required to respond in damages to the injured consumer.[6]

The liability of the manufacturer or the retailer is greater under this theory of recovery for the simple reason that the plaintiff does not have to prove negligence on the part of the defendant. It is difficult to imagine the case in which the plaintiff's attorney would not include an implied warranty count in an Illinois food product liability complaint.

There may be some question as to what type of implied warranty the courts in the above cases were upholding under section 15 of the Illinois Sales Act.[7] However, the implied warranty of merchantability described in section 2-314(2)(c) of the Illinois Uniform Commercial Code[8] clearly would cover the sale of food. Section 2-314 also makes it clear that the serving of food or drink is a sale and hence subject to the implied warranty of merchantability. The Illinois courts had reached the same conclusion prior to the enactment of the Code.[9]

B. Effect of Lack of Privity

In sustaining actions based on implied warranty brought by consumers against manufacturers, as described in the preceding sec-

[1] *Tiffin v. Great Atl. & Pac. Tea Co.*, 18 Ill. 2d 48, 162 N.E. 2d 406 (1959).

[2] *Sharpe v. Danville Coca-Cola Bottling Co.*, 9 Ill. App. 2d 175, 132 N.E.2d 442 (3d Dist. 1956); *Williams v. Paducah Coca-Cola Bottling Co.*, 343 Ill. App. 1, 98 N.E.2d 164 (4th Dist. 1951); *Patargias v. Coca-Cola Bottling Co., Inc.*, 332 Ill. App. 117, 74 N.E.2d 162 (1st Dist. 1947).

[3] *Wiedeman v. Keller*, 171 Ill. 93, 49 N.E. 210 (1897); *Tiffin v. Great Atl. & Pac. Tea Co.*, see footnote 1.

[4] *Sloan v. F. W. Woolworth Co.*, 193 Ill. App. 620 (3d Dist. 1915); *Chapman v. Roggenkamp*, 182 Ill. App. 117 (1st Dist. 1913); see also *Freeman v. Great Atl. & Pac. Tea Co.*, 284 Ill. App. 648, 3 N.E.2d 154 (1st Dist. 1936).

[5] *Fry v. Hobson Drug Co.*, 16 Ill. App. 2d 152, 147 N.E.2d 425 (2d Dist. 1958); *Duncan v. Martin's Restaurant, Inc.*, 347 Ill. App. 183, 106 N.E.2d 731 (1st Dist. 1952); *Greenwood v. John R. Thompson Co.*, 213 Ill. App. 371 (1st Dist. 1919).

[6] *Tiffin v. Great Atl. & Pac. Tea Co.*, see footnote 1, at 56, 162 N.E.2d at 411.

[7] Ill. Laws 1915, at 609.

[8] Ill. Rev. Stat. ch. 26, § 2-314 (2) (c) (1963).

[9] *Greenwood v. John R. Thompson Co.*, see footnote 5.

tion, the Illinois courts have eliminated the privity requirement. In doing so, they have followed the majority rule in the United States. It should be noted that the Uniform Commercial Code has no language on whether lack of privity prevents a consumer from suing a manufacturer. A Uniform Code comment clearly states that this point is to be determined by case law.[10]

There is another area, however, where the privity requirement has been discussed by the Illinois courts. These cases concern factual situations where the injured party was not the purchaser of the food. The courts have extended implied warranty to (1) a member of purchaser's family,[11] (2) a child of a purchaser,[12] and (3) a donee from the purchaser.[13] The Uniform Commercial Code has a specific section dealing with this particular problem. Section 2-318 states:

> A seller's warranty whether express or implied extends to any natural person who is in the family or household of his buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this Section.[14]

To a large extent the above section of the Code has merely codified the decisions already rendered by the Illinois courts in food cases under the Uniform Sales Act.

C. Right to Recover Under Express Warranty Theory

While there apparently have been no Illinois cases concerning express warranties in connection with food products, other jurisdictions have upheld recoveries by plaintiffs in this area.[15] Either the advertising or the labeling of the product may be grounds for action on an express warranty theory. The somewhat more liberal definition of express warranty found in section 2-313 of the Uniform Commercial Code[16] may induce more use of this theory of recovery. Failure of the product to comply with statements on the label is also a basis under the Uniform Commercial Code for a suit on an implied warranty theory.[17]

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[10] *Uniform Commercial Code* § 2-318, comment 3.

[11] *Haut v. Kleene*, 320 Ill. App. 273, 50 N.E.2d 855 (1st Dist. 1943).

[12] *Welter v. Bowman Dairy Co.*, 318 Ill. App. 305, 47 N.E.2d 739 (1st Dist. 1943).

[13] *Blarjeske v. Thompson's Restaurant Co.*, 325 Ill. App. 189, 59 N.E.2d 320 (1st Dist. 1945).

[14] ILL. REV. STAT. ch. 26, § 2-318(1963).

[15] *Bonker v. Ingersoll Prods. Corp.*, 132 F. Supp. 5 (D. Mass. 1955); *Lane v. C. A. Swanson & Sons*, 130 Cal. App. 2d 210, 278 P.2d 723 (1955).

[16] ILL. REV. STAT. ch. 26, § 2-313(1963).

[17] *Id.* § 2-314(2) (f).

D. Right to Recover Under Negligence Theory

The Illinois courts have consistently held that a manufacturer of foods is required to exercise due care to see that such articles are wholesome,[18] and where he fails to do so he is liable to the ultimate consumer in damages. Although the lack of privity might be raised as a defense in this type of situation, in the only Illinois case where it was successfully raised the supreme court reversed the decision.[19] Furthermore, where this defense has been raised in food cases in other jurisdictions it has not been sustained.[20]

The writer has failed to find any Illinois cases holding a retailer (nonmanufacturer) liable solely on a negligence theory. This may be due to the fact that a warranty action is a more favorable basis for such a suit or to the fact that in sealed containers the negligence is more likely to be that of the manufacturer. Certainly it would be difficult to prove negligence on the part of a retailer in a case involving a foreign substance in a sealed container. It should be less difficult to prove negligence on the part of a retailer if the foreign substance was in an unsealed container, or if the case involved food poisoning.

The liability of a restaurant owner to a consumer on a negligence theory was established by the supreme court at a very early date.[21]

E. Doctrine of Res Ipsa Loquitur

Since direct proof of negligence on the part of either a retailer or manufacturer is almost always lacking in food product liability cases, the plaintiff usually relies upon the doctrine of *res ipsa loquitur*. The Illinois Supreme Court, in the case of *Bollenbach v. Bloomenthal*,[22] has described this doctrine as follows:

> The doctrine of *res ipsa loquitur* is, that whenever a thing which produced an injury is shown to have been under the control and management of the defendant and the occurrence is such as in the ordinary course of events does not happen if due care has been exercised, the fact of injury itself will be deemed to afford *prima facie* evidence to support a recovery in the absence of any explanation by the defendant tending to show that the injury was not due to his want of care. The presumption or inference of negligence raised by the application

[18] *Paolinelli v. Dainty Foods Mfrs. Inc.*, 322 Ill. App. 586, 54 N.E.2d 759 (1st Dist. 1944).

[19] *Salmon v. Libby, McNeill & Libby*, 114 Ill. App. 258 (1st Dist. 1904), *rev'd*, 219 Ill. 421, 76 N.E. 573 (1905). See also *Rotche v. Buick Motor Co.*, 358 Ill. 507, 193 N.E. 529 (1934), where the court listed "contaminated foods" as one of the exceptions to the rule that manufacturers are not liable in damages to persons with whom they have no contractual relations.

[20] *Coca-Cola Bottling Works, Inc. v. Williams*, 111 Ind. App. 502, 37 N.E.2d 702 (1941); *Burkhardt v. Armour & Co.*, 115 Conn. 249, 161 Atl. 385 (1932).

[21] *Shaffer v. Willoughby*, 163 Ill. 518, 45 N.E. 253 (1896).

[22] 341 Ill. 539, 173 N.E. 670 (1930).

of this doctrine is not absolute or conclusive but is rebuttable, and vanishes entirely when even slight evidence appears to the contrary.[23]

Although the above statement is an accurate description of the doctrine, an analysis of the *res ipsa loquitur* food cases indicates that if the court holds the doctrine applicable, the presumption raised by the doctrine is sufficient to get the plaintiff's case to the jury even though the defendant offers evidence of due care. This question of rebutting the presumption was raised by the defendant in *Paolinelli v. Dainty Foods Mfrs., Inc.*,[24] but the court held the presumption was not rebutted. Again, in *Welter v. Bowman Dairy Co.*,[25] the defendant offered evidence of its elaborate inspection procedure but the court nevertheless held the presumption was not rebutted. It appears that more than "slight evidence" is necessary to rebut the presumption of negligence.

An analysis of the food cases applying *res ipsa loquitur* indicates that many of them have required that the thing which produced the injury be under defendant's control and management at the time of the injury.[26] Since a literal interpretation of this requirement would eliminate the application of the doctrine in most food cases, a different approach had to be found. Some courts have adopted the theory that if the manufacturer or bottler had control at the time of the negligence causing the injury, then the "control" requirement is satisfied.[27] Other courts simply do not consider it important that the item in question had physically passed from the defendant to the plaintiff prior to the time of the injury. In the case of *Rost v. Kee & Chapell Dairy Co.*,[28] the court stated that the "physical control and management at the time of the injury, that is, at the time the milk was being drunk, and with it the broken bits of glass taken in, was unimportant and immaterial." [29] *Welter* was a similar case with an identical result.

There are also two food container cases involving the question of the *res ipsa loquitur* doctrine. In *Johnson v. Stevens Bldg. Catering Co.*,[30] a decanter of tea broke after the plaintiff had obtained it in a

[23] *Id.* at 542, 173 N.E. at 671. This paragraph is quoted with approval by the court in *Paolinelli v. Dainty Foods Mfrs., Inc.*, see footnote 18, at 608, 54 N.E.2d, at 769.

[24] 322 Ill. App. 586, 54 N.E.2d 759 (1st Dist. 1944).

[25] 318 Ill. App. 305, 47 N.E.2d 739 (1st Dist. 1943).

[26] In *Duval v. Coca-Cola Bottling Co.*, 329 Ill. App. 290, 68 N.E.2d 479 (1st Dist. 1946), the question of lack of exclusive control was raised by the defendant and rejected by the court. However, it appeared clear that the bottle was never out of defendant's control. See also *Poteraske v. Illinois Meat Co.*, 342 Ill. App. 555, 97 N.E.2d 475 (1st Dist. 1951).

[27] *Beaumont Coca-Cola Bottling Co. v. Guillot*, 222 S.W.2d 141 (Tex. Civ. App. 1949); *Williams v. General Baking Co.*, 48 Del. 104, 98 A.2d 779 (1953).

[28] 216 Ill. App. 497 (1st Dist. 1920).

[29] *Id.* at 505.

[30] 323 Ill. App. 212, 55 N.E.2d 550 (1st Dist. 1944).

cafeteria line. The court did not feel that plaintiff's temporary possession of the decanter in any way prevented the doctrine of *res ipsa loquitur* from applying. In *Roper v. Dad's Root Beer Co.*,[31] the case involved the explosion of a bottle on the display rack in a retailer's store. This court also held that *res ipsa loquitur* should apply:

> However, when the doctrine has been applied to carbonated beverages, which are referred to in the cases as potential explosives if improperly compounded, bottled or distributed, it is only necessary that the beverage be under the control and management of the defendant at the time of the negligence causing the injury.[32]

The court went on to say, however, that as a condition precedent to recovery, the plaintiff must show affirmatively that there was no intervening negligence in the handling of the beverage after it left the control and management of the manufacturer and bottler. As plaintiff did not offer evidence of this type, the court affirmed a verdict for the defendant.

It is interesting to note that while the courts have consistently held against defendants in food and food container cases whenever the defense was that the instrumentality causing injury was not under the "control and management" of the defendant at the time of the injury, an opposite result was reached in a container case not involving food. In this case a bottle of acid had been delivered to the plaintiff just a few minutes before it broke. The court held that since the plaintiff had exclusive possession of the bottle, the doctrine of *res ipsa loquitur* did not apply.[33]

Res ipsa loquitur has also been held not to apply in food cases if the plaintiff introduces direct evidence of the negligence alleged,[34] or if the plaintiff alleges specific acts of negligence.[35]

F. Right to Recover Under Violation of Statute Theory

The Illinois courts have upheld counts in complaints based on alleged violation of the Illinois pure food statutes.[36] The appellate court, in *Sloan v. F. W. Woolworth Co.*,[37] commenting on the Illinois statute, stated:

> The Statute . . . is simply an enunciation of the law and affixes a penalty upon sales made in violation of it. These statutes are police regulations in the

[31] 336 Ill. App. 91, 82 N.E.2d 815 (1st Dist. 1948).

[32] *Id.* at 94, 82 N.E.2d at 816.

[33] *Mabee v. Sutliff & Case Co.*, 335 Ill. App. 353, 82 N.E.2d 63 (2d Dist. 1948).

[34] *Kirchoff v. Tzinberg's Park "N" Shop Food Stores, Inc.*, 7 Ill. App. 2d 201, 129 N.E.2d 279 (4th Dist. 1955).

[35] *Welter v. Bowman Dairy Co.*, see footnote 12.

[36] ILL. REV. STAT. ch. 56½, § § 7, 8 and 41 (1963).

[37] 193 Ill. App. 620 (3d Dist. 1915).

interest of public health, and do not make knowledge by the retailer a necessary element of the offense. . . .

A civil action for injuries caused by a violation of public policy statutes will lie although the statute may not in terms give a civil right of action.[38]

In *Gray v. Pet Milk Co.*,[39] one of the counts was based on the Illinois statute covering adulterated foods. The court upheld the count and held that the absence of an intent to place a foreign substance in a container does not make the statute inapplicable.

In *Greenwood v. John R. Thompson Co.*,[40] the court sustained a count which alleged failure to comply with the criminal code and the pure food law.

The only case placing a limiting effect on the charge of violating a food statute is *Welter v. Bowman Dairy Co.*,[41] In this case the plaintiff in the lower court had requested and obtained a jury instruction that a violation of the food statute will constitute negligence on the part of the violator. The court found that the authorities supported "defendant's objection . . . that a violation of a statute is not in and of itself negligence, but merely evidence of negligence." [42]

Most factual situations which will support a count on any other theory will also support a count on violation of the pure food statute. It is therefore recommended that such a count be included in the complaint, if for no other reason than that a charge of violating a criminal statute may well have a beneficial psychological effect on the jury.

II. Questions of Proof

A. Who Manufactured the Product Involved?

While the identity of the manufacturer of the product involved will be clear in the case of most food items, in some situations it presents a very serious problem.[43] With unpackaged or unlabeled items, quite often neither the consumer nor the retailer knows who manufactured or supplied a particular product. This is so because the retailer often buys the same product from more than one source during the same period of time. In the only Illinois food case involving this question, the court held that the defendant did not put into the record sufficient facts to properly raise the question on appeal as to whose product was involved.[44]

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[38] *Id.* at 625.

[39] 108 F.2d 974 (7th Cir.), *cert. denied*, 309 U.S. 688, 60 Sup. Ct. 890 (1940).

[40] 213 Ill. App. 371 (1st Dist. 1919).

[41] 318 Ill. App. 305, 47 N.E.2d 739 (1st Dist. 1943).

[42] *Id.* at 366, 47 N.E.2d at 764.

[43] *Werner v. Armour & Co.*, 320 Pa. 440, 183 Atl. 48 (1936).

[44] *Harris v. Coca-Cola Bottling Co.*, 35 Ill. App. 2d 406, 183 N.E.2d 56 (1st Dist. 1962).

B. Was the Product Contaminated?

1. Foreign Substances and Food Poisoning

The burden is on the plaintiff to establish by competent evidence the poisonous or unwholesome condition of the food.[45] As with the previous question, this question may be very easy or very difficult to answer. Generally, cases involving the presence of a foreign substance present little difficulty. However, in food poisoning cases this may be the most critical factual question in the case. Often there is no sample of the product available for testing. Even if some of the product remains, it may have been mixed with other products [46] or there may have been an opportunity for further contamination after the meal in question was served.[47] Where several foods were eaten, there may also be the question of which food caused the illness.[48]

The one practical suggestion that can be made on this matter of proof of contamination in food poisoning cases is to have an expert bacteriologist examine any available sample and testify. This suggestion applies equally well whether you represent plaintiff or defendant. In the case of *Tornello v. Deligiannis Bros.*,[49] testimony of this type won the case for the plaintiff.

It must be admitted, however, that when the defendant in *Harris v. Coca-Cola Bottling Co.*[50] tried to prove, by expert testimony, that drinking Coca-Cola from a bottle containing a mouse would not cause injury (because the chemical composition of the product would prevent bacteria from growing rapidly), the jury was unconvinced. No doubt juries will continue to manifest a certain skepticism towards this type of testimony.

2. Substances Natural to the Food

Although the supplier is held to an implied warranty regarding the fitness of food for human consumption, the appellate court, in the only Illinois case in point,[51] denied recovery where the substance

[45] *Boulahanis v. Great Atl. & Pac. Tea Co.*, 348 Ill. App. 546, 109 N.E.2d 262 (1st Dist. 1952).

[46] *Bowman v. Woodway Stores, Inc.*, 345 Ill. 110, 177 N.E. 727 (1931).

[47] *Tiffin v. Great Atl. & Pac. Tea Co.*, see footnote 1. See also *Yohalem v. Matalone*, 225 Ill. App. 221 (1st Dist. 1922).

[48] *Shaw v. Swift & Co.*, 351 Ill. App. 135, 114 N.E.2d 330 (1st Dist. 1953).

[49] 180 F.2d 553 (7th Cir. 1950).

[50] 35 Ill. App. 2d 406, 183 N.E.2d 56 (1st Dist. 1962).

[51] Although the case of *Paolinelli v. Dainty Food Mfrs., Inc.*, see footnote 18, involved a bone in chicken noodle soup mix, the question as to whether the bone was a natural substance was not discussed by the court. This case was decided one day before the *Goodwin* case.

found in the food was natural to that type of food. This rule was applied to both the breach of implied warranty and the negligence count. In *Goodwin v. Country Club*,[52] death resulted from an injury to the esophagus caused by a bone contained in creamed chicken. It was found that creamed chicken was customarily prepared from turkey and that the bone involved was a turkey bone. Defendant's motion for a directed verdict was denied; the jury found for the plaintiff. On appeal the defendant, as the first ground for reversal, urged that the presence of a bone which is natural to the type of meat served is not a breach of the implied warranty. The court held:

> The instant case presents a situation involving the question of implied warranty of reasonable fitness of food for human consumption and whether such warranty is breached by the presence therein of a substance natural to the food being served, and not removed therefrom in the process of its preparation for consumption. . . . Although the rule that a restaurant keeper is liable for foreign substances in food served to patrons, and is held to impliedly warrant food to be fit and wholesome to be eaten, is well settled in this State, yet the precise question presented by this appeal presents a new situation. We do not believe the rule as established in this jurisdiction, exceeds an implied warranty that food served shall be wholesome and fit to be eaten. The importance of pure food to the public must not be ignored. Modern conditions require that establishments serving food shall be operated in a sanitary way and furnish food that is wholesome and fit to be eaten. However, such rules should be construed and applied in a reasonable manner, taking into consideration the common experience of life. When viewed in this light, it must be conceded that practically all meat dishes, whether they consist of beef, pork, fish or fowl, do contain bones peculiar to the food being served.
>
> . . .
>
> We are of the opinion the rule upon which appellant bases its first ground for reversal is a sound and well reasoned one, and should prevail in cases of this character.
>
> In view of this situation, appellant's motion for directed verdict was in order. The judgment is therefore reversed.[53]

The court concluded that bone in a meat product is not a foreign substance. Other cases in other jurisdictions have held that other natural substances do not violate the implied warranty of fitness.[54] On the other hand, some courts have held that the question must be decided on the basis of reasonable expectation and that what should be reasonably expected in a food is a jury question.[55]

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[52] 323 Ill. App. 1, 54 N.E.2d 612 (2d Dist. 1944).

[53] *Id.* at 8, 54 N.E.2d at 615-16.

[54] *Mix v. Ingersoll Candy Co.*, 6 Cal. 2d 674, 59 P.2d 144 (1936) (chicken bone in chicken pie); *Brown v. Nebiker*, 229 Iowa 1223, 296 N.W. 366 (1941) (bone in pork chop); *Webster v. Blue Ship Tea Room, Inc.*, 198 N.E.2d 309 (Mass. 1964) (fish bone in fish chowder).

[55] *Wood v. Waldorf System, Inc.*, 79 R.I. 1, 83 A.2d 90 (1951) (bone in chicken soup); *Bonenberger v. Pittsburgh Mercantile Co.*, 345 Pa. 559, 28 A.2d 913 (1942) (oyster shell in oyster stew).

3. Trichina in Pork Products

It is generally recognized that raw pork often contains trichina, a parasite which causes trichinosis. However, the Illinois courts have concluded that the warranty which arises from the sale of raw pork is a warranty that pork is wholesome and fit for human consumption *if it is properly cooked.* In *Zorger v. Hillman's,*[56] the court said:

> The use for which pork is purchased is to eat it cooked, not raw. A number of cases in other jurisdictions involved the scientific facts relating to trichinae and these decisions support our view that pork chops are not sold to be eaten raw, and that the wholesomeness required by our pure food statute means that pork is fit for food when properly cooked.[57]

In the case of *Nicketta v. National Tea Co.,*[58] the court went one step further and took judicial notice of the fact that a person cannot contract trichinosis from properly cooked pork. The higher court sustained the lower court and said:

> [Plaintiffs] also alleged that they purchased the pork from the defendant; that it was properly cooked; that they ate it; and that they acquired or became infested with trichinosis. They alleged a factual impossibility, a fact irrefutable by a well established scientific rule, of which it was the duty of the trial court to take judicial notice, namely, that a human being cannot acquire trichinosis from eating pork which has been properly cooked.[59]

In *Golaris v. Jewel Tea Co.,*[60] the court followed the two previous Illinois trichinosis cases as to (1) the Illinois warranty on trichinosis, and (2) the taking of judicial notice of the effect of proper cooking on trichina. The court did suggest that the Illinois rule limiting the warranty to instances of "proper cooking" was harsh, and observed that requiring "ordinary domestic cooking" instead before the warranty applied "appears to be more nearly consonant with the state of common knowledge regarding pork." [61]

Under the present Illinois law concerning trichinosis contracted from raw pork, it is virtually impossible for the consumer to state a proper cause of action. If, however, a consumer contracts trichinosis from precooked pork, he should be successful in bringing an action against the retailer or manufacturer. While there are no Illinois cases in point, this is the result reached in other jurisdictions.[62]

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[56] 287 Ill. App. 357, 4 N.E.2d 900 (1st Dist. 1936); see also *Wiehardt v. Krey Packing Co.,* 264 Ill. App. 504 (4th Dist. 1932).

[57] 287 Ill. App. at 360, 4 N.E.2d at 901.

[58] 338 Ill. App. 159, 87 N.E.2d 30 (1st Dist. 1949).

[59] *Id.* at 168, 87 N.E.2d 34.

[60] 22 F.R.D. 16 (N.D. Ill. 1958).

[61] *Id.* at 18; *accord, Holt v. Mann,* 294 Mass. 21, 200 N.E. 403 (1936).

[62] *Vaccarezza v. Sanguinetti,* 71 Cal. App. 2d 687, 163 P.2d 470 (1945); *Catalanello v. Cudahy Packing Co.,* 27 N.Y.S.2d 637, *aff'd,* 264 App. Div. 723, 34 N.Y.S.2d 37 (1942).

C. When Did the Product Become Contaminated?

1. Food Cases

Although a manufacturer impliedly warrants that his product is fit for human consumption, the warranty applies as of the time the product leaves his possession. The burden which this imposes upon the plaintiff was set forth by the supreme court in *Tiffin v. Great Atl. & Pac. Tea Co.*:[63]

> However, since a manufacturer's product may pass through many hands before it reaches the ultimate user, public policy does not require the manufacturer to warrant that no one will tamper with or adulterate the food after it leaves his control and before it is received by the consumer, and where a party elects to hold the remote seller liable he must, in the absence of direct evidence of contamination by the manufacturer, prove that there was no opportunity for adulteration after it left the manufacturer's control (in which case there is an inference of contamination by the manufacturer) or, if there was a reasonable opportunity for later tampering, that no tampering or adulteration in fact occurred.[64]

The court went on to hold that since both the retailer and the consumer had an opportunity to contaminate the product in question the plaintiff had not met his burden in this case.[65] It is easy to see that the plaintiff's burden of proof in a suit against the manufacturer is much greater than when his suit is against the retailer from whom he purchased his product.

The question as to when the contamination occurred was emphasized in another Illinois case involving a consumer and a retailer. The Illinois Supreme Court, in *Bowman v. Woodway Stores*,[66] said:

> Assuming for the present purpose that a cause of action is stated in the declaration, there can be no dispute that, to establish liability on the part of the plaintiff in error the evidence must show that the milk, at the time the can was opened, was unfit for human consumption and caused the child's illness and death.
>
> . . . The unwholesome condition of the milk when sold was an essential element to be proved, and the evidence failed in that respect. The court should have instructed the jury to find the plaintiff in error not guilty.[67]

2. Beverage Cases

In beverage cases defendants often raise the question of whether their product was tampered with between the time it left the manufacturer's control and the time it was purchased by the seller. The Illinois courts have adopted a rule covering this situation which is similar to that set forth above in the *Tiffin* case. This rule is described by the court in *Sharpe v. Danville Coca-Cola Bottling Co.*:[68]

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[63] 18 Ill.2d 48, 162 N.E.2d 406 (1959).
[64] *Id.* at 56, 162 N.E.2d at 411.
[65] *Accord, Tornello v. Deligiannis Bros.*, 180 F.2d 553 (7th Cir. 1950).
[66] 345 Ill. 110, 177 N.E. 727 (1931).
[67] *Id.* at 116-17, 177 N.E. at 730.
[68] 9 Ill. App. 2d 175, 132 N.E.2d 442 (3d Dist. 1956).

One who purchases food which is deleterious has a remedy against either the person from whom the food was last purchased or against any prior seller thereof. Where it is sought to recover from a remote seller the plaintiff must assume the burden of proving that the condition of the food at the time it left such seller's control was the same as immediately prior to its consumption, or that it had not been contaminated in the interim.[69]

In *Williams v. Paducah Coca-Cola Bottling Co.*,[70] the method by which plaintiff may meet this required burden is spelled out:

In the type of case we are here considering this burden may be fulfilled in one of two ways, *viz.*: (1) by proof that there was no reasonable opportunity for tampering with the bottle, in which case there is an inference that the bottle was in the same condition as when it left the manufacturer's control; and (2) if the evidence discloses there was reasonable opportunity for tampering, by proof that there actually was no tampering or adulteration. The evidence bearing on these propositions may be direct or may of necessity be circumstantial, but the burden is on the plaintiff.[71]

In the beverage cases involving tampering, we find a variety of results depending upon the facts in each case. In the *Sharpe* case the court, impressed by the fact that there was ample opportunity for tampering and that the Coca-Cola tasted flat when it was opened, held for the defendant. In *Williams,* the court also held for the defendant, stating that there was ample opportunity for tampering and that plaintiff had failed to produce any evidence showing an absence of tampering. In *Heimsoth v. Falstaff Brewing Corp.*,[72] the lower court had granted a motion for defendant at the close of the evidence. The appellate court reversed the lower court and held that the question of whether or not there had been tampering or possible tampering should have gone to the jury. The court was particularly impressed with the fact that the bottle foamed when opened. In *Harris v. Coca-Cola Bottling Co.*,[73] the court held that there was sufficient evidence to raise a question for the jury on whether the bottle of Coca-Cola had been tampered with after it left the control of the defendant. The jury's verdict for the plaintiff, the court concluded, was not against the manifest weight of the evidence. In *Patargias v. Coca-Cola Bottling Co.*,[74] the defense of possible tampering was raised by the defendant; however, the court did not give this possible defense serious consideration:

We do not think that this suggestion is seriously made or intended to be seriously considered, in view of the fact that the bottle of Coca-Cola was sealed with a Coca-Cola cap when it was ordered and taken from the cooler and that

[69] *Id.* at 178, 132 N.E.2d at 444.

[70] 343 Ill. App. 1, 98 N.E.2d 164 (4th Dist. 1951).

[71] *Id.* at 11, 98 N.E.2d at 168.

[72] 1 Ill. App. 2d 28, 116 N.E.2d 193 (4th Dist. 1953).

[73] 35 Ill. App. 2d 406, 183 N.E.2d 56 (1st Dist. 1962).

[74] 332 Ill. App. 117, 74 N.E.2d 162 (1st Dist. 1947).

said cap was removed by the waitress with a bottle opener when the bottle was served to plaintiff.[75]

It would appear that the question of tampering will continue to be raised in most suits by consumers against bottlers. In most cases the plaintiff should, as in the *Harris* case, be able to obtain a jury determination on whether the bottle had been tampered with after it left the control of the defendant.

D. Did the Food in Question Cause the Plaintiff's Illness?

1. General Proof of Proximate Cause

In a food product liability case, it is essential that the plaintiff clearly show a causal connection between his illness and the product involved in the lawsuit. Particularly in a food poisoning case, it is often very difficult to prove that one specific food caused the plaintiff's illness. The court stated the general rule in *Blarjeske v. Thompson's Restaurant Co.*:[76] "The burden was on plaintiffs to show a causal connection between the eating of the roast beef sandwich and their subsequent illnesses. A jury cannot be allowed to determine disputed questions of fact from mere conjecture."[77] In the case of *Shaw v. Swift & Co.*,[78] the court reversed the judgments of the lower court which, it said,

> . . . are predicated upon speculation or conjecture and have no probative force. In the instant case the processor sold a pork product which, so far as the evidence is concerned, was fit for human consumption when properly cooked, as these chitterlings were. The assumption of possible contamination of the chitterlings and hog maw, after they were prepared, is too broad and speculative to permit of the inference by either a court or a jury that Shigella was present in the product when it was purchased.[79]

A case with a more liberal interpretation of the need for evidence of the causal relationship between the food and the illness was that of *Duval v. Coca-Cola Bottling Co.*[80] In this case the court upheld the plaintiff's evidence of causation and stated:

> Defendant contends that there was no testimony to show that plaintiff's sickness was proximately caused by the contents of the bottle of Coca-Cola. It points to the absence of medical testimony and to the likelihood that plaintiff's eating in restaurants and the flight may well have been responsible for his sickness. We think plaintiff's experience was sufficient basis itself for a finding by the jury that the substance which he drank caused his illness.[81]

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[75] *Id.* at 125, 74 N.E.2d at 165-66.

[76] 325 Ill. App. 189, 59 N.E.2d 320 (1st Dist. 1945).

[77] *Id.* at 194-95, 59 N.E.2d at 323.

[78] 351 Ill. App. 135, 114 N.E.2d 330 (1st Dist. 1953).

[79] *Id.* at 145, 114 N.E.2d at 334.

[80] 329 Ill. App. 290, 68 N.E.2d 479 (1st Dist. 1946).

[81] *Id.* at 295, 68 N.E.2d at 481-82.

In this case the plaintiff noticed the mouse in the bottle of coke after drinking part of the bottle and immediately felt ill.

The most recent supreme court case dealing with the proximate cause question in a food case is *Tiffin v. Great Atl. & Pac. Tea Co.*[82] In this case the court said:

> Liability may not be based on imagination, speculation, or mere conjecture, and the question of its existence should be submitted for jury determination only where there is some direct evidence supporting each material allegation of the complaint or some circumstantial evidence from which inference of such facts clearly preponderate. . . . Here, the plaintiffs alleged the ham was unfit for human consumption when sold by A & P, and the burden was upon them to prove it. . . . The evidence which they presented, however, even when considered in its aspects most favorable to the plaintiffs, showed only that the illnesses may have resulted from staphylococci poisoning and that in all probability the ham was the contaminating agent. There was no competent proof that A & P was responsible in any way for this occurrence. Although one could theorize that perhaps the bacteria was present at the time of purchase, and by some means survived the cooking, there are other theories which are equally plausible under the facts of this case, particularly the suggestion that contamination may have occurred while the cooked ham was cooling. Be that as it may, certainly it cannot be said that plaintiffs have established their facts by circumstantial evidence where contrary facts may be inferred from the same evidence with equal certainty.[83]

It is interesting to note that the recent trend in other jurisdictions toward liberal decisions on the question of the standard of proof required of plaintiffs in product liability cases [84] has not, to any appreciable extent, been followed by the Illinois courts in food cases.

2. The Necessity for Medical Evidence

While it will always be advantageous to the plaintiff to have competent medical evidence that the food in question caused his illness, whether such evidence is necessary apparently depends on the particular facts of the case. In *Duncan v. Martin's Restaurant,*[85] the court said: "As to the hypothetical question asked the doctor, it is generally considered necessary to resort to medical testimony to prove a causal connection between the occurrence complained of and the alleged injury or illness." [86] On the other hand, there are two Illinois cases holding that medical evidence is not necessary to prove the causal connection where it is clearly apparent from the illness

[82] Ill. 2d 48, 162 N.E.2d 406 (1959). See text accompanying footnotes 63-65.

[83] *Id.* at 60, 162 N.E.2d at 412-13.

[84] *Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358, 161 A.2d 69 (1960); *Dement v. Olin-Mathieson Chem. Corp.*, 282 F.2d 76 (5th Cir. 1960).

[85] 347 Ill. App. 183, 106 N.E.2d 731 (1st Dist. 1952).

[86] *Id.* at 188, 106 N.E.2d 733; *accord, Blarjeske v. Thompson's Restaurant Co.*, 325 Ill. App. 189, 59 N.E.2d 320 (1st Dist. 1945); *Jensen v. Elgin, Joliet & E. R.*, 15 Ill. App. 2d 559, 147 N.E.2d 204 (1st Dist. 1958).

itself and the circumstances attending it.[87] In both cases the illness occurred very shortly after the individuals had consumed the beverage in question.

In another case, the plaintiff's doctor did not testify but the defendant's attorney on cross-examination brought out from the plaintiff that "he [plaintiff's doctor] told me that the Coca-Cola did make me sick."[88] While this was hearsay, it was brought out by the defendant and the court held the jury had a right to consider it. This appears to be an example of asking one question too many on a cross-examination.

In considering the desirability of having medical testimony, it should be remembered that the symptoms of food poisoning are very similar to those caused by certain virus type illnesses.

3. Evidence of Illness of Others Eating the Same Food

The Illinois cases, which are summarized below, have consistently held that evidence concerning the illness of others consuming the same food product is relevant in proving whether or not a particular meat or particular food caused the plaintiff's illness.

In *Duncan,* evidence that 11 out of 16 guests at a restaurant developed cramps, diarrhea, and vomiting after eating a common meal was sufficient to take the issue of unwholesomeness to the jury. In *Sullivan v. Coca-Cola Bottling Co.,*[89] the fact that the druggist and the plaintiff both became ill after drinking from the same bottle was considered an important fact by the court in affirming a jury verdict for the plaintiff. In the case of *Lowe v. Alton Baking & Catering Co.,*[90] the court said:

> It appears to us entirely proper that the other guests at the banquet should have been permitted to state whether they were or were not affected in the same manner as appellee as bearing upon the question whether such illness was or was not produced by food served at the banquet.[91]

In *Shaw v. Swift & Co.,*[92] testimony was introduced that an entire family became ill, but it was not sufficient evidence to prove that the illness was caused by the defendant's product. Likewise, in the

[87] *Patargias v. Coca-Cola Bottling Co.,* 332 Ill. App. 117, 123, 74 N.E.2d 162 (1947); *Duval v. Coca-Cola Bottling Co.,* 329 Ill. App. 290, 68 N.E.2d 479 (1st Dist. 1946).

[88] *Sullivan v. Coca-Cola Bottling Co.,* 313 Ill. App. 517, 520, 40 N.E.2d 579, 580 (1st Dist. 1942); *cf. Sweany v. Walgreen Co.,* 323 Ill. App. 439, 55 N.E.2d 723 (1st Dist. 1944).

[89] 313 Ill. App. 517, 40 N.E.2d 579 (1st Dist. 1942).

[90] 158 Ill. App. 458 (4th Dist. 1910).

[91] *Id.* at 462.

[92] 351 Ill. App. 135, 114 N.E.2d 330 (1st Dist. 1953).

Blarjeske case,[93] two people testified that they became ill after eating from the same sandwich, but this was not enough evidence of the cause of illness. Although the court in *Duncan* relied heavily on the illness of other individuals, ordinarily this fact is only one among many to be considered in determining if there was sufficient evidence of causation.[94]

E. Proof of Contributory Negligence

There are three reported Illinois cases in which defendants have raised the question of contributory negligence.[95] In each of the three cases the plaintiff continued to eat or drink the product after realizing that there was something wrong with it. In each case, the court let the issue of contributory negligence go to the jury and the jury found the plaintiff not guilty of contributory negligence. On appeal, the procedures and verdicts of the lower courts were upheld. Until now, then, the defense of contributory negligence has not proved of any practical advantage to defendants in food cases.[96]

While logically the defense of contributory negligence should only be available against a negligence count and not an implied warranty count, the Illinois courts have not clearly drawn this distinction. In two[97] of the above three cases warranty and negligence counts were before the court, but no comment was made as to whether contributory negligence was a defense only to the negligence count. There is a split of authority on this question in other jurisdictions.[98]

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[93] 325 Ill. App. 189, 59 N.E.2d 320 (1st Dist. 1945). See text accompanying footnote 76; *cf. Tiffin v. Great Atl. & Pac. Tea Co.*, 18 Ill.2d 48, 162 N.E.2d 406 (1959); *Sweany v. Walgreen Co.*, see footnote 88.

[94] While evidence that others became ill after eating the same food may help the plaintiff's case, evidence that others did not become ill may likewise assist the defendant. See, for example, *Geisness v. Scow Bay Packing Co.*, 16 Wash. 2d 1, 132 P.2d 740 (1942); *Landfield v. Albiani Lunch Co.*, 268 Mass. 528, 168 N.E. 160 (1929); *Schuler v. Union News Co.*, 295 Mass. 350, 4 N.E.2d 465 (1936).

[95] *Patargias v. Coca-Cola Bottling Co.*, see footnote 87; *Duval v. Coca-Cola Bottling Co.*, see footnote 87; *Sloan v. F. W. Woolworth Co.*, 193 Ill. App. 620 (3d Dist. 1915).

[96] See, for example, *Sullivan v. Coca-Cola Bottling Co.*, see footnote 88. In this case the plaintiff continued to drink after noticing a metallic taste. However, the court does not discuss contributory negligence.

[97] *Patargias v. Coca-Cola Bottling Co.*, see footnote 87; *Sloan v. F. W. Woolworth Co.*, see footnote 95.

[98] For cases allowing the defense of contributory negligence against a warranty cause of action, see *Missouri Bag Co. v. Chemical Delinting Co.*, 214 Miss. 13, 58 So. 2d 71 (1952); *Fredendall v. Abraham & Straus, Inc.*, 279 N. Y. 146, 18 N.E.2d 11 (1938); *contra, Walker v. Hickory Packing Co.*, 220 N.C. 158, 16 S.E.2d 668 (1941); *Kassouf v. Lee Bros.*, 26 Cal. Rptr. 276 (Ct. App. 1962).

F. Evidence of Due Care

It is standard defense procedure in a food product liability case to present evidence that the manufacturer exercised due care in the making of the product. This is usually done through testimony of the plant superintendent, and, if available, the federal inspector stationed at the plant. This author is in complete agreement with this procedure. It is interesting, however, to note some comments of the appellate court to evidence of this type.

In *Paolinelli v. Dainty Foods Mfrs.*,[99] the court said: "The fact that the oil was government inspected was proper evidence for the consideration of the jury on the question of negligence. However, it is well established that government inspection is not a substitute for due care."[100] Little objection can be made to the above statement of the court, as a defendant should not be able to avoid liability by delegating his duty of due care.

However, in *Sullivan v. Coca-Cola Bottling Co.*,[101] the court apparently used the testimony of the plant superintendent to support its own conclusion that evidence of the defendant's negligence had been introduced. The court particularly referred to (1) the finding of foreign substances in bottles returned to the plant, (2) inspection at a high rate of speed, and (3) failure to inspect each bottle after filling.

This same viewpoint is more dramatically set forth in the following quotation from *Patargias v. Coca-Cola Bottling Co.*:[102]

> While it is true that no particular act of negligence on the part of the defendant was shown by plaintiff, in the very nature of the case that could not be done. However, it may be fairly inferred from the defendant's own evidence that it did not use reasonable care in inspecting the bottles. The mere fact that it was considered necessary to inspect the bottles for the presence of foreign substances therein after they had been finally discharged from the washer is significant in that it indicates that defendant knew of the likelihood or at least, the possibility of such a substance remaining in a bottle after it had gone through the washer. The fact that defendant's inspectors, whose job was admittedly 'tedious,' were required to examine the bottles for breaks, cracks and foreign substances, after they were washed, at the rate of 264 bottles a minute is hardly consistent with the exercise of due care on its part. As a matter of common knowledge and experience a reasonably careful inspection for breaks and cracks as well as foreign substances could not have been made by an examination of the bottles at the rate of 264 a minute.[103]

In view of the beneficial effect on the trial court and jury, it is suggested that plant witnesses describing the manufacturing process should continue to be used regardless of the above cases.

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[99] 322 Ill. App. 586, 54 N.E.2d 759 (1st Dist. 1944).

[100] *Id.* at 607, 54 N.E.2d at 769.

[101] See footnote 88.

[102] 332 Ill. App. 117, 74 N.E.2d 162 (1st Dist. 1947).

[103] *Id.* at 125, 74 N.E.2d at 166.

The question of whether evidence of due care is admissible as a defense against a warranty count is sometimes raised. However, because most complaints also contain a negligence count, as to which the evidence is admissible, this question does not frequently arise. No Illinois food cases on this point have been found, and there is a split of authority in other jurisdictions as to whether proof of due care is admissible in defense of warranty actions.[104]

III. Food Container Cases

We have already discussed the two container cases which deal with the application of the *res ipsa loquitur* doctrine when possession of the article is no longer in the defendant at the time of the injury.[105] But, probably the most important food container case in Illinois is that of *Crandall v. Stop & Shop, Inc.*[106] In this case the court held that even though there is an implied warranty as to the wholesomeness of food it does not extend to the container in which the food is packed. This means that container cases must be brought in Illinois on a negligence theory.

There have also been two exploding bottle cases in Illinois involving customers in retail stores. In *Kirchoff v. Tzinberg's Park "N" Shop Food Stores,*[107] the bottle exploded when a third party hit the exploding bottle with another bottle. The court held for the defendant retailer, stating that the plaintiff failed to prove the defendant negligent. In *Roper v. Dad's Root Beer Co.,*[108] the customer who was hit by an exploding bottle sued the bottler instead of the retailer. However, the court held for the defendant on the theory that plaintiff did not show an absence of intervening negligence after the bottle left defendant's control.

In both *Crandall* and *Brooks v. Hill-Shaw Co.,*[109] the plaintiffs argued the "inherently dangerous" doctrine with little success. In *Crandall,* the court held that the item in question (a jar lid) was not in fact "inherently dangerous"; while "any innocent article might under some extraordinary circumstances injure a person, yet, this

[104] Evidence admitted, *Conklin v. Ossining Food Center, Inc.*, 48 N.Y.S.2d 716 (Co. Ct. 1944). *Contra, Sharp v. Pittsburgh Coca-Cola Bottling Co.*, 180 Kan. 845, 308 P.2d 150 (1957).

[105] *Roper v. Dad's Root Beer Co.*, 336 Ill. App. 91, 82 N.E.2d 815 (1st Dist. 1948); *Johnson v. Stevens Bldg. Catering Co.*, 323 Ill. App. 212, 55 N.E.2d 550 (1st Dist. 1944).

[106] 288 Ill. App. 543, 6 N.E.2d 685 (1st Dist. 1937).

[107] 7 Ill. App. 2d 201, 129 N.E.2d 279 (4th Dist. 1955).

[108] 336 Ill. App. 91, 82 N.E.2d 815 (1st Dist. 1948).

[109] 117 F.2d 682 (7th Cir. 1941).

does not render the article itself inherently and imminently dangerous." [110] In the *Brooks* case, the court held that even if the item in question (a coffee pot) was inherently dangerous, it did not follow that the manufacturer was liable, as it must also be shown that his negligence caused the accident.

A review of all the container cases shows that most of the decisions have been for the defendant. It would appear much more difficult, regardless of what theory of recovery is used, to win a container case than one involving food or beverage.[111]

IV. Conclusion

The Illinois courts have followed the current trend in the United States of allowing recovery in food cases on an implied warranty theory without regard to privity. Illinois has also allowed recovery on a negligence theory and has been liberal in applying the doctrine of *res ipsa loquitur* to food cases. In the natural-substances-in-food cases and in the trichinosis cases the Illinois courts have adopted a conservative policy. Finally, the most important observation which can be made from reviewing the Illinois cases is that the courts have resisted any relaxation in the standard of proof required of plaintiffs.

Applying the above conclusions to a typical food products liability case in Illinois, a plaintiff should plead in the alternative, using separate counts for implied warranty, negligence, and violation of the pure food statute. When it comes to the various questions of proof discussed in the second section of this article, plaintiff should remember that the Illinois courts will require strict proof of all essential facts. It is in this area that a well prepared defendant has the best opportunity to obtain a favorable result. **[The End]**

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[110] 288 Ill. App. at 549, 6 N.E.2d at 687, quoting from *Miller v. Sears, Roebuck & Co.*, 250 Ill. App. 340, 344-45 (1st Dist. 1928).

[111] For two additional Illinois food cases, see *Seymour v. Union News Co.*, 349 Ill. App. 197, 110 N.E.2d 475 (1st Dist. 1953), holding that the two-year statute of limitation applies to suit by consumer against restaurant for serving unwholesome food; *Barbour v. Great Atl. & Pac. Tea Co.*, 143 F. Supp. 506 (E.D. Ill. 1956), holding that where a married woman has recovered damages for personal injuries, the husband also has a separate cause of action for loss of wife's services.

Latin-American Food Code 1964 Edition

In August of 1964 the Latin-American Food Code Council Published the Second Edition of the Latin-American Food Code. Information Concerning the Latin-American Food Code and a Table of Contents for the Entire Code Appear in 20 *Food Drug Cosmetic Law Journal* 238 (April, 1965). The First Five Chapters of the Code Are Published Here; Remaining Chapters Will Be Published in Future Issues. The Translation Is by Ann M. Wolf of New York City.

Chapter I: General Provisions

Article 1.—Any person, commercial firm or establishment that manufactures, packs, holds, transports, sells, exhibits or handles foods or household articles or the raw materials used in such products, shall comply with the provisions contained in this Code.

Article 2.—Any foods and household articles, and any raw materials used in the same, which are manufactured, packed, held, transported, sold or exhibited shall meet the requirements of this Code. Their sale shall be authorized by the competent health authority, not in any case by police authorities or organizations formed under private law.

Article 3.—Any process not specifically mentioned in this Code as either standard or optional shall be lawful if it does not modify the composition of the product; does not introduce undesirable or prohibited extraneous elements capable of endangering the health of the consumer or reducing the nutritive value of the product; and does not change the constituent elements to an extent exceeding that of natural causes.

Article 4.—Any term defined in one section of this Code shall have the same meaning in any other section in which it is used.

Article 5.—The following definitions are hereby established for the purposes of this Code:

1. *Consumer:* Any person, group of persons, firm or institution that procures foods for personal consumption or for consumption by others.

2. *Natural Product,* or *Product in its Natural State:* Any product from which no constituent has been abstracted and which has its original appearance, without ostensible changes in its composition.

3. *Food:* Any natural or artificial, processed or unprocessed product which, when ingested, provides men and animals with the substances and energy their bodies require to perform the biological processes. By extension, the term "food" shall further mean any substances which, regardless of whether or not they have nutritive qualities, are added to foods and dishes as correctives or additives; or the consumption of which is customary or pleasurable and takes place with or without a nutritional purpose. Therefore, whenever reference is made in this Code to "foods," the term means not only solid, liquid or gaseous food products, but also the raw materials used in the same and any additives added to improve their appearance, color, aroma, preservation, etc., such as acidulants, alkalizers, anti-ebullition agents, antioxidants, aromatics, colors, sweeteners, emulsifiers, stabilizers, foam producers, anti-foaming agents, hydrolizers, preservatives, flavors, etc.

The designation *"ingredient"* refers not to the chemical components, but to the food elements used in the preparation of a product.

4. *Genuine, Standard* or *Legal Product:* This term when applied to a food means any product which complies with the legal specifications, has been prepared under hygienic conditions, does not contain any pathogens, unauthorized substances or additives representing an adulteration and is sold under its legal name and labeling, without any legends, signs or designs which may be misleading with respect to its origin, nature or quality. Such products are prohibited from being called "pure."

5. Illegal or non-standard foods:

a. *Misbranded Food:* Any food which without being the legitimate product, has the appearance and general characteristics of a legitimate product that may be protected by a registered trademark, and is sold under the name of such legitimate product; or any product which does not come from the true manufacturer and zone of production known and/or declared.

b. *Spoiled Food:* Any food the intrinsic composition of which has suffered damage, deterioration or injury from natural causes, such as humidity, temperature, air, light, enzymes, micro-organisms, or parasites.

c. *Contaminated Food:* Any food manufactured, handled or packed under insanitary conditions, or containing undesirable, obnoxious or poisonous mineral or organic inpurities. The term covers also any food manufactured from animals affected with a disease the agents of which may appear in the product, except in cases specifically authorized by the official veterinary inspection authorities.

d. *Adulterated Food:* Any food the valuable constituents or characteristic nutritive principles of which have been abstracted, in whole or in part, and replaced by inert or extraneous ingredients, or foods to which an excessive amount of water or other filler has been added, or which have been artificially colored or artificially treated in order to conceal spoilage, objectionable manufacturing processes, or inferior raw materials, or to which unauthorized substances have been added, or the composition, quality or other characteristics of which do not correspond to the name and description under which the product is sold.

"Extraneous elements" or *"foreign substances"* in a food ready for consumption are any substances which, under this Code, are neither constituent elements nor approved harmless ingredients. (Technical additives used to stabilize, preserve, flavor, aromatize, or color.)

e. *Injurious Product:* Any product which, for some reason, contains added or natural substances injurious to the health of the consumer. In certain circumstances, the illegal products listed hereinbefore may also be injurious.

Article 6.—Substances or ingredients (additives) not authorized under this Code, or under complementary provisions issued by the health authorities, are prohibited from being added to foods and beverages. Additives must have the proper degree of purity or nutritive properties and must be added to the food or beverage at the time of processing or preparation in the proportion required for the intended and authorized purpose; they may not be

added later to conceal, reduce the effects of or correct flaws in the manufacture, handling or preservation.

Article 7.—Only additives which have been subjected to pharmacological tests shall be recognized as innocuous or safe, provided that:

a. Such tests have been conducted on different animal species, testing the effects of the additive during the whole life-span of each animal, and over several generations;

b. Concentrations of up to 100 times the technically useful amount are found to be harmless;

c. The additive has been tested not only separately, but also as used in the food product for which it is intended.

Article 8.—The use of an additive in a food or beverage shall be permitted only:

a. For economic and sanitary reasons, to improve and/or maintain its suitability for consumption: to prevent fatty products from getting rancid; to preserve the potability of drinking water, and as prophylaxis against endemic diseases;

b. To prevent the loss of valuable substances: vitamins, oligo-elements, essential fatty acids, essential amino acids, etc.;

c. To restore valuable elements which have disappeared or have been reduced appreciably during processing or preparation;

d. For organoleptic reasons, or to give the product a better appearance (psycho-sensorial factors);

e. For technical reasons: stabilizers, clarifiers, buffers, emulsifiers, foam preventers, acidulants, alkalizers, anti-ebullition agents, thickeners, flavors, aromatics, flavor and/or aroma strengtheners, protective substances, hydrolizers, etc.;

f. For reasons due to unexpected precarious events, such as social unrest, strikes, war, droughts, floods, fires, earthquakes.

Article 9.—The addition to a food or beverage of an additive shall not be permitted when:

a. It appreciably reduces the nutritive value or abstracts an important element;

b. It causes, or may cause losses of valuable nutritive elements;

c. It permits the concealment of a defective or inadequate technique;

d. It may mislead the consumer about the true quality of the product, and may mislead the analyst and thus distort analysis results;

e. It can be avoided or replaced by the use of an adequate technique, greater hygienic precautions, more practical processes, ventilation, refrigeration, etc.

Article 10.—All authorized *additives* must have a well-defined composition and the purity degree required for their use in foods; they shall be sold under a scientific or technological name (not in any case under a registered trademark), and simple and practical quality and quantity tests of such additives must have been conducted by the manufacturer or seller.

Article 11.—When an official technical department serves notice of having detected in a food or beverage a substance not permitted under this Code or a complementary provision, such notice shall not be legally valid unless it states at the same time the method employed for such detection, which method, if it is not official, must have been published in a scientific publication to be named.

Article 12.—All *food inspectors* must be sworn by the competent authority faithfully to perform their duties and not to reveal or use to their personal advantage what they come to know by virtue of their office.

Article 13.—The term *"food poisoning"* means a pathological process caused not only by spoiled food, but also by the ingestion of foods of no matter what origin which, notwithstanding their normal appearance, contain products injurious to the body. Physicians who treat such cases of poisoning are obligated to report them immediately to the local health authority in order that the same may adopt the necessary measures, for which purpose the physicians shall give whatever information they deem helpful.

Article 14.—Articles prepared in one country which imitate the products of another shall be prepared in accordance with the processes used in the home country and meet the character-

istics of the original products (Port, Malaga, Marsala, etc. wines; Roquefort, Gruyère, etc. cheeses).

Article 15.—In advertising food products (by word of mouth, over the radio, on television, or in writing) the definitions and other requirements of this Code shall be respected. The composition, properties, qualities, effects and nutritive value of dietetic products may be advertised only with the written approval of the competent authority.

Alcoholic beverages are prohibited from being advertised as providing stimulation, well-being or other sensations, in the same manner as the smoking of filter cigarettes or the use of filter cigarette-holders is not permitted to be encouraged by advertisements nourishing the belief that with filters the pleasure of smoking is harmless.

Article 16.—The countries which adopt this Code shall issue broader supplementary local provisions in a body of regulations which may be named a "Food Code" or "Bromatological Code."

Article 17.—The presence of the metals and metalloids (*accidental or residual additives*) listed hereinafter shall be tolerated in foods (with the exception of drinking water, fish and shellfish), provided that they occur naturally and do not exceed the following limits:

Aluminum	Maximum:	250 parts per million
Antimony	Maximum:	20 parts per million
Arsenic:		
Liquid	Maximum:	0.1 part per million
Solid	Maximum:	1 part per million
Barium	Maximum:	500 parts per million
Boron	Maximum:	100 parts per million
Cadmium	Maximum:	5 parts per million
Zinc	Maximum:	100 parts per million
Copper	Maximum:	10 parts per million
Tin	Maximum:	500 parts per million
Fluorine	Maximum:	1.5 parts per million
Iron	Maximum:	500 parts per million
Mercury	Maximum:	0.05 parts per million

Nickel	Maximum:	150 parts per million
Silver	Maximum:	1 part per million
Lead:		
Liquid	Maximum:	2 parts per million
Solid	Maximum:	20 parts per million
Selenium:		
Liquid	Maximum:	0.05 parts per million
Solid	Maximum:	0.3 parts per million

A canned product is allowed to contain a larger than standard amount of iron due to its association with the container, provided that the container is not swollen and that in every other respect the product meets the requirements that make it suitable for consumption.

With regard to the amounts of *pesticide chemicals* tolerated in foods, see Articles 771, 772 and 773 of this Code.

In special cases, the health authorities may allow exceptions to the limits fixed above, when the food is not consumed in its natural state (boron in cacao beans), is consumed in small quantities (copper in nuts and red pepper, lead in oysters, etc.) or during processing undergoes transformations which render it less harmful.

Article 18.—Persons who prepare foods and beverages intended for export may add to the same substances not authorized under this Code, always provided that they can prove that such substances are permitted in the country of destination.

Chapter II: General Requirements for Food Factories and Food Outlets

General Rules

Article 19.—The name *"Food Factory"* means any establishment in which foods are processed, manufactured, or packed.

The name *"Food Outlet"* means any business enterprise in which foods are held, packaged, or sold for consumption by the public.

Article 20.—Food factories and food outlets may be installed and operated only after a permit has been obtained from the competent health authorities, which permit shall be re-

newed whenever the factory or outlet is moved; when expansions take place which entail fundamental changes; or when there is a change in the name of the proprietor or company.

Article 21.—As a general rule, foods are prohibited from being extracted, processed, manufactured, handled, stored, packed or sold on premises which, because of their size, temperature, lack of light, ventilation, or other hygienic conditions, are unsuitable for such purposes.

Such premises shall meet the following general sanitary requirements:

1. They shall be kept perfectly clean at all times and may not be used as dwelling or sleeping quarters, or as passageways leading to dwelling or sleeping quarters.

2. Smoking shall not be permitted in factories and rooms in which foods are handled, nor may such premises be used to keep products that yield odors susceptible of being absorbed by foods.

3. If unpackaged foods are handled or stored in rooms which connect with the outside and for this reason cannot be kept insect-free, all openings shall be provided with devices preventing the entry of insects.

4. Finished products, raw materials, and containers shall be kept on adequate stands or shelves, and stacked products shall be placed on stands or raised platforms.

5. In rooms in which foods are processed, only the raw materials necessary therefor may be kept, but no other products, articles, implements or materials.

6. If products returned to a plant because of faulty processing or poor preservation are kept there for more than 48 working hours, their presence will be interpreted as an intention to use them (reprocessing, correction, resterilization, etc.). No argument will be accepted to justify it, for which reason their possession will always be penalized, without prejudice to the confiscation and destruction of the products.

7. Companies which own establishments, plants, and factories shall be liable for any product released for sale with manufacturing defects or in defective containers and shall be obligated to take any precautions necessary to prevent such occurrences. If such defects can be proved, no excuse intended to reduce or shift this liability will be accepted.

Companies shall also make sure that the processes or methods used to prepare food products be satisfactory from the sanitary point of view, with the proviso that any batch of merchandise proved to have been prepared under unsatisfactory sanitary conditions, or in violation of the provisions in force, shall be seized forthwith.

8. Establishments, plants, factories, warehouses, wholesale and retail groceries and shipping depots handling food products which are located within city limits are not permitted to communicate directly with stables for horses, animal breeding places or other similar establishments which are considered as jeopardizing the safety of the foods.

9. All basements shall be well ventilated and lighted and shall be accessible easily and safely. Their walls, floors, and ceilings shall be protected against humidity by a waterproof material.

10. Foods may not under any circumstances be stored on premises which do not comply with the requirements fixed for such purpose.

11. Companies which own establishments, plants, factories, warehouses, wholesale and retail groceries and shipping depots for food products must fight the presence of rodents and insects on such premises. Negligence in this connection will be subject to penalties.

12. All premises occupied by establishments, plants, factories, warehouses, wholesale and retail groceries, and shipping depots for food products shall be equipped with faucets for drinking water, with the sinks necessary to wash containers, etc., and with drains connected with the sewer system or regulatory cesspools. They shall always be kept in a state of good repair, appearance, and cleanliness and shall have waterproof floors. The health authority may order the premises to be cleaned, whitewashed or painted whenever it deems it advisable, and wherever necessary may also order the walls to be waterproofed up to a height of 1.80 meters. All machinery, utensils, and other materials shall likewise be kept in a satisfactory sanitary condition.

13. All food outlets selling products easily spoiled by heat shall have refrigeration equipment for their preservation.

14. Foods packed in bulk may be repacked only at the time of sale, directly from the original container and in front of the purchaser.

15. Kerosene, soap, disinfectant fluids and similar products packed in bulk containers shall be kept in adequate places, separate from foods, even if they are sold in their original containers.

Article 22.—Industrialists and merchants are obligated to make available to official inspection agents whatever data such agents require in their line of duty and any elements and samples of raw materials and finished products which the agents may request for analyses and checks.

Article 23.—All workers and employees of food factories and food outlets shall at all times take good care of their personal hygiene, to which end the owners of such establishments shall provide the necessary installations and equipment such as: wardrobes and wash basins with soap and a sanitary dryer; drinking water dispensers (fountain, tank, barrel, etc.), the number and capacity of which shall be proportionate to the number of persons using them; toilets, separated from the work rooms, with waterproof floors and walls waterproofed up to a height of 1.80 meters. Hands shall be washed with water and soap each time the toilet is used; employees shall be so instructed by permanently posted signs.

Persons employed in food factories and food outlets, no matter in what capacity, shall be permitted to enter and work in such establishments only if they are in possession of a health certificate issued to them by the competent authority. This obligation applies also to owners who participate in person in the activities of the establishment, regardless of the type of activity in which they engage. All health certificates shall be kept in the administrative department of the establishment and be available for exhibition to the official inspectors upon request. This requirement does not apply to employees who work outside the establishment, who shall always carry their health certificates with them.

The first certificate shall state the results of the chest X-rays and examination of the faeces.

In addition, any persons employed to handle and serve foods in grocery stores, bread shops, pastry shops, pantries, delicatessens, butter shops, beverage outlets, lunch counters, candy shops, restaurants and similar establishments, luncheonettes, bakeries, oyster bars, tea rooms, cocktail lounges, pizzerias, kitchens, factories preparing fritters, meat pies and sandwiches, milk bars, ice shops, ice cream parlors, etc., shall wear uniforms (blouses, smocks or aprons) and washable white or cream colored caps; in butcher shops, vegetable shops, fruit shops, markets and food and beverage factories (canned foods, jams, biscuits, sausages, etc.), the wearing of white aprons or smocks and

caps is compulsory. In special cases, the use of dark aprons or grey, blue or khaki overalls may be permitted. These pieces of clothing must at all times be kept in a perfect condition of repair and cleanliness.

Moreover, female personnel shall wear hair nets and shall not be permitted to use nail polish or wear jewelry of any kind.

Ambient Air

Article 24.—The composition of the ambient air on any closed premises inhabited or occupied by humans shall meet the following specifications:

Carbon dioxide	Maximum:	1,500 parts per million
Carbon monoxide	Maximum:	200 parts per million
Hydrochloric acid	Maximum:	100 parts per million
Fluorine	Maximum:	2.5 parts per million
Ammonia	Maximum:	50 parts per million
Hydrogen sulfide	Maximum:	0.15 parts per million
Sulfur dioxide	Maximum:	20 parts per million
Chlorine and bromide	Maximum:	2 parts per million
Carbon sulfide	Maximum:	0.1 part per million

Other harmful substances: none:

With regard to the radioelements of the uranium and thorium series that may be found in the air one breathes, the following limits, expressed as muCi per liter shall be permitted: U^{238} — 0'0003; Th^{232} — 0'002; Ra^{226} — 0'0000008; Rn^{222} — 0'1; Pb^{210} — 0'4.

Kitchens and Dining Rooms

Article 25.—*Kitchens:* The kitchens of bars, chophouses, canteens, eating houses, guest houses, clubs, grills, restaurants, boarding houses, hotels, inns, etc., shall be of a size proportionate to the size of the establishment and shall meet the following requirements:

1. They shall be well aired and ventilated; floors shall be made of a waterproof material approved by the competent authority and walls shall be wainscotted with a similar material up to a height of not less than 1.80 meters.

2. All openings shall be equipped with automatic shutters and metal or plastic screens to prevent the entry of insects.

3. All brick ranges or ovens shall be covered with a suitable material, except for their upper part (called top) which may be made of steel, colored tile of the type known as "Marseilles tile" or a similar material.

4. They shall have a sufficient number of sinks large enough to wash the working utensils, with an adequate running water supply and drains connected with the sewer system or regulatory cesspool and open sewers. These sinks may not under any circumstances be used to launder clothes. Each sink shall have two drain basins, one for the dirty pots, dishes and other utensils, and the other for clean material. With regard to the utensils, see Articles 58 to 77.

5. Chimneys, ranges, and ovens shall be installed and operated in accordance with the provisions in force on this subject matter.

6. No objects other than kitchen utensils, working gadgets, and the products required for the daily meals may be kept in kitchens, where they shall be placed in a manner safeguarding their sanitary condition.

7. The products to be used in the preparation of meals shall be stored in a suitable separate room; vegetables shall be kept on racks protected by metal or plastic screens; meat shall be kept in insect-proof containers ("fiambreras"), refrigerators, or refrigeration chambers, and fish and shellfish likewise in refrigerators or refrigeration chambers.

8. During the hours when meals are prepared, no sawdust may be on kitchen floors, except for small quantities around the stoves.

9. When the ambient air in kitchens does not meet the requirements fixed in Article 24 of this Code, exhaust fans shall be installed in sufficient numbers, this being compulsory in tropical climates.

10. Garbage and trash shall be disposed of in suitable cans provided with lids, to be emptied with the necessary frequency. Raw garbage may not be used to feed hogs.

11. All persons working in kitchens, pastry shops, and ice cream parlors shall wear clothing suitable for their jobs, which clothing shall be kept perfectly clean at all times. In no case, and under no circumstances, may clothes be changed in said work rooms. Bus boys, waiters, and kitchen personnel are prohibited from carrying cleaning rags under their arms or on their shoulders. Employees who wait on the public or handle food may not be employed to clean the premises, urinals, toilets, floors, furniture, spittoons, etc., the cleaning of which shall be left exclusively to the cleaning men.

Article 26.—In establishments in which meals are prepared, such meals once prepared may not be kept for more than 24 hours. Left-overs may never be used to prepare new dishes, but shall immediately be thrown into the garbage cans. The term "left-overs" means any remnants of food not eaten by patrons which go back on the plates. Portions of food which come back from the tables may not be used to be served to patrons; if they are to be kept for other purposes, this shall be done in a separate room set aside for this purpose.

Dishes which are usually kept semi-cooked (spaghetti, rice, boiled vegetables, etc.) shall be consumed within 24 hours after cooking time. Only raw materials to be used in the kitchen (meat, fruits, eggs, milk, butter, cold cuts, etc.), mayonnaise and similar products, as well as dressings (except "tuco"*) and beverages may be kept in refrigerators. Any products found to be in violation of this article shall be destroyed forthwith, without prejudice to the imposition of the respective penalties.

Article 27.—Kitchens of first and second class hotels and restaurants shall have the following facilities:

1. A refrigeration chamber and antechamber meeting the conditions set forth in Articles 44 ff. of this Code.

2. Separate rooms which meet the legal requirements to pluck fowl, clean vegetables, prepare pastry, ice cream, coffee, and serve as pantry.

3. Garbage incinerators wherever the city or state does not provide for garbage collection.

Kitchens are prohibited from being installed in basements, with the proviso that basement kitchens existing upon the entrance into effect of this Code may remain in use.

Kitchens built on the ground floor of buildings may not have openings to the street. Such kitchens may receive light from the street only through sealed windows.

Article 28.—Dining rooms: Any rooms to be used as dining rooms in hotels, clubs, guest houses and other establishments as mentioned in Article 25 hereof shall have sufficient natural ventilation, space, and light to meet the requirements of this Code.

*Note of the Translator:
A type of spaghetti sauce.

Walls must be plastered, whitewashed, painted with oil paint, or covered with stucco. The use of wallpaper shall be permitted, provided that the wallpaper is attached directly to the plaster above a panel of wood, or another suitable material, not less than 1 meter high. Floors shall be covered with mosaic, tile, linoleum, parquet, or another authorized material. Ceilings shall be made of cement, plaster, metal, fiber-cement, plastered arches, masonry, or another authorized material.

Toilets shall be separate for each sex, in numbers proportionate to the number of tables of the establishment. They shall be provided with toilet paper and comply with all other requirements. They shall be disinfected daily and be cleaned as often as necessary to keep them perfectly clean at all times. The wash basins shall be supplied with liquid soap or soap powder, hot and cold water and paper towels, or another type of dryer, the use of another type of soap being prohibited.

Article 29.—Products which violate this Code in their composition, make-up, labeling, or for any other reason, are prohibited from being kept and/or used in restaurants, eating houses, confectionery shops, bars, and similar establishments. Products found to violate this Code will be seized forthwith, without prejudice to the imposition of the respective penalties.

Bread, bread sticks and other bread products served in restaurants, eating houses and similar establishments must be in their original hermetically sealed wrappers.

Article 30.—Waiters and other persons who wait on the public shall wear clean and proper clothing and enjoy good health, which must be evidenced by an official certificate. They may not carry cleaning rags on their shoulders or under their arms or use the same to wipe off perspiration.

Employees who wait on the public, handle foods and beverages, or wash dishes may not be employed to clean the premises, urinals, toilets, floors, spittoons and furniture, the cleaning of which shall be left exclusively to the cleaning men.

Minors are not permitted to be hired to wait on patrons in factories, kitchens, diners, luncheonettes, and similar establishments.

Open Air Markets

Article 31.—All products sold at open air markets shall be grouped by kinds, exhibited on wood or metal stands or platforms and maintained in a state of good preservation and cleanliness.

They are definitely prohibited from being kept on a level with the sidewalk or street and from being exposed to the sun and flies. Moreover, at least one pair of scales shall be available to the public to permit it to check the weight of the merchandise purchased by it.

Live fowl sold at stands shall be kept in cages large enough to prevent the birds from suffering, and a supply of clean water shall be held available for them.

Injured, diseased, or dead birds shall be taken out of the cage and may not be sold for human consumption.

Article 32.—Vendors shall wear white blouses or dusters, and aprons which shall be kept perfectly clean and shall, as the products, comply with all other requirements of this Code.

For reasons of hygiene (contamination by street dust, handling, etc.), products such as butter, cold cuts, canned tomatoes, jams, etc., which are ingested without previous washing or cooking are prohibited from being packed at open air markets but shall be taken to the market already packaged as provided for by the regulations. Fruit stands shall display signs reading: "For reasons of hygiene, please do not touch the fruit."

Kiosks and Stationary Vehicles

Article 33.—The terms *"Kiosk"* or *"Cart"* mean small retail stands or counters set up in booths, halls that open to the street, and hallways, or as annexes to business establishments of various kinds.

Such *Kiosks* and *Stationary Vehicles* may sell foods in their original get-up, beverages prepared by licensed plants, shellfish, cigarettes, and other goods, such sales to be handled by different vendors for different types of goods. Stands that sell meat pies, fritters and hot sandwiches shall be provided with the devices required to prevent the smoke and odors from reaching the public. Stands which sell fruit juices or fruit sections shall not be permitted to keep them for periods of more than 24 hours from the time of their preparation and shall sell the beverages in wax paper cups, to be kept in sanitary tubes or a similar device that protects them from contamination. The water supply and elimination system for such kiosks and stationary vehicles shall be governed in each case by the local food or health regulations. They shall also satisfy the other requirements of this Code. Persons who fail to comply with these requirements shall be subject to the respective penalties.

Markets, Supermarkets and Groceries

Article 34.—Markets, Supermarkets, and Groceries shall comply with the following requirements, in addition to the general rules provided for in this Code:

1. They shall be large enough to accommodate the greatest prospective number of patrons.

2. They shall have the regulatory installations for the different sales stands; separate garbage deposits, and a running water supply and drainage system, for each stand, all of which shall be kept in a state of good repair, painting, and cleanliness.

3. Indoor aisles and indoor and outdoor sidewalks shall have waterproof floors.

4. Products the preparation of which requires frying or cooking on stoves are prohibited from being prepared indoors without a special permit from the health authorities.

5. Market premises are prohibited from being used as sleeping or dwelling quarters.

Public Auctions of Food Products

Article 35.—Public auctions or sales of the food products, the bromatological conditions of which are regulated by this Code, shall be subject to the following requirements:

1. All products must have been inspected and approved by the competent health authority; otherwise, they shall be withdrawn from the sale or confiscated, without prejudice to the imposition of the respective penalties.

2. Applications to perform the inspection referred to in the preceding paragraph shall be accompanied by an itemized inventory of the merchandise to be sold that specifies the brands of products, their nature and quantities for each lot, stating the different container sizes if the products come in containers.

3. While the auction goes on, a copy of the inventory referred to in paragraph 2 hereof shall be exhibited to the public. This copy shall be signed by the persons responsible for the sale and bear the stamp of approval of the health authority with a statement that the merchandise is suitable for consumption by the standards fixed in this Code.

4. The premises on which public food auctions are held shall be kept in good sanitary condition.

5. The products to be auctioned are prohibited from being repacked or refilled on the premises referred to in the preceding paragraph.

Itinerant Distributors and Vendors

Article 36.—In general, foods and beverages are prohibited from being sold by itinerant vendors with the exception of fruits, vegetables, and the following products: candy bars, peanuts, corn, almonds, soft drinks, pastry, crackers and cookies, meat pies, sandwiches, hard candy, chocolates, wafers, and ice creams, provided that said products are sold in their original factory get-up, that their sale has been authorized by the health authority, and that they come from inspected factories.

Fruit juices, coffee, tea, mate, milk and cocoa may likewise be sold by itinerant vendors provided that the beverages are kept in refrigerators or thermos containers and are dispensed in wax paper cups or similar containers which shall be kept in sanitary tubes. The cups shall be destroyed after use. The health authority may also, in special cases and at its discretion, permit the sale by itinerant vendors of other products, such as fish, etc.

All vendors shall wear uniforms (blouses, dusters and aprons, preferably white) which shall be kept in a state of perfect cleanliness. They shall display on their uniforms the badge issued to them by the health authority as proof of their being licensed vendors, without which they are not permitted to sell any merchandise. In addition they shall hold a health certificate from the health authority, which they shall carry with them at all times and present to the inspectors whenever asked to do so. Said health certificates can never be valid for more than six months.

Article 37.—In the interest of hygiene and the better protection of the consumer, delivery men making home deliveries of foods and beverages shall carry the same in the original wrappers used by the firm for which they work. As itinerant vendors, they shall wear uniforms (blouses, aprons, and dusters) and caps (preferably of a light color) which shall be perfectly clean, and they shall also hold health certificates issued to them by the health authority, on the same conditions as set forth in the preceding article.

Article 38.—The carts, baskets, cases, hampers and other receptacles used by delivery men and itinerant vendors of foods and beverages shall not only be suitable for the use made of them, but shall also at all times be in a state of perfect repair and cleanliness and be provided with the devices required to protect the merchandise (canvas, cover, lid, etc.). The health authority may require itinerant vendors to have storage rooms for their products if the nature of the products makes this advisable.

Home Deliveries of Meals

Article 39.—The preparation of meals for delivery to homes shall take place under perfect hygienic conditions, using food products which, in accordance with this Code, are suitable for consumption, a staff provided with health certificates, and thermos equipment or food carriers made of a suitable material and kept in a state of perfect repair and cleanliness.

Article 40.—Families who prepare in their private homes meals for delivery to outsiders whose number does not exceed six a day (or 12 meals) shall not be considered *eating houses,* but shall report to the health authority that they engage in the supply of cooked food for pay. They shall permit health inspectors to enter their homes in order to inspect the kitchens and to check whether the persons engaged in the preparation of the foods and the raw materials used in the preparation of the meals comply with the requirements of this Code.

Suppliers of Meals

Article 41.—*Eating houses* and *boarding houses* shall register with the health authority.

Article 42.—Eating houses, boarding houses, inns, restaurants, grills, hotels, and private individuals engaged in the preparation of meals for home delivery shall make sure that the transportation of the food takes place under hygienic conditions, by delivery men who satisfy the requirements of this Code. They shall be liable to the health authority for any violation proved.

The fats in which foods are cooked must be found suitable for consumption whenever they are inspected and are not permitted to be used after they have undergone ten hours of heating.

Chapter III: The Storing, Preservation and Processing of Foods

Article 43.—Foods may be preserved by physical methods (heat, refrigeration, filtration, acoustic, electric or neon waves, radiation, ionizing radiation, cathodic rays, gamma rays, etc.); physico-chemical methods (smoking and the action of certain metals, such as silver); chemical methods (elimination of air and substitution of inert gas, authorized anti-fermentation agents, such as kitchen salt, oil, vinegar, ethyl alcohol, antibiotics), and biological methods (antibiotic or antagonistic bacteria). Any product sold as "pasteurized" or "sterilized" must have undergone the type of preservation process named after it was packed in a hermetic container at the place of origin.

Although the term "sterilization" means the removal or killing of all live elements present, it means, from the technological point of view, the removal or killing of all pathogenic bacteria and most non-pathogenic micro-organisms. To prevent confusion, such technological sterilization is usually distinguished by the name "sanitation" and the act of performing it by the verb "to sanitize."

The term "antibiotic" means any non-toxic substance, minimal quantities of which are capable of inhibiting the development of micro-organisms. Residues of antibiotics in amounts not exceeding 7 p.p.m. may be present in raw foods to be consumed cooked, and in ice to be used for the preservation of fish products, after a special permit has been obtained in each case from the health authorities. Preference should be given to antibiotics with a full spectrum, such as tetracyclines, etc., which can be destroyed by heat at a temperature of 100° C., and such others as the health authorities may authorize in the future.

Refrigeration Chambers

Article 44.—The term "Refrigeration Chamber" means a closed room in which foods are preserved by means of artificial cold.

All food products stored in refrigeration chambers are presumed to be destined for human consumption. Any foods found unfit for human consumption shall be confiscated immediately, therefore.

All refrigeration chambers shall be disinfected at least once a year. Their inside temperature may not under any circumstances

exceed the temperature required for the various types of foods to be preserved. The chambers, as well as any utensils and equipment used in them, shall be maintained perfectly clean and tidy, and under no circumstances may food products be kept next to articles of another kind. The chambers shall be provided with good lighting to facilitate the control of the food products stored in them.

Refrigeration chambers shall have a good ventilation system, so that the air inside them may be renewed whenever necessary to keep it as pure as possible and at a hygrometric degree which may vary between 60 and 95 percent.

Refrigeration chambers and appliances may be put into use only after inspection and approval by the health authority and shall be subject to official control at all times. All refrigeration chambers shall have a thermometer recording maximum and minimum temperatures, and a hydrometer.

Article 45.—As a general rule, meats (including domestic and wild fowl) shall, before being stored in refrigeration chambers used also for other animal products, be kept for some time in an antechamber, which shall likewise be relatively cold.

Carcasses may be put into the chamber only if they are in a perfect state of preservation. They shall be hung on a line of hooks so as to remain separate from each other, and shall not touch the floor or walls of the chamber.

Fish may be put into it only if it is perfectly clean, well preserved and properly spaced.

The cases in which fish, eggs, fruit and other food products are packed shall always be perfectly clean. They shall be placed on shelves or boards spaced so as to permit the cold air to circulate freely, and with enough space between them to allow easy passage and control.

Frozen meats, once defrosted, and refrigerated meats, domestic and wild fowl, and eggs, once taken out of the refrigeration chamber and exposed for some time to room temperature, are strictly prohibited from being returned to the refrigeration chamber, except when they were removed to be shipped or transferred to other refrigeration chambers.

Article 46.—In general, artificial cold may be used to preserve perishable products of animal and vegetable origin, provided that it is employed in compliance with the requirements of this Code.

Article 47.—Failure to comply with the operating requirements fixed by the health authority shall result in a temporary injunction or the confiscation of the goods found in the refrigeration chamber for as long as their fitness for consumption has not been clearly established, without prejudice to the imposition of penalties for such failure.

Article 48.—Substances, products, etc., not destined for the purposes for which refrigeration chambers and antechambers are intended are strictly prohibited from being stored in the same.

Preserved Foods in General

Article 49.—The term "preserved food" means any product of an animal or vegetable origin used for purposes of nutrition which, having undergone adequate processing for sale in hermetically sealed containers, retains its principal properties and remains suitable for consumption for some time.

Preserved foods sold in tin-plate cans are usually distinguished by the name "canned goods."

The name "semi-preserved foods" means perishable foods, got up or packed so as to ensure limited preservation: fresh cheeses, jams, tomato preserves, spaghetti sauces, vegetables, and super-frozen dishes, etc., in containers of cardboard, aluminum, plastic, etc. The temperature at which they shall be kept shall be marked on the container, i.e. in an ordinary refrigerator at not above 10° C., or in a special cooler etc., not below -18° C., depending upon the product.

Article 50.—Plants which prepare preserved and semi-preserved foods shall comply with the general rules and the following special requirements:

1. All departments in which food products are received, processed, and packaged shall have a waterproof floor and a waterproof wainscott not less than 1.80 meters high. They shall, whenever inspected, be found in a state of perfect repair, operation and cleanliness.

2. Containers are prohibited from being filled by way of submersion in the product to be preserved. The re-use in association with foods of residues of brines, juices, syrups, oils, sauces, etc., obtained during canning operations is likewise prohibited when such residues are not fit for consumption.

3. All batches of preserved foods shall be kept under observation for not less than six days before being released for circulation.

4. After sterilizing preserved foods, particularly canned vegetables, the cans shall after leaving the autoclave be cooled for not more than five hours in order to overcome the danger zone in which heat-resistant germs proliferate.

Article 51.—Preserved or semi-preserved foods are prohibited from being manufactured:

1. In establishments not licensed by the health authority or in which the pertinent rules of hygiene are not being observed.

2. From substances which are spoiled, damaged, contaminated, poorly preserved or lacking nutritive properties, or which for some reason are not fit for consumption.

3. By way of processes which fail to meet the necessary sanitary requirements or do not guarantee the perfect preservation of the product.

4. With substances or containers prohibited under this Code and/or by the health authority.

Article 52.—As a general rule, preserved and semi-preserved foods shall meet the following requirements:

1. Their organoleptic and morphological characteristics shall not differ appreciably from the original characteristics of the same product when cooked (meats, vegetables, fruits).

2. Their containers, labeling, and contents shall comply with the provisions of this Code. The labeling may be affixed only within the plants, and manufacturers are prohibited from sending out labels to be affixed to containers outside their establishments. Preserves which contain more than one product shall be labeled "Mixed Preserves," "Mixed Jams" etc., and their components shall be mentioned individually in decreasing order of quantity. Exempted from this require-

ment are mixed preparations sold under the name of a special dish, such as "stuffed cabbage," "ragout," etc.

3. They shall not contain harmful amounts of pathogenic bacteria, dangerous toxines, or other products derived from a bacterial action, especially hystamine.

4. They shall not contain extraneous matters, prohibited ingredients, toxic metals or metalloids in amounts exceeding the tolerances fixed in Article 17 hereof, calculated on the solid product.

5. They shall be in a state of perfect preservation and shall not react to ammonium or sulphur compounds (Eber). Canned meats (corned beef, tongue, hash, etc.) may contain slight traces of hydrogen sulfide. As an exception, incipient darkening may be tolerated in canned crustaceans, always provided that it is due to the formation of ferrosoferric polysulfides.

6. The salt used (except in canned fish and shellfish) shall contain not more than 5% of saltpeter (potassium or sodium nitrate) or more than 0.4% of sodium nitrite.

7. They may not contain any organic or mineral substance capable of reducing the commercial or nutritive value of the product, or an excessive amount of condiments intended to conceal defects of the raw materials used in their preparation.

8. In special cases, as determined by the health authorities, their labeling shall include the month and the year of canning, to be stamped clearly on the principal label or engraved on the closure.

9. Containers shall be filled with the largest possible quantity of canned product and shall not contain excessive amounts of sauce, or cooking or covering liquid.

Article 53.—The term "frosted" may be applied to any product preserved by cold treatment, regardless of the process used. However, products may only be marketed as:

a. *Refrigerated:* if they are refrigerated products none of whose parts has reached the freezing point;

b. *Frozen:* if they are products whose temperature throughout has been reduced below freezing and which remain frozen until they are sold to the public;

c. *Quick frozen or superfrozen:* raw products (vegetables, fruits and fruit by-products, meat and meat by-products, etc.) or precooked products (ready dinners) which meet all the requirements imposed by the application of the quick freezing technique in its various stages until they are sold to the public. The raw materials used shall be suitable for consumption. The time within which the temperature of the products is dropped from 0° C. to -40° C. shall not exceed two hours, and the time required to continue the process down to a preservation temperature of -18° C., or lower, shall not exceed four hours. Only products processed in this fashion may be distributed and sold as quick frozen. The purchaser shall be warned that these products may not be kept at room temperature like ordinary canned food. Superfrozen products must be kept at a temperature of -18° C. from the moment they leave the plant to the time of purchase by the consumer.

Article 54.—Foods dehydrated at a low temperature in a vacuum, in the absence of oxygen, are considered lyophilized or criodried foods.

Article 55.—The distribution, holding and sale of spoiled preserved or semi-preserved foods is prohibited. Any preserved or semi-preserved foods stored, exhibited or sold which have been prepared by a not officially licensed plant shall be seized forthwith, without prejudice to the imposition of the respective penalties.

Disinfestation of Foods

Article 56.—The preventive or active disinfestation of cereals, vegetables, fresh and dried fruits is permitted, provided that the following requirements are complied with:

1. Except for the presence of insects or mites, the products must be in a state of good preservation.

2. The disinfestation shall take place in suitable installations, preferably first in a vacuum, and by means of processes authorized by the health authorities.

3. Immediately after disinfestation, the products shall undergo a physical or mechanical treatment which assures the removal of any impurities of parasitic origin and the disinfestant.

4. The provisions contained in Articles 772, 773 and 774 of this Code must have been complied with.*

Article 57.—The substances or physical processes used for disinfestation may not alter the purity, natural composition, or physico-chemical nature of the nutritive principles contained in the food treated. Any poisonous substances used to remove live insects must be removable easily by simple subsequent airing.

The following substances may be used as disinfestants: technically pure carbon sulfide, sulfur dioxide, carbon tetrachloride, ethylene oxide, methyl bromide, methyl formate, and such other substances as the health authorities may authorize in the future.

Hydrogen cyanide treatment shall be permitted only at plants which have special installations and special personnel available for such treatment, and only in specific cases.

The use of the following disinfestants is prohibited: p-dichlorobenzene and carbon disulfide for flours; hydrocyanic acid and ethylene oxide for fresh fruit; carbon disulfide for fatty products, and gammexane for cereals. See Article 773.

Chapter IV: Utensils, Receptacles, Containers, Wrappers, Machinery, and Accessories

Article 58.—All utensils, receptacles, containers, wrappers, machinery parts, pipes, and accessories that come into contact with foods must at all times be in perfect hygienic condition, be made of or coated with materials practically impervious to the product, and not yield harmful substances or substances capable of contaminating or modifying the organoleptic characteristics of the food. These requirements apply also to linings, which must be unbroken and continuous and practically impervious to the products used in their sanitation.

The use of the following materials shall be permitted without first obtaining an authorization:

1. Stainless steel, steel, cast iron, all of which may be coated with technically pure tin, and chromium-plated iron;

* Note of the Translator: Provisions on fumigants and chemical pesticides.

2. Copper, brass, or bronze, lined with a coating of technically pure gold, silver, nickel, chromium, or tin. Such lining shall not be required for the boilers, vessels, and kettles used to cook jams and sugar syrups, for mortars, pans of balances, and weights;

3. Technically pure tin, nickel, chromium, aluminum or other metals, or alloys thereof with harmless metals;

4. Virgin tin plate;

5. Glazed or enamelled iron which, when exposed to acids, does not yield lead or other harmful compounds, provided that it is kept in a good condition of preservation;

6. Cookware of different metals with a non-stick coating of pure polytetrafluoroethylene (Teflon, Fluon, etc.) which permits the frying of foods without fat;

7. Ceramic materials, baked clay with an inside glazing which, when exposed to acids, do not yield lead or other harmful compounds, glass, crystal, marble, and nonodorous woods;

8. Pasteboard, cardboard, paper, or substitutes therefor; vegetable or animal, artificial (with a base of regenerated cellulose) or synthetic (polyester, polyamides, polypropylene, polyethylene, etc.) fiber fabrics, waterproofed or non-waterproofed, with or without the protective agents authorized by this Code or the health authority; sulfurized papers, papers containing antioxidants, fungicides, etc.;

9. Paper coated with wax, stearin or paraffin, and parchment or parchment-like paper, free from boric acid, formol, or other preservatives (particularly when used for dairy products), paper impregnated with 20% of a nonodorous mineral oil (only to wrap fruit);

10. Pulp prepared from various flours, fatty materials, mineral salts, and other substances the use of which is permitted. For the manufacture of ice cream containers, borax may be added in amounts of up to 0.5 grams per kilogram of pulp or board;

11. Gum or rubber or substitutes therefor, free from harmful metals, which must not yield generally toxic substances;

12. Plastics (polyethylene, polyvynil, polyamides and similar products) which do not yield harmful substances;

13. Cloths made of artificial or synthetic vegetable or animal fibers, plain, or waterproofed with harmless substances. When used

for hams and sowbelly, these cloths may be coated with petroleum tar; the use of coal tar or other tars which have a phenol or anthracene reaction, or an acid or alkaline reaction, is prohibited;

14. Such other materials as the health authorities may approve.

Galvanized iron or zinc-plated iron is generally prohibited from being used in association with foods or raw materials for foods, except at meat markets. The food industry shall be granted a term of ten years from the date of promulgation hereof within which to replace these materials. Once this term has elapsed establishments preparing or handling food products shall be prohibited from using machines or utensils made of materials containing them.

In the same manner, containers, pipes, utensils and any devices or implements used in association with foods are prohibited from being coated with cadmium.

Article 59.—Substances which come into contact with foods (metals, plastics, etc.) may not impart to the same any metals or metalloids in amounts exceeding the limits fixed in Article 17 of this Code, or other substances considered toxic.

The tin plate intended for canning foods and raw materials used in foods shall meet the following requirements:

a. *Containers whose inside has not been varnished or enamelled:* electrolytic tin plate may be used with a tin coating of not less than 11 g/m^2 between the two sides (equivalent to a minimum nominal tin weight of 0.50 lb./BB).

b. *Containers whose inside has been varnished or enamelled:* for liquid products, electrolytic tin plate may be used with a tin coating of not less than 5.6 g/m^2 between the two sides (equivalent to a minimum nominal tin weight of 0.25 lb./BB). For products in powder form, or relatively dry products, electrolytic tin plate may be used with a tin coating of not less than 3.1 g/m^2 between the two sides (equivalent to a minimum nominal tin weight of 0.14 lb./BB), or a simple plate covered with a protective layer of varnish.

The surface of all enamelled, lacquered, or varnished materials must be covered completely in accordance with the best technological practice suitable for the product to be packed and must not impart metal or metalloids in a proportion exceeding the limits fixed in Article 17 of this Code, or other elements considered injurious.

Article 60.—Whenever this is considered necessary, the inside of metal containers may be protected with varnishes, lacquers, enamels, or other coatings or protective treatments that meet the requirements of this Code.

Only the following substances may be present in varnishes and plastics intended for use in association with foods:

a. Natural or synthetic resins and/or insoluble polymers which do not react to foods;

b. Solvents having a boiling point of less than 150° C., or other solvents the complete elimination of which in the finished product is assured;

c. Plasticizers: paraffin oil, castor oil, glycerine, diethylene glycol, triethylene glycol, propylene glycol, stearates and ricinoleates of ethyl, butyl, amyl, and metals which do not impart toxic substances; benzobutylamide, dioctyl phtalate, glycerol triheptanoate, octyl sebasate and adipate, tributyl acetylcitrate, heptyl and nonyl double phtalate, etc.;

d. Stabilizers: hexamethylenetetramine; diphenyl thiourea, urea, sodium sulfonate, sodium alkylsulfonate, alkyl naphthalene, cobalt and manganese resinates;

e. Pigments: colors authorized under this Code;

f. Improving agents or fillers: talcum, mica, titanium oxide, sawdust, siliceous earth, and other inert bodies the use of which is permitted;

g. Other materials specifically authorized by the health authorities;

h. Moreover, varnishes and plastics must, when subjected to commercial canning tests, react satisfactorily, i.e. must not change the organoleptic properties of the food to be canned.

Article 61.—Only safe colors may be used to paint, decorate, and enamel the containers, household, commercial, or industrial utensils and other materials mentioned in the preceding articles. The use of dyes containing antimony, arsenic, barium, cadmium, copper, chromium, mercury, lead, uranium, or zinc in soluble form is prohibited.

Article 62.—The varnishes sold to protect the inside of tanks used for drinking water must be impervious to potable water and chlorinated water and are not permitted to contain: antimony, arsenic, barium, copper, mercury, lead, zinc, or cobalt in a proportion exceeding 1 percent by weight.

Article 63.—The inside weldings of, and the substances employed to weld, containers, utensils, and accessories used in association with foods or beverages must meet the purity standards fixed in Article 59 hereof. Outside weldings and the substances used therefor may have any amount of impurities.

Article 64.—The canning industry shall use preferably mechanical closures (rivets); any rubber or rubber substitute packings used may contain talcum, chalk, magnesium, and other harmless products, but must seal the cans hermetically without breaks in the continuity.

Article 65.—The closures of containers of foods and beverages may be made of the following materials:

1. Technically pure tin (canned products), except for cans to be used for evaporated milk and similar products which, to permit the sealing of the pouring perforations, may be welded with tin lead;

2. Virgin cork and cork substitutes (plastics, etc.) which do not yield injurious substances;

3. Virgin rubber and rubber substitutes which do not yield injurious substances;

4. Metal, tin-plated, varnished, enamelled or ceramic caps mounted on rings made of cork, rubber, or substitutes therefor which are free from injurious substances;

5. Metal caps (crown corks and similar closures) which have on the inside a disk made of cork, aluminum, tin or another metal, or plastic, or a special lining, none of which must impart injurious substances to the bottled product;

6. Glass, porcelain or such other suitable materials as the competent health authority may approve;

7. Electric thermo-welding in the case of plastic containers.

Article 66.—Containers for precooked and superfrozen dishes must meet the following requirements:

a. Any material used for such containers must not have any flavor or odor, must not color the contents or affect it in any way.

b. It must not prevent the elimination of heat during the freezing process.

c. It must be moisture-proof and not soften when in contact with liquid ingredients or sauces, and must not react in any way to additives.

d. It must not crack at low temperatures (-45° C.).

e. It must be used easily.

f. It must not stick to the contents.

g. It must be impervious to fatty substances and not swell when in contact therewith.

h. It must permit heating in a water bath or directly on a burner.

As an exception to Article 64, aluminum containers used for precooked or superfrozen foods may have a closure affixed by a simple border or overlapping border.

Article 67.—Industrialists, merchants, or representatives are strictly prohibited from using receptacles or containers which bear legends or trademarks belonging to other products that circulate on the market, or which were used previously for products not coming from the manufacturer or merchant who uses them, with the special exceptions fixed in this Code. Such receptacles and containers, as well as containers with a chipped neck, shall be confiscated immediately.

Article 68.—The air in containers may be replaced by an inert gas, such as nitrogen, carbon dioxide, or other gases permitted by the competent authority. This operation need not be declared in the labeling.

Article 69.—Returned containers, with the exception of siphons which are provided for in Article 458, may be re-used, provided that they can be sanitized properly before re-use and do not bear trademarks or other legends belonging to other firms or commercial products. Such containers must be cleaned thoroughly and must be disposed of when, due to prolonged use, they are oxidated, stained, or deformed, or when they can no longer be identified properly.

Article 70.—Foods are prohibited from being manufactured, held, and sold if they are in direct contact with:

1. Printed paper;

2. Used or stained paper, burlap, fabric, cellophane or similar materials;

3. Paper containing harmful products, or products the use of which is prohibited, such as: plaster, alum, baryta, synthetic resins, coal tar and anthracene by-products, aniline dyes not permitted by the competent health authority, unauthorized preservatives, etc.;

4. Papers colored with vegetable or synthetic dyes the use of which is permitted, which rub off easily, however;

5. Lead paper or tin foil containing lead or antimony in amounts of more than 1 percent or arsenic in amounts of more than 0.01 percent;

6. Cardboard, paper, cork, and substitutes therefor which are not of virgin grade.

Any products which violate this article shall be considered unsuitable for consumption and shall be confiscated immediately, without prejudice to the imposition of penalties.

Article 71.—Food products exhibited for sale or shipped for sale to the public must be protected from every possible contamination (dust, mud, insects, etc.); unpacked foods may be handled only by authorized personnel in possession of health certificates. Any paper in direct contact with foods must be virgin grade paper and comply with the requirements fixed in the preceding article.

Article 72.—Lead or tin foil containing too much lead, and papers dyed with aniline dyes which are considered harmful, but do not rub off easily may be used, provided that a sheet of white or waterproof paper, as the case may be, is placed between them and the food.

Article 73.—In wrappers for sausages, chocolate, bonbons, hard candy, etc., the tin or aluminum foil may be replaced by colorless cellophanes, emerosin, cephalin, pure cellulose sheeting, cellophanes, and similar products, plastics (resins and resin compounds) and other authorized substances which do not yield substances considered toxic.

Article 74.—Receptacles which originally or at some time have been in contact with products other than foods, or are incompatible with foods, are prohibited from being used for food products. Moreover, food and beverage receptacles are prohibited from being sealed with used caps, and industrial products are prohibited from being packed in food containers.

Article 75.—The granulated metals, small shot or bird shot used to clean receptacles and containers intended for foods, beverages and the raw materials used therein must not yield substances considered toxic.

The sponges, woolen rags and metal pads used to clean receptacles, containers and utensils intended to contain or come into contact with foods and beverages must not yield any substances considered toxic.

The only detergents permitted to be used to clean premises on which foods and beverages are prepared, kitchen utensils, containers and dishes are detergents with a base of sodium lauryl sulfate, sodium alkyl-amyl sulfonate and similar substances.

Article 76.—Containers, utensils, and other elements to be used in association with foods may be disinfected only with chemicals that cannot affect the foods or produce toxic effects. After disinfection they must be thoroughly rinsed with large amounts of potable water the active chlorine content of which may not exceed 5 to 10 p.p.m., or steamed.

Article 77.—At confectionery shops, bars, hotels, restaurants, eating houses, hostelries, beverage outlets, cocktail lounges, dairies, cafeterias, and similar establishments, the dishes, silverware, plates, cups, glasses, and goblets must first be washed under running water and then for two minutes be disinfected with boiling water and/or steam, or immersed for at least twenty seconds in a solution containing free chloride in an amount of 60 p.p.m. The sterilization may also be effected by way of another authorized chemical or physical method. Whenever glasses, goblets and cups are not sterilized, only utensils may be employed which are used only once and are made of one of the materials mentioned in Article 58 of this Code.

Dishes, plates, cups, glasses, and goblets which are cracked or have chipped rims are not permitted to be used and must be destroyed. The use of wooden plates, jars, and cups is prohibited.

Chapter V: Labeling

Article 78.—The term "labeling" means any inscription, legend, or marking printed upon, affixed to or engraved upon a product or the container or wrapping in which it is marketed to identify the product in accordance with the laws in force and the provisions contained in this Code.

Article 79.—Any food product which circulates in commerce or is held for sale shall have a clearly visible label in the national language which states:

1. The designation of the product and its nature, or the exact composition if the product is a mixture. For the purposes of this provision, the term "mixture" means any product that consists of elements or commercial articles of a different composition, class or species, in which case the composition shall be declared in the labeling, for instance as follows: Mustard with curcuma and sugar; torrone made of almonds, honey and sugar. On the other hand, if vegetable oils, wines, ciders, neutral alcohols, etc. are mixed or combined with each other in different proportions to obtain a better balanced product and/or maintain its characteristics practically uniform or constant, the resultant mixture is considered a "cut" and in such cases, the composition need not be declared, as is true also for generic names defined in this Code, unless there exist specific requirements to the contrary.

2. The measure, size, weight, or net volume of each unit, expressed in accordance with the decimal metric system. For this purpose, the term "gross weight" means the weight of the container plus the contents; the term "tare," the weight of the container, including the closure; the term "total contents," the difference between gross weight and tare; the term "net weight," in the case of homogeneous products (fruit juices, sauces, tomato extracts, etc.) the total contents, and in the case of heterogeneous products, if the liquid medium is consumed as part of the product (oil, sauce, broth, starch, or even brine if it can be used) the net contents is also the total contents; but if the liquid medium is not usually consumed (olives in salt water, chilies in vinegar, etc.), one must weigh the edible part,

separate it through a sieve and deduct the tare to obtain the net contents to be declared.

3. The name of the manufacturing establishment or the manufacturer or seller, and the place of manufacture. If the product has been imported, the place of origin of the merchandise and the name and domicile of the importer, packer, distributor, or seller. Moreover, it shall bear the clearly visible legend "Product of . . ." (name of the country).

4. All other indications required by the laws and regulations in force and/or by the present Code.

Article 80.—The names of fruits, foods, and other articles originating in a certain country shall be stated in their national language. In addition, translations may be given if this is considered practical, but such translations may not appear in a form or in letters more prominent than the markings written in the national language. Any symbols or designs used must always correspond to the products packed and the quality offered.

Expressions and references which may be confusing or misleading, or expressions intended to suggest distinctions which do not exist, are prohibited from being used on labels, in business papers and advertisements directed to foods and beverages through modern media of communication (press, radio, television, motion pictures, posters, billboards, etc.)

Article 81.—To prevent deception or confusion, receptacles used to store foods shall bear inscriptions stating clearly and visibly the exact name of the food, as defined in the present Code.

Article 82.—Without prejudice to the right to employ registered trademarks, it shall not be possible to justify the use of any false, exaggerated, or misleading statement in any part of the labeling by quoting the opinion of a technician or specialist, or by explaining the reasons why such statement was used.

Article 83.—Artificial products are not permitted to have in their labeling any symbols or designs which represent raw materials of natural products.

Any artificial product not clearly marked as such for the benefit of the purchaser will be considered as mislabeled.

Article 84.—Labels of food products may not bear any statements relative to medicinal or therapeutic properties. Products which bear statements of this kind or are exhibited for sale with a claim to curative properties shall be considered "medicinal specialties" and as such shall require the approval of the competent health authority.

Article 85.—As a general rule, geographic names of a country, region or town may not be used to designate products manufactured elsewhere when this may be deceiving. Exceptions to this rule are made for foreign geographic names which, through usage, have become generic for certain articles and for this reason are no longer considered indications of origin, such as: French bread, Parmesan cheese, French Vermouth, Roquefort cheese, Indian sauce, English sauce, Portuguese sauce, and other names that may be approved. Products (wines, cheeses and others) are prohibited from being designated by geographic names when they have not been prepared in the particular region or locality.

Article 86.—Containers the contents of which may spoil once the container is opened, shall have a warning statement on the principal or a secondary label to the effect that the product must be consumed immediately, or that once the container is opened (in the case of a canned product), any contents left over must be kept in a container of glass, ceramics or plastic.

[The end of Chapter V.]

ANTIBIOTIC EXPERIENCE RECORDS NOW GENERALLY REQUIRED

Regulation § 146.14 requiring maintenance of records and filing of reports on clinical and other experience with antibiotic drugs has been adopted by the FDA. The regulation is of general application, having been adpoted pursuant to Sec. 507(g)(1) of the Federal Food, Drug and Cosmetic Act.

Persons engaged in manufacturing, compounding, processing, packing or labeling any antibiotic for which a certificate or release has been issued must maintain required records and file reports at specified times. Information required includes clinical and animal experience, studies, investigations, and tests; copies of all advertising used in the drug's promotion; unexpected side effects or sensitivity reactions; and information concerning any unusual failure of a drug to exhibit expected pharmacological activity.

The full text of Regulation § 146.14 is reported in FOOD DRUG COSMETIC LAW REPORTS ¶ 74,264.

RESOLUTIONS ADOPTED BY THE FOOD DRUG AND COSMETIC LAW SECTION OF THE INTER-AMERICAN BAR ASSOCIATION

The following resolutions were adopted by the Section at a meeting in San Juan, Puerto Rico, in November, 1964. They were approved by the Inter-American Bar Association Council on November 27, 1964:

1. Proposals have been made in some countries of the Western Hemisphere to virtually abrogate drug patents by requiring compulsory licensing of these patents, whether or not the product to which the patents relate is adequately marketed in the country concerned. If enacted such legislation will greatly diminish the significance of patent rights relating to pharmaceuticals. In consequence they will (1) Reduce the value of patents in stimulating the discovery and marketing of future pharmaceuticals; (2) Curtail the influence of patents in encouraging local manufacture, local employment and the development of local skills and know-how; and (3) Increase the emigration of scientists from such countries to those countries where their work will be better recognized and protected through patents.

The results are contrary to the well-being and continued economic progress of the countries of the Western Hemisphere. Additionally, these proposals involve an undesirable distinction between patents for pharmaceuticals and patents in other fields, which is contrary to the desirable state of the law.

NOW, THEREFORE, the Council of the Inter-American Bar Association recommends that drug patents like all patents receive equal and effective protection.

2. BELIEVING that the public interest is best served by stimulating research and development and the discovery of new remedies for the diseases that afflict mankind, and that the sale of drug products at a reduced price, commonly referred to as "Social Medicines," should therefore be restricted to government institutions or organizations rendering free medical service, and that such products should meet the same standards of quality and purity as other products;

NOW, THEREFORE, the Council of the Inter-American Bar Association recommends that "Social Medicines" should bear the manufacturer's name; trademark, if any; code or batch number; and a seal similar to that used on free samples; and that unauthorized sales should be prevented by appropriate prosecution;

AND FURTHER RECOMMENDS that at the present time the best way to maintain the safety of our most prized possession "health" is by maintaining and in some cases strengthening patent protection as a spur to industry to make bigger and more important discoveries.

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