Equally satisfactory results were obtained with plates incubated at 35°C or 37°C. Since 37°C incubators are not normally found in dairy laboratories, 35°C would be the more realistic temperature to recommend for incubating plates when testing for penicillin in milk.

Zones of inhibition were observed on a very few plates in 2½ hours, on approximately one-half of the plates in four hours, and on all of the plates in six hours when incubated at 35°C. Hence, to assure visible zones of inhibition, plates should be incubated from four to six hours, or until growth is apparent.

The above suggested changes make the Arret and Kirschbaum method less restrictive, more applicable to dairy laboratory procedures, and more likely to detect all positive samples. In fact, these changes, with minor exceptions, renders the method described by them indistinguishable from the modified Difco method suggested in the Standard Methods for the Examination of Dairy Products.

REFERENCES

FEDERAL REGULATION IN THE FIELD OF IDENTITY, QUALITY AND SANITARY STANDARDS FOR MILK AND MILK PRODUCTS

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At one time or another most everyone has undertaken to put a jigsaw puzzle together. It is, as a matter of fact, somewhat of a minor satisfaction when, after fitting together a few hundred oddly shaped pieces, there finally emerges an integrated picture. It might be a landscape or pastoral scene or it might be a map of a foreign land, but in any event, the result represents a whole unified pattern.

An investigator who undertakes to assemble the few hundred oddly shaped pieces which represent federal activity in the field of identity, quality and sanitary standards of dairy products will not finish, I can assure you, with any unified integrated pattern — much less a pastoral scene.

This is not to say there is not a good deal of dovetailing between the programs of the several federal agencies involved. As a matter of fact, despite the fact of duplicate authorizations in a number of fields, there has been a large measure of cooperation — both inter-agency and between agencies and industry. This has resulted in less conflict than one would suspect, since the three agencies of the federal government have responsibilities in the field of standards for dairy products.

The subject assigned is of treatise magnitude. In a paper of appropriate length for a meeting such as this it will be attempted to sketch the outlines of the subject matter in three ways. First, to outline the enabling laws; second, to briefly review what has been done under these laws; and third, to discuss some similarities, differences and areas of possible duplication.

It seems to me that the proper starting point is with the federal statutes involved.

Even though three agencies of the federal government are concerned with standards for dairy products, one of the first distinctions which becomes apparent is the different underlying purposes on which the authority is grounded. While it is perhaps an over-simplification, and although there is some overlap, I think it fair to say that standards of identity established pursuant to the Federal Food, Drug and Cosmetic Act are designed to prevent the perpetration of economic fraud upon consumers. The purpose of model ordinances and codes of the Public Health Service is, to be sure, the preservation of the public health. Whereas, the purpose underlying the activity of the Department of Agriculture in the field...
of standards is to improve the orderly marketing of dairy products.

Turning to the statutes themselves, two of the laws may be passed over quickly. These are laws which by their own terms establish statutory standards of identity for butter (1) and nonfat dry milk (2). Both of these brief laws recite that the standards which they establish are for the purposes of the Food and Drug Act. As a matter of practice, however, as standards of identity, they are accepted as such by all other federal agencies which have something to do with butter and nonfat dry milk, as we shall see when we speak of the Department of Agriculture's and Public Health Service's involvement with nonfat dry milk.

The responsibility of the Public Health Service in the field of its model code and ordinance activity, as well as the Voluntary Program for the Certification of Interstate Milk Shippers, derives mainly from an amendment (3) to the basic Public Health Service Act, which recites that the Surgeon General shall assist the states and their political subdivisions in the enforcement of their quarantine and other health regulations, and in carrying out the purposes specified in Section 246 of this title, and shall advise the several states on matters relating to the preservation and improvement of public health.

The PHS regulation of milk on interstate carriers derives from Sec. 264 of Title 42 of the U. S. Code which authorizes the Surgeon General to make and enforce regulations to prevent the introduction, transmission or spread of communicable disease between states.

The principal thrust of the Federal Food, Drug and Cosmetic Act passed in 1938 and importantly amended in 1954 and 1958 by the addition, respectively, of the so-called pesticides and food additives amendments, is the prohibition of interstate traffic in adulterated and misbranded foods, drugs and cosmetics.

Pertinent to our present review are the definitions and standards of identity for a number of dairy products which have been established under Sec. 401 of the statute.

Briefly condensed for our present purpose this section of the Food and Drug Act provides that "Whenever in the judgment of the Secretary (that would of course be the Secretary of Health, Education and Welfare), such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container."

Standards promulgated under the Food and Drug Act are primarily concerned, as has been said, with preventing economic fraud by prescribing minimum amounts of valuable characterizing ingredients in food, and by excluding or limiting those ingredients or constituents where it is found that their unlimited use would not promote honesty and fair dealing in the consumers interest. The standards of identity themselves, are not generally concerned with quality or sanitary requirements. These considerations are, however, involved in other provisions of the Food and Drug law.

For example, a food shall be deemed to be adulterated regardless of whether or not it meets the requirements of the standard, if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (4).

Or take the matter of antibiotic or pesticide residues. At the recently held Dairy Industry Conference at Cornell, M. R. Stephens, Director of the Bureau of Enforcement, Food and Drug Administration, put the position of the Administration tersely when he said:

"Since there is no legal tolerance for any pesticide residue in milk, the interstate shipment of milk containing such a residue is illegal under the Act and the milk itself is subject to seizure . . . . Residues of antibiotics in any amount also are illegal in milk. Such residues result from a failure, through ignorance or through deliberation, to reject milk from treated animals."

A dairy product for which a standard has been established, if contaminated by the presence of an antibiotic or pesticide residue, would be unlawful on two grounds. It would violate the standard and it would also be deemed adulterated because of the presence of the antibiotic or pesticide residue, as the case may be, in violation of those specific provisions of the law which prohibit unsafe pesticides or unsafe food additives.

The authority of the U. S. Department of Agriculture in the field of standards for grades of dairy products derives from the Agricultural Marketing Act of 1946 (U. S. C. 1621 et seq.). While it is true that the statutes from which authority flows to PHS, FDA and USDA ultimately are grounded in the consumers interest, there is a special rationale supporting USDA activity in the field of standards.

Congress, in enacting the Marketing Act as the popular name of the statute, suggests, was interested in the improvement in the marketability of agricultural products through differentiations of products on the basis of quality. Such differentiations and universal acceptance of the grades have been a great boon
in the orderly marketing of the graded products.

The Agricultural Marketing Act contains an extreme broad declaration of Congressional purpose reciting, among other things, that a prosperous agriculture is indispensable to the maintenance of full employment and to the welfare, prosperity and health of the Nation. The declaration of purpose also admonishes the Secretary in carrying out the Act to cooperate with producers and industry organizations in the development of programs. An admonition, I might add, which has been scrupulously heeded by the present Director of the Dairy Division, Agricultural Marketing Service, who acts for the Secretary in the administration of the program.

The specific provisions of the Act which bear on our subject are three in number (5). First, the Secretary is directed and authorized to develop and improve standards of quality, quantity, grade and packaging, and recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices. Second, the Secretary is authorized and directed to inspect, certify and identify the class, quality, quantity and condition of agricultural products on a voluntary basis. Such service to be financed by reasonable fees. Third, the Secretary is authorized to develop and promulgate, for the use and at the request of any Federal agency or State, procurement specifications for agricultural products.

One further word about the function of the department under the Marketing Act should be mentioned. This is the directive of Congress to conduct, assist, foster and direct studies and informational programs designed to eliminate artificial barriers to the free movement of agricultural products (6).

The second phase of the subject has to do with the programs of the several agencies under the statutes. I shall confine my remarks, as far as the subject matter permits, to responsibilities directly related to standards although each agency is engaged in closely related activities. I have in mind here, research, educational programs, information activities and the like.

Turning first to the programs of the Public Health Service. We are interested in two activities, with which I am sure you are familiar. It is nevertheless desirable to sketch them briefly because of their relationship and contrasts with activities of the other agencies.

A significant part of the PHS milk sanitation program is the development and periodic revision of model ordinances and codes, and the other recommended program guides, for use by states and municipalities. Among those developed to date are the "Milk Ordinance and Code" (12th ed.); "Frozen Desserts Ordinance and Code"; and "Recommended Sanitary Standards for Dry Milks Used in Grade ‘A’ Pasteurized Fluid Milk Products." An example of the manner in which states and municipalities utilize these model ordinances is indicated by the fact that the provisions of the "Milk Ordinance and Code" have been incorporated into the laws or regulations of 36 states and have been adopted by more than 1900 counties and municipalities.

PHS participates with the states in the conduct of a voluntary program for the certification of interstate milk shippers. This program was initiated by PHS on the basis of requests from the Association of State and Territorial Health Officers. The basic objective of this activity is to assist the state and local health authorities in milk shortage areas to obtain reliable data on the sanitary quality of fluid milk shipped into their jurisdictions from out-of-state sources, thus eliminating the necessity of inspections by one state of a milk source existing in another state.

Routine inspections and laboratory control of interstate milk shippers are performed by the state and municipalities in which the supply is located, using the "Milk Ordinance and Code" and the rating method developed by the PHS as uniform criteria for evaluation. The states report to PHS those shippers whose products and plants have been rated by them in accordance with agreed upon sanitary requirements. PHS functions and responsibilities include:

(a) Comprehensive evaluation of the program of each participating state including appraisal of rating methods and adequacy of laboratory procedures.

(b) Endorsement of satisfactory state programs.

(c) Quarterly publication of a list of certified interstate milk shippers.

(d) Periodic spot checks of certified shippers in order to validate the sanitation compliance ratings submitted by the states.

At present 36 states and approximately 700 shippers participate in this voluntary program. These shippers obtain their supplies from an estimated 100,000 Grade "A" dairy farms.

I cannot leave my discussion of the PHS program without saying that I am continuously impressed with the competency of John Faulkner and his small staff in the discharge of their responsibilities in the field of milk sanitation.

The program of the Food and Drug Administration in the field of standards, tied as it is to enforcement proceedings of a criminal and civil nature, involves formal administrative proceedings which distinguishes the activities from the other two agencies. Shortly after the 1938 Act was passed the Food and Drug Administration began its program of establishing standards of identity for dairy products. The first
of these was the standard for evaporated milk promulgated more than 20 years ago. Incidentally, the Food and Drug Administration has not established a standard of identity of "milk" as such. Wherever the necessity of defining milk in the standards for dairy products arises the statement is simply, "The word milk means cows milk." FDA has also defined and established standards of identity for cream, light cream or coffee cream, light and heavy whipping cream. Standards exist for concentrated milk and sweetened condensed milk including condensed milk which contains corn syrup solids. In the field of cheese standards there has been more or less continuing action involving numerous amendments over the past 15 years.

There are 65 separate standards for cheeses and cheese products ranging alphabetically from "A"—Asiago, an Italian-type cheese—to "W"—Washed curd cheese.

I hesitate to mention ice cream standards but a statement on FDA's activities in the area of dairy products standards would not be complete without doing so. Hearings on standards for ice cream and related products began in January 1942. It appeared that they may have been promulgated in the forties, except that the War Food Administration, because of its War Food Order No. 8, intervened with a request to FDA that they be held up. Nothing further was done until January 1951, when a second hearing commenced which ran intermittently for 2 years, adjourning on New Years' Eve 1952—more than 7 years ago. While many forecasts have been made over this period as to when the final order establishing standards will be promulgated, there is good reason to believe that the final order will be published in the very near future. The most recent obstacles to the conclusion of the matter has been the general workload imposed upon FDA by the Food Additives amendment, but also involved is the particular application of the food additives amendment to several of the emulsifiers which were excluded in the tentative order under the so-called per se doctrine but which now appear to be safe food additives under tolerances which may be permitted.

Under the Agricultural Marketing Act of 1946, grades have been published and amendments added for the following products: butter, cheddar cheese, swiss cheese, nonfat dry milk, both spray and roller, dry whole milk, dry buttermilk and dry whey. In connection with the butter grades, a final revision has been published which will become effective on April 1. As supplemental material to the butter grades, is a publication titled "Probable Causes of Certain Characteristics in Butter." This document is not a part of the standards but is intended primarily for the information of butter makers. It spells out the causes for some 25 flavor defects in butter and is an extremely valuable tool to assist in upgrading butter. Dairy products processed and packaged in an approved plant shall be graded and/or inspected and may be identified with official inspection or grade labels including the USDA seal. The familiar AA grade butter is such a product. Closely associated with the grades established for the dairy products mentioned is the "Minimum Specifications for Approved Plants Manufacturing, Processing and Packaging Dairy Products," the enabling statute authorizing this which I previously mentioned.

The Dairy Division also has a responsibility delegated to it by the General Services Administration under which it develops and publishes, after extensive collaboration with the federal purchasing agencies and consultation with the affected industries, Federal Specifications for Dairy Products which are purchased by the several government procurement agencies. Ed Small, who under Herb Forest, does a remarkably fine job in this field had occasion at the time the Cottage Cheese specifications were under development stated:

"In developing a Federal Specification or revision thereof we consult and obtain data from various agencies and industry groups as considered necessary. With respect to industry contacts it has been our policy to work with and through trade associations and their committees on research, quality specifications and packaging.

"Federal Specifications are designed solely for the purpose of product procurement by Federal civilian and military agencies, other than Commodity Credit Corporation. They have no application to any operation other than the selling or offering of products for sale to such agencies."

Specifications for some 15 dairy products purchased by government agencies are presently involved; many of them are in the process of revision. Among these are milk itself, cottage cheese, liquid skim or defatted milk, chocolate milk and chocolate drink, cultured buttermilk, sour cream, half and half, ice cream, butter, cheddar cheese, swiss cheese, process American cheese. Many of these specifications are in various stages of revision.

At the outset, I indicated that I would discuss some similarities, differences and areas of possible duplication in the programs. In this connection, I would mention—first, that the tendency, purpose or effect of at least parts of the programs of each of the three federal agencies is the elimination of trade barriers. In the famous Dean Milk Company case (7) involving the milk ordinance of the City of Madison, the value of the model ordinance and code in overcoming interstate barriers is reflected by the Supreme Court which held that a provision of a Madison ordinance imposing a 5-mile limit on the location of pasteurization plants selling milk in that city was unconstitu-
tional in that it unreasonably discriminated against interstate commerce. In support of its holding, the Court pointed out that, in lieu of the 5-mile limitation, Madison could avail itself of reasonable nondiscriminatory alternatives adequate to protect the health and safety of its people, such as the provisions of the milk ordinance developed by the Public Health Service.

With respect to the Interstate Milk Shipments Program of PHS, it can be said that although there is no requirement that a would-be importing state must accept milk from another jurisdiction which has been certified under the program, the increasing use of the program has had an important tendency in the direction of the free flow of milk between the states.

So far as the Department of Agriculture's contribution to the demolition of trade barriers, I have previously quoted the directive of Congress concerning trade barriers. In the case of standards of identity under the Food and Drug Act, the impact on trade barriers derives from the application of the legal doctrine of Federal occupation of the field or preemption. This matter is one which has been receiving particular attention recently in view of the long expected and soon to be promulgated standards for ice cream and related products.

As counsel for the International Association of Ice Cream Manufacturers, I was asked for an opinion on the question of whether or not an importing state whose standard of identity for ice cream was different from the Federal standard, could exclude a product produced in another state conforming to the Federal standards. A higher butterfat requirement in the importing state would present the question. My opinion, based on a number of decided cases presenting similar situations, was to the effect that the importing state could not exclude such a product. The general counsel of the Food and Drug Administration has expressed the same view in responding to inquiries presented.

A question which I believe is somewhat perplexing to the Department of Agriculture has to do with the absence from its standards for grades of some of the requirements of the Food and Drug Act. For example, the standards for grades do not provide for zero tolerances for antibiotics and pesticide residues. All of the USDA grades provide, "that compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug and Cosmetic Act." It seems to me that such a provision is all that is necessary in the public interest.

Since, in prosecutions under the Food and Drug Act, there is taken into account, in appropriate cases, the terms of the USDA grades, in addition to the specific requirements of the Food and Drug Act itself; there is ample protection for the buyers of such graded products.

Concluding, let me say—as I am sure you have noted—I have really only scratched the surface of the subject assigned. I am impressed by two facts, however; (a) despite all of the activity in the field of Federal standards there is surprisingly little real conflict, and (b) in political matters it becomes clearer every day that we are necessarily having to make policy and take action because the nations are living in one world. So in the field which we have been discussing, it appears that the regulatory trend is necessarily taking cognizance of the fact that we are living in one country.

REFERENCES
The following citations found in the body of the paper (except the Dean Milk Case) refer to titles and sections of the United States Code relating to the jurisdiction and authority of the Food and Drug Administration, the United States Public Health Service, and the United States Department of Agriculture:

(1) 21 U.S.C. 6, 32 (a)
(2) 21 U.S.C. 321 (c)
(3) 42 U.S.C. 243
(4) Sec. 402 (a) (4)
(5) 7 U.S.C. 1622 (c) (h) (1)
(6) 7 U.S.C. 1622 (d)
(7) Dean Milk Co. v. City of Madison, 340 U. S. 349