In order to appraise properly the legal and economic aspects of chemical additives in dairy products, it is desirable to have a perspective of the origin and role of dairy products in the American diet. Relatively few staple foods are processed into as many useful forms as is milk. Milk is wholly useable as food. It may be converted into many forms such as cheese, butter, evaporated and condensed milk, skimmed milk, cream, ice cream and frozen desserts, dehydrated products, and so on. There are many forms of fractionated products. It has been reported over 500 varieties of cheese are made using only milk, rennin, microorganisms and salt. In these many forms, milk solids have been adopted for nutrition of all ages of man. The annual per capita consumption of milk by man in the United States is about 1,700 pounds. The annual per capita consumption of fluid milk equivalent is about 700 pounds. Thus the form and character of dairy products is important in the American diet.

Not all milk produced is consumed in the form into which it is processed. Milk and milk products have great versatility as an ingredient in many food products: in bakery goods, cereals, soups, sauces, spreads, dressings, and so on. Many dairy product derivatives are processed especially for functional uses in food products. The synthesis properties of milk and its components with other ingredients is of great importance in the food industry.

Although fluid milk is one of the most perishable of foods, it is processed into forms that have relatively long commercial stability. Unlike many other foods, milk and its products vary greatly from season to season. Nearly twice as much is produced in the spring as in the fall. Current production of milk in the United States is approximately 125 billion pounds annually, equivalent to 748 pounds per capita. The tremendous quantities of flush and surplus production is stored in processed form for use in periods of lesser production.

The storage qualities of dairy products are important in surplus commodity storage. Of the 125 billion pounds of milk produced in 1956 with a farm value of 4.5 billion dollars, 4.1 per cent or the equivalent of 5.1 billion pounds with a farm value of 1.84 billion dollars were represented in purchases by the government in price support programs. The purchases in 1956 included 165 million pounds of butter, 188 million pounds of American cheese, and 754 million pounds of nonfat dry milk solids. Much of this was involved in long periods of storage.

The processing of milk involves in nearly every case, adjustments in the ratio of its major components: in some cases the components are concentrated, in others fractionated or altered in proportions. These changes affect not only physical form, but also physico-chemical properties and behavior. Each of the applied processing modifications usually affects in some way the critical behavior of at least one of the components: fermentation, acidification, neutralization, salting, dilution, concentration, crystallization, homogenization, emulsification, dispersion, aeration, whipping, aggregation, separation, agglomeration, gelation, bleaching, coagulation, vaporization, and so on. Obviously, many of these treatments are affected by both incidental and intentional additives, and, in many instances, are achieved only by their use.

The legal aspects of chemical additives in dairy products should be appraised in the light of historical precedent. The waning decade of the last century in the United States was one of a gradual development of urban areas swelled by immigrants. The mortality of infants was high, in part because of insanitary conditions, lack of pediatric knowledge, and because of unwholesome milk. From this developed a legal concept of the necessity for local supervision of the quality and composition of milk. This concept is in use in virtually every community in the country today. Thus there prevails, by local fiat, regulations governing the sanitary and gross chemical composition of milk, and of its related products, in every community. The regulations in adjacent communities, and elsewhere, may vary in sufficient respect to prevent the ready interchange of milk and its related products among them. The barriers to interchange were long ago apparent. Beginning in 1923, the U. S. Public Health Service developed and made available a Recommended Milk Ordinance and Code to serve as a pattern for uniformity of regulations. Several major revision issues of the Recommended Ordinance and Code have been made in the interim. A major portion of the total bottled milk supply of this country is
today produced, processed and marketed under the provisions of this ordinance, or of those in principle much like it. In a similar manner, the statutory issues and regulations of many states developed under a concept of necessity of local supervision for milk and its products in many states have been frequently very different, and in many instances confounding. The Recommended Milk Ordinance and Code has been adopted per se, or in principle, by a number of states.

In 1951, the National Conference on Interstate Milk Shipments was established for the purpose of enabling certification of rating and acceptance of fresh milk for intershipment of milk between states. In a recent period some 20,800 shipments involving 304,000,000 pounds of milk were interchanged among states on the basis of the Conference agreements. The Conference, participated in by regulatory officials of 34 states and the District, has adopted the Recommended Milk Ordinance and Code, or its principle, as the basis for certification rating of milk supplies. In like manner, a Conference on Intrastate Milk Shipments was established in 1956 in Wisconsin to enable ready interchange of milk and processed milk products between cities within the state.

Prior to 1940, the qualification of the sanitary sufficiency of design of milk processing equipment was subject to approval of local health departments. The concept of adequacy of sanitary design of equipment was almost as varied as the number of departments. For a period of years, virtually all equipment used in processing milk and similar products was, in effect, custom-made. Such equipment could not be moved intercompany, intercommunity, or interstate without custom inspection of farm or factory. The cost of custom manufacture, and multiple inspections obviously were prohibitive. In many instances processing plants have been subject to as many as 15 - 25 separate inspections annually by regulatory officials representing various communities and states. Frequently procedures or equipment mandatory by one were prohibited by another. Subsequent to 1940 there had been developed what is now known as the 3A Sanitary Standards for Dairy Equipment. These have been developed through joint effort of the Dairy Industry Committee representing product and equipment manufacturers associations, the U.S. Public Health Service, and the International Association of Milk and Food Sanitarians. Standards have been established for some 30 categories of processing equipment. This concept of sanitary design standards is being patterned in other foods industries.

In the light of the historical sequence in the development of regulatory standards for milk at the local level, it should be apparent there has been a serious and zealous intent to protect the inherently good qualities and characteristics of milk. Born of an era of dilution of milk by water, doctoring by simple preservatives, in a period of a great strife to eradicate a rampant cattle tuberculosis, within a period of development of mechanical refrigeration, pasteurization, and of the transition from farm to factory dairy production, it is not surprising that regulatory concepts traditionally have been cool to necessity of functional additives in dairy products. It may appear that regulations covering the sanitary qualities of milk and its products are beyond the realm of subject of chemical additives, but they definitely are not. Virtually all city and state ordinances or regulations for sanitary standards of fluid milk and its related products contain definitions of each of the specific dairy products. Thus there exists a set of standards of identity which are inviolable, and preclude modification by additives.

The 1906 act covering foods required a long period of some 30 years before its final formulation as the Heyburn bill and adoption by Congress. Among reasons for delay in the passage of such a bill was the strong political movement for protection of states rights, and the implication that the philosophy of caveat emptor should prevail. Among the problems of that period were the need for (a) a uniform law in supervision of foods, (b) need for specific control of various forms of adulteration, and (c) the relatively limited supervision over foods in a number of states. It was within the period of this act that many states established varying standards not only in quality but also in composition of manufactured dairy products. Once established, any exceptions have been only painfully undertaken. The 1938 Federal Act undertook not only the establishment of the integrity of foods, but several distinctive objectives which affect dairy products, including: (a) it prohibits traffic in foods which may be injurious to health in contrast to the previous provision which prohibited injurious food only when a poisonous substance was added; (b) it specifically prohibits the addition of poisons to foods with defined exemptions; (c) it specifically requires label declaration of the presence of artificial coloring, artificial flavoring, and chemicals present in the foods, but specifically exempts butter, cheese and ice cream from the requirement on artificial coloring; (d) it provides for promulgation of standards of identity and of fill of containers of foods, although, butter was specifically exempted in this provision but was included by statutory reference; (e) it requires that labels for foods for which no definition or standards of identity have been promulgated bear the common or usual name of the food, and if of two or more ingredients, the common or usual name of these, excepting spices, flavorings, and colors which need not be specifically
so named; (f) it requires that labels of foods for specific dietary uses inform the purchaser fully of its vitamin, mineral and other dietary properties; (g) it avoids the "distinctive name" proviso; and (h) it specifically prohibits the presence of filthy, putrid or decomposed material, and prohibits unsanitary conditions whereby the food may or may not be subject to contamination.

These provisions all have implications for dairy products. While many states have locally developed standards for dairy products, many others gradually have adopted in form or principle those of the 1938 Federal Act.

The procedure of the Standard of Identity had several objectives; the enabling of fair trade of common foods and the establishment of integrity and of consumer understanding of foods. It contemplates not only a specification of the ingredients that may be used, but also where practicable, their quantitative limits. These objectives undoubtedly have been attained where such standards have been developed. The establishment of such standards has in many instances been painful and costly for both government and industry, requiring sometimes a period of years. Having been established, thus painfully, there has been generally great reluctance to propose changes in the light of new process developments or ingredients. It is generally believed the scope and intensity of research and development of new features for standardized food products is scanty in comparison with that of non-standardized food products. Consideration of a change may involve a large development expense, it may involve industry opposition, it may involve considerable legal expense in its prosecution. Experimental marketing to test consumer approval of a new product is possible via temporary permit which is an authority of the Food and Drug Administration. A successful product development and test must be followed by exposure in hearings or prospectus of the technical experience thus acquired at considerable cost. Thus, in effect, the objectives of the standards of identity have been beneficial on the one hand, but limiting on the other.

One of the earliest standards of identity developed within the 1938 act was for evaporated milk. Although a number of experimental modifications of this product have been conceived, none has been proposed. An evaporated product in which vegetable fats have been substituted for butterfat was developed many years ago. It has been excluded from interstate trade by a prior Filled Milk Act. It is, however, produced extensively statewise and the protective effect of the federal act greatly diminished. Recent developments of sterile concentrated milks have many potentials of form and application.

The standards for butter were originally provided by statute in 1923 and thus included by reference in the 1938 act. Although modification of butter to produce a wholesome, nutritional and less costly new product is technically feasible, apparently no change, or proposal for change of the standard has been made in the interim. Congressional action may be necessary to enable modification of the standards of butter. An "imitation butter", marketed apparently under the aegis of the decision on "imitation jam" is now being test marketed.

At least two court decisions bearing on the scope and application of standards of identity for foods have had implication for dairy products. The farina case involved the propriety of adding vitamin D to regular farina, the standard of identity of which did not provide for it. Another standard for an enriched farina, containing added nutritional factors, was available. The decision held that the common name farina would be clouded if permission were granted to modify it at will, even addition of a beneficial factor. This decision probably influenced possible modification, or consideration of modification of standard foods for many years. In the jam case, historically more recent, a manufacturer made and offered for sale properly identified as "imitation jam", a product made of the same ingredients as provided in the standards for jam, but of different proportion or composition. The court held that since the product was properly labeled "imitation jam", it did not purport to be a true jam, and was in fact, a different product, and properly labeled. This decision has implications for many dairy products, since many are subject to convenient modification simply by varying the amounts of the components cited in the standards of identity.

The identity of skim milk powder was established by statute in 1941 in the definition of nonfat dry milk solids. There are a number of possible modifications of this product through use of fat, emulsifiers or vitamin components. Modification of the act, however, probably could be achieved only by Congressional action. Following lengthy hearings in 1947, standards of identity were issued for some 36 varieties, 8 classes and 16 categories of cheese. The development of these standards has aided in defining composition limits of the respective varieties and forms of cheese, as well as what is essential in the art and technology of their manufacture. Just recently proposed standards of identity were issued for ice cream, frozen custard, ice milk, fruit sherbets and water ices. The hearings for these standards lasted about two years beginning some five years ago. Standards have been issued for ice cream and plain and sweetened condensed milks.

Shortly after the enactment of the 1938 act prosecution was made of a creamery company in allegation of
both presence of filth in butter, and, because it was packed under conditions where it may have become contaminated with filth. The decision supporting this allegation of adulteration is an outstanding example of shift in philosophy for responsibility of hazard in a food; from caveat emptor to the concept that the consumer has every right to assume that not even the chance of hazard is involved. The act further provides that a food product is adulterated if it bears or contains any poisonous or deleterious substances which may render it injurious to health; the interpretation of this part of the act is commonly referred to as the "per se" doctrine which prohibits, with certain exceptions, chemicals which of themselves are harmful. These two provisions within the 1938 act on adulteration have had their implications in the dairy industry.

**INCIDENTAL RESIDUES**

Chemical additives may be incidental or intentional. The control of presence of the incidental residues, those which become present, not by intent, is sometimes difficult under the system of producing and handling milk and its products, and requires constant vigil. An example of a problem of incidental residues is antibiotics used for control of biological infections of animals. Most currently used antibiotics are stable to the processes normally used for milk and dairy products. The antibiotics are extensively marketed as over the counter items, and used in remedial and professional treatments of animal infections. Unless the milk is withheld for periods of at least 72 hours after application, the presence of residual antibiotic is possible. Currently no known universal rapid critique has been developed for identification of the presence of the several antibiotics presently used. The most recent approach to the problem of control has been in limit of concentration of antibiotic in the medicant. Another example of form of incidental residue is that which devolves to milk via residues on forage or feed fed the cow. The use of synthetic chemical insecticides in crop insect control has increased tremendously since their introduction ten years ago; under conditions of ill-advised application, residues of certain insecticides on forage are transmissible through the animal in minute though measureable quantity into the milk. It is conceivable certain insecticides may be transmitted through forage to milk through carry over in soils from applications made to previous crops in previous seasons. In a similar manner certain insecticidal sprays are transmissible via absorption, into milk, when applied to the animal. The presence of incidental residues in milk may occur through improper use, or selection of insect sprays, detergents or sanitizers which remain as residues of films on contact surfaces.

Although direct steam injection has long been used in heat processing certain dairy products the use of this system in flash vacuum aeration treatments of fresh milk has resulted in critical analysis and criticism because of the possible presence of undesirable hazardous contaminants in the steam.

Because dairy products are processed in many forms and are subject to a tremendous range of processing treatments, virtually every conceivable form of package material has been applied; wood, cloth, waxes, paper, plastics, films, foils and rigid and flexible laminants. The selection of such package materials necessarily must be based within the limits of technical judgement and according to the criteria of safety recommended by the Food and Drug Administration.

**INCIDENTAL ADDITIVES**

Modern dairy products frequently are blends of ingredients; a tremendous range of functional and nutritive components may be used. Indirectly, however, incidental or intentional residues in the components may become residues in the final food product. Examples of such incidental residues derived from ingredients are emulsifiers or solvents in flavors, colors, or vitamin preparations, antioxidants or stabilizers in nut meats, or in fruits or flavors, diluents in functional preparations, and so on. Considerable need exists for more complete understanding of the precise chemical nature of the additives which normally are used in routine formulary work in processing dairy products. A bromacopoeia has been proposed and would be a highly useful tool for qualifying many necessary ingredients used in dairy products, as well as in other foods.

**INTENTIONAL ADDITIVES**

Standards of identity have been established, and are in proposal for virtually all the major categories of dairy products. Out of a total of 677 million pounds of milk equivalent represented in domestic milk products, essentially 95 per cent is covered by standards of identity or statute law, where it is involved in interstate trade. Virtually all major manufactured dairy products are destined for interstate trade. Within the past 15 years there has been a great consolidation of facilities for processing fluid milk and cream and related products, and now much of the output of these are involved in interstate trade. In effect then, the standards of identity are both helpful in protecting integrity of dairy products and at the same time limiting in the modifications or improvements which might be used or adopted. There have been listed 12 categories of intentional chemical additives in the report "The Use of Chemical Additives in Food Processing" (Bulletin 398 of the National Research
Council). Virtually every category of additive is represented by one or more chemical substances in the various standards for dairy products that have been established or currently proposed. In the light of the great number of chemical substances that are being developed, it is important to the dairy industry that the potentiality of these be fully known to enable convenient and economical dairy products in the diet, and because of the great competitive position of other foods not defined by similar specification standards.

There are many areas in which improvement of nutritional, economic or quality value of dairy products may be achieved by use of selected functional additives such as stabilizers, antioxidants, antimycotics, and emulsifiers, but which are not used because of lack of legal provision for them in federal or state standards. The Food and Drug Administration is empowered to grant temporary permit for test incorporation of a new ingredient in standardized foods. The temporary permit, which forestays the application of a "purports to be" rule, is a useful tool, and should be used more extensively collectively by the industry in achieving desired modifications in the existing standards. There is a great need for a similar procedure within state regulations. The Hale Amendment to the Food and Drug Act should enable ready consideration of proposed changes in the standards.

A major problem within the dairy industry is the rather great variation in the state standards and regulations which define various products, and which provide for labeling terminology. Although the various state standards tend to encompass the federal standards when such products are not locally produced, this is certainly not the case for many products which are, or may be produced or processed locally under a community, or state, jurisdiction.

As specific examples, there occur variations within cities, and between states on regulations permitting uses of products such as the following: preservatives, colors, flavors in fruit in ice cream, the use of single and multiple vitamin additives in milk, the form of carrier or solvent for vitamin additives for milk, the use, or form of stabilizer for ice cream, chocolate milk, or buttermilk, the use of acidifiers, or stabilizers, in cream for cottage cheese, the use of enzyme as antioxidant curd modifier of milk, the use of mold inhibitors in product or package as for cheese, and so on. Although cream is covered in a standard of identity, frozen cream which is extensively used in product manufacture is not; hence modifications of cream, as by use of antioxidant to enhance its storage quality while frozen, is not. The possible modification of frozen cream by modifying agents which have not been adjudged harmful, is a subject entirely of local interpretation. Another example of a problem of interpretation is that of identity and classification of processed modified dairy products as ingredients in dairy products; thus ion exchange treated milk solids is especially useful in condensed ice cream paste and so modified casein is effective as a stabilizer in ice cream mixes. When a process or product is not already defined by a local state regulatory category of exceptions, then reference is made to federal standards for precedent, or a local concept is imposed. This variation in regulations is, of course, difficult for manufacturers of dairy products and of various functional agents which may be destined as intentional additives, or which may be considered in their light as incidental residues. This variation in regulations is difficult also for processors of products whose operations cross state lines; many processors of perishable fresh milk and related products now are engaged in interstate and intrastate commerce, either in procurement of their milk supplies, or in their marketing.

Although variation in specification in components is in itself a major problem for interstate purveyors, variation in requirements for labeling are similarly involved; even at the simplest level confusion can exist as shown by sample selected names for ordinary milk. Dairy products are quite amenable to modification and new products can be conceived for which special category classification, regulation and terminology may be involved; thus nonfat dry milk solids can be added to improve certain characteristics of chocolate milk, buttermilk, or skim milk for cottage cheese, or in modification of skim or whole milk. On the other hand, although the term nonfat dry milk solids has been established by federal statute, it is not acceptable nor permissible to use it in certain state areas. The specification in terminology as developed in standards of identity is sometimes limiting in the use of dairy products as an ingredient in foods; thus a blend of two types of cheese has been made for special use in a bakery product, but for purposes of label declaration, no name exists for the blend.

In summary, the production and marketing of dairy products is quite subject to many legal specifications which proscribe and prescribe use of possible chemical additives.