FOOD AND DRUG ADMINISTRATION ATTITUDES ON IMITATIONS

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As the industry is concerned about the impact of substitutes, regulatory and public health officials are concerned with protecting consumers against substitute dairy products which are unsafe, or nutritionally inferior, or which do not bear informative, non-misleading labeling. In carrying out our obligation we must, of course, act in accordance with applicable laws and regulations presently in effect or which may be enacted to deal with new problems. It is the administration of these laws that is discussed in this paper.

TWO CATEGORIES OF SUBSTITUTE DAIRY PRODUCTS

FDA consideration of substitute dairy products can basically be broken down into two categories: (a) products defined by specific Congressional acts, such as the Filled Milk Act or the Filled Cheese Act and (b) other substitute products—not covered by these specific acts—but which are subject to labeling requirements for imitation foods under provisions of the Federal Food, Drug, and Cosmetic (FDC) Act. This last category covers a wide range of products—and the marketing of these products in interstate commerce is somewhat confused because of the different labeling requirements under the FDC Act plus many different state laws.

FILLED MILK ACT

There is one subject that should be clarified now—before proceeding with our discussion. The Filled Milk Act is a Congressional Act—not a Standard of Identity promulgated under the FDC Act. A Congressional Act can only be changed by Congress. Regarding the Filled Milk Act specifically—we in FDA cannot change this Act—we can only enforce the Filled Milk Act as written and passed by Congress.

The Food and Drug Administration has taken the position that the Filled Milk Act is quite specific in defining the compositional framework in which a food is violative of the Act. In evaluating whether a product is violative, we consider three phases. First, does the product consist of "... any milk, cream or skimmed milk whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated . . .?" Second, "... to which has been added or which has been blended or compounded with any fat or oil other than milk fat . . ." Third, "... so that the resulting product is imitation or semblance of milk, cream or skimmed milk whether or not condensed . . . ."

With all the words of the English language available, Congress in its wisdom chose to use the words, "milk, cream or skimmed milk," in describing the base to which a fat or oil other than milkfat is added to make a product in imitation or semblance of milk, cream or skimmed milk. This wording provides the Administration's basis for determining the status of these products. We consider the quantitative formula and usually examine the product before issuing an opinion on a product.

In our opinion, products on the market fabricated basically from water, vegetable oil, and non-fat dry milk which imitate or simulate milk or cream are "filled milk" products, and as such, cannot be shipped in interstate commerce under any form of labeling unless meeting the specific exemption in the Filled Milk Act.

Products which purport to be or resemble milk but which do not violate the Filled Milk Act since they contain no milk, cream or any dairy ingredient specified in the Filled Milk Act should—in our opinion—be clearly labeled as "imitation milk" and must comply with the general labeling requirements of the FDC Act.

Many of the milk and cream substitutes referred to consist of sodium caseinate in combination with vegetable oil or fat and certain other non-dairy ingredients. We believe that it is important that these combinations of sodium caseinate, vegetable oils and other ingredients should be marketed for what they are—imitation milk or imitation cream.

SODIUM CASEINATE

This brings us to the sodium caseinate question and its relation to the Filled Milk Act. We are aware that within the dairy industry, there is some

misunderstanding of the Food and Drug Administration's position on sodium caseinate. The situation is this: We have not considered sodium caseinate to be a "dairy product" in the same sense that you would consider market milk, ice cream, butter, or cheese to be a "dairy product."

You may have heard that the Administration considers sodium caseinate to be a chemical product. We do consider sodium caseinate to be a chemical product—a chemical product derived from milk, or saying it another way, a milk derivative.

We are of the opinion—and have so stated—that when sodium caseinate is used as a food ingredient in the fabrication of another food—the ingredient statement of the final fabricated food would be more informative if, in addition to the usual or common name required by the FDC Act, in this instance sodium caseinate, the phrase "milk derivative," or similar wording was used—thus, "sodium caseinate, a milk derivative." Incidentally, this position would apply to any of the various salts of casein.

In relation to the Filled Milk Act, however, the chemical and physical properties of sodium caseinate are different from the three products specifically named in the Filled Milk Act and from non-fat dry milk as defined by Congress. Accordingly, sodium caseinate is not one of the three products included in the Filled Milk Act. This, I believe, is the area where the dairy industry has misunderstood the Food and Drug position on sodium caseinate. We do consider sodium caseinate to be a milk derivative even though not a "dairy product." But, regardless of the "flag" that you attach to sodium caseinate, that is, "milk derivative" or "dairy product," etc., the product, sodium caseinate, is still not one of the three basic products specifically mentioned by Congress in the Filled Milk Act.

Therefore, products are not "filled milks" that are made using sodium caseinate as the base to which a fat or oil other than milkfat is added to make products that are imitations of milk. Such articles may, therefore, be shipped interstate provided they are not adulterated or misbranded in violation of the Federal Food, Drug, and Cosmetic Act.

THE FOOD, DRUG, AND COSMETIC ACT

This brings us to consideration of how that Act—the FDC Act—applies to these imitation products. The first provision to which I would like to direct your attention is Section 403(c) under which a food is deemed to be misbranded if it is an imitation of another food, unless it's label bears, in type of uniform size and prominence, the word "Imitation" and immediately thereafter, the name of the food imitated.

Many state laws include a similar provision, and some of which the sale of filled milk is not illegal require that filled milk products be labeled as "imitation milk," "imitation cream," "imitation half-and-half," etc. We exercise no jurisdiction over such articles, which are marketed solely in intra-state commerce.

DISTINCTION BETWEEN FILLED MILKS AND "NON-DAIRY" PRODUCTS

There are some who believe that there should be a distinction between the designation of these filled milks and the so-called "non-dairy" products. If the "non-dairy" substitutes are, in fact, imitations we have no choice under the Act—we are bound by the Act and the decision of the Court in the case of U. S. vs. 651 Cases, More or Less, Each Containing 24 Boxes of "Chocolate Chil-Zert." The food involved here was a frozen dessert labeled in part "Rich's Chocolate Chil-Zert, not an ice cream, and contains no milk or milk fat." The claimant contended that this labeling was truthful and more effectively informed consumers than would the words "imitation ice cream." The Court held that it was not for the claimant to choose the means or method of advising the public that his product was not ice cream; Congress had specified the method of advising the public that a product is not in fact the one which is imitated.

In applying Section 403(c) the first step is to determine whether the article is, in fact, an imitation of another food. The best guidelines we have received from the Courts in making such determination were included in the Chil-Zert decision. The Court declared that resemblance alone is not enough to establish that a food imitates another, and stated, "As indicated above, Chil-Zert is identical with ice cream in its method of manufacture, packaging, and sale. It is similar in taste, appearance, color, texture, body, and melting qualities. It has identical uses; its composition differs only from ice cream in the substitution of a cheaper ingredient, namely, vegetable oil in place of milk products. It is, therefore, something less than the genuine article, chocolate ice cream. It is inescapable that the ordinary understanding of English speech would denominate it as an imitation of ice cream." The Court also held that the food imitated need not be one for which a standard of identity has been established.

STANDARDS OF IDENTITY

As I mentioned earlier, we are concerned with protecting consumers against substitutes which are nutritionally inferior or which do not bear informative, non-misleading labeling. We believe these problems could be best be solved by establishing, in accordance with Section 401 of the Act, standards of identity and of quality for imitation milks and creams. Most of you are probably acquainted
with the proposed standards which were published in the Federal Register of May 18, 1968.

We believe that standards of identity will promote honesty and fair dealing in the interest of consumers by requiring that ingredients be safe and suitable; by specifying the substances derived from milk which may be included; by requiring that the food be pasteurized, sterilized or sealed in a container and so processed by heat as to prevent spoilage; by specifying that the name must include the word "imitation" followed by the common name of the food imitated; and by requiring the listing of ingredients except that artificial flavor or color may be declared as "artificial flavor added," or "artificial color added."

The prescribed names include the word "imitation" followed by the name of the dairy product imitated. The names of the dairy products follow the definitions in the 1965 revision of the Grade "A" Pasteurized Milk Ordinance. We believe the required labeling is informative and not misleading.

The proposed standards of identity specify levels of fats the same as those prescribed for their dairy counterparts by the Pasteurized Milk Ordinance.

The purpose of the proposed standards of quality is to assure consumers the imitations will either be nutritionally equivalent to milk (in terms of specific nutrients for which milk is a significant food source) or will warn purchasers about nutritional deficiencies by a prominent statement "Below Standard in Quality" followed by an explanation of the deficiency such as "Low in Protein." The proposed standards specify not only the amount of protein but require that this be of a biological value equivalent to casein. The published proposal also prescribes levels of calcium, phosphorus, vitamin A, and riboflavin. Addition of vitamin D is optional, but if added there must be 100 U.S.P. units per 8-fluid oz serving.

During the comment period (ending October 15, 1968) about 85 comments were received. These comments were discussed with the NAS/NRC Food and Nutrition Board and additional suggestions were made. A revised draft of the proposed standard has been prepared and is currently being considered by the Commissioner of Food and Drugs. We anticipate a decision and publication in the near future.

New proposed standards of identity for imitation milks were published in the Federal Register 34 (194:15657-15658 (October 9, 1969).

Because of the present interest in the substitutes for fluid milk and cream, I have devoted most of my discussion to these products. I would like, however, to make brief comments concerning certain other imitation or substitute dairy products.

MELLORINE

With regard to the frozen dessert sometimes called "Mellorine," we believe that this is definitely an imitation ice cream, meeting all the criteria of the Chil-Zert decision. When shipped in interstate commerce, it should be labeled as "Imitation Ice Cream" even when the shipment is between states which have established standards of identity for "Mellorine."

IMITATION MARGARINE

Sometimes, however, an imitation meeting the criteria of the Chocolate Chil-Zert decision receives recognition under another name. This has been the case with margarine which Congress, by the Statute for Colored Margarine of 1950, has defined as "(1) all substances, mixtures and compounds known as oleomargarine or margarine; (2) all substances, mixtures and compounds which have a consistency similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter." But, the first definition of "margarine" by Congress was by Act of August 2, 1886.

The most recent ruling concerning use of the word, "imitation" resulted from a seizure involving an article labeled as "Imitation Margarine," which contained about half as much fat as required by the standard of identity for margarine. We argued that the article was made in imitation or semblance of butter, therefore, was "margarine" as defined by the Statute, and that it, therefore, should comply with the provision of the standard of identity for margarine. The article was intended for use by persons who wish to restrict their intake of fats or calories. The Court did not agree with our contention that there could not be an imitation of the food "margarine"—the ruling was that an article not complying with the standard but still "purports to be" could be labeled and sold as "Imitation Margarine."

LOW-FAT BUTTER

Some butter manufacturers have expressed an interest in marketing a low fat butter similar to the "imitation margarine." Congress, by the Act of March 4, 1923, defined butter as follows: "For the purposes of this chapter 'butter' shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 percentum by weight of milk fat, all tolerance having been allowed for."

Any butter in interstate commerce found to contain less than 80% milk fat is subject to action. We have sometimes been asked whether a low fat butter might be marketed as "imitation butter." We
have commented that such an article would probably be subject to the taxes, licensing provisions, labeling, and other requirements of the Adulterated Butter Act of May 9, 1902, administered by the Internal Revenue Service. The definition of “adulterated butter” in the Act includes “any butter or butter fat with which there is mixed any substance foreign to butter as herein defined, with intent or effect of cheapening in cost the product, or any butter in the manufacture or manipulation of which any process or material is used with intent or effect of causing the absorption of abnormal quantities of water, milk, or cream.” This however, would be for a decision by the Internal Revenue Service.

**Cultured Dairy Products**

It might be well to briefly discuss the acid type or cultured dairy foods. For purposes of this discussion, let us consider that the various cultured dairy products fall in three categories. The first category consists of foods covered under the mandatory Federal Definitions and Standards of Identity. The second classification includes the foods coming under Advisory Federal Definitions of the *U. S. Public Health Service Milk Ordinance and Code*, while the third category or classification consists of foods not covered by any definition but for which Federal advisory opinions have been issued.

The primary concern regarding these cultured dairy products is, “What shall they be called?” From the FDA standpoint, “What are the labeling requirements for these various foods?” Mandatory standards of identity have been promulgated under the Federal Food, Drug, and Cosmetic Act for Cottage cheese, creamed Cottage cheese, Cream cheese, Neufchatel cheese, cream cheese with other foods, and Neufchatel cheese spreads with other foods. These standards are quite specific in their labeling requirements, composition, etc. For these products, as for any product covered by and in compliance with a standard of identity, it is not necessary to include an ingredient statement listing the mandatory ingredients used in manufacturing the product. In all instances when certain optional ingredients provided for in the respective standard of identity have been added, these optional ingredients must be listed conspicuously on the label preceding or following the name of the product, for example, “Vegetable gum added.”

When these products, covered by a mandatory standard of identity, are mixed with other foods all other foods that have been added must be declared on the label. Using an example familiar to all—“Creamed Cottage Cheese with Chives.” An ingredient declaration must include all components of the mixture by common or usual name in descending order of prominence.

The products having advisory definitions and the products for which advisory opinions have been issued all come under the general provisions of the FDC Act. The product known as “cultured cream” or “sour cream” or “cultured sour cream” as to its composition is based on the FDA Standard of Identity for cream class of food, Section 18.500. The product, cream, containing not less than 18% fat and containing no added non-fat dry milk, stabilizers, or flavors which simulate fermentation-developed flavors is soured by lactic acid-producing bacteria or similar cultures. The resulting product is a fluid or semi-fluid cream containing not less than 0.2% acidity expressed as lactic acid. Likewise, cultured, or sour half-and-half, or cultured buttermilk refer to products defined in the *U. S. Public Health Service Milk Ordinance and Code* and which have been soured by the action of lactic acid-producing bacteria or similar cultures.

The product made in the same manner as sour cream but from cream containing added non-fat dry milk, stabilizers, synthetic flavor, i.e., starter distillate, should have the term, “dressing” after the name—thus, “sour cream dressing.” The ingredient statement for “sour cream dressing” should name all the ingredients. The reason for the term “dressing” is that the addition of non-fat dry milk, stabilizers, etc., has the net effect of substantially altering these products. Thus, they should have a different name. In other words, such additions to “sour cream” result in products with improvement in body, less syncreis or “wheying off,” etc. These additions serve a useful purpose—but the consumer should be informed by appropriate labeling that the product is not simply cream which has been soured. The addition of the term “dressing” serves to alert the consumer that there is some difference.

**Products Made by Direct Acidification**

Acidified products made by the addition of food-grade acids and containing, of necessity, artificial flavors and possibly added non-fat dry milk, stabilizers, etc., should be qualified by a name such as “product.” Thus, cream containing added non-fat dry milk, synthetic flavors, stabilizer, and acidified by the direct addition of acid would be properly labeled by the name, “acidified sour cream product.” The same type of labeling should be used for the other directly acidified products. For example, the buttermilk product when made by direct acidification is “acidified buttermilk product.”

The term “product” should also be used even if on occasion the cream soured by direct acidification does not contain added ingredients other than the
acid. These products are not made by the normal culturing or souring process. Thus, the product is not exactly what the consumer has been purchasing under a given name over the years. For this reason, the product should have a distinguishing name and, of course, all of the ingredients must be listed.

Foods made in semblance of cultured cream, sour cream, or sour cream dressing but with the milk fat substituted whether in whole or in part by another fat are "imitation" products. This decision stems from Section 403(c) of the FDC Act. Although there are products on the market resembling sour cream or sour cream dressing which contain a vegetable fat and some form of milk, there has been no decision by the Federal courts as to whether such products come within the definition of "filled milk." We have indicated we will not seek a ruling from the courts so long as the articles are labeled as imitations and otherwise comply with the FDC Act.

**Imitation Cheese Products**

I have said nothing so far about imitation cheese and cheese products. Many products which imitate standardized cheeses or cheese products are on the market. Most of these are properly labeled as imitations. As you know, the addition of any vegetable or other fat or oil to cheese brings it within the definitions of "filled cheese," making it subject to the Filled Cheese Act administered by the Internal Revenue Service. You may not be aware that this includes cheeses made with milk or skimmed milk admixed with butter. Filled cheese may be shipped interstate if it is manufactured and labeled in accordance with the Filled Cheese Act and complies with the Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act.

Usually a filled cheese is made in imitation of one of the cheeses for which a Standard of Identity has been established. In addition to the labeling required under the Filled Cheese Act, such cheese should be labeled "Imitation—Cheese" (the blank being filled with the name of the cheese imitated). Since the article is not standardized, all ingredients should be listed.

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**SANITATION IN THE RETAIL FOOD INDUSTRY**

**Gale Prince**

*Elmer Food Stores*

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The subject of this paper involves a very important commodity, namely food. Throughout history food has been one of man's major concerns. Of the essentials of life, none is more vital. Yet over the years, mishandling of food has caused illness, and occasionally death. Thus, food distribution is an important part of our daily lives. Sanitation in the retail food distribution channels has been receiving more attention from both governmental agencies and industry. Before sanitation aspects in the retail food channels are described, some information on the magnitude of the retail food industry will be presented.

**Size of Retail Food Industry**

The cans which you see on the shelves in your local supermarket do not appear there automatically as some people think. It takes people to put them there, and lots of them. In fact, of every seven people working in this country, one person works in some field of the food industry. Just the number of store employees alone is approximately 1.2 million or a population equivalent of about four of our states.

If all the eleven million shopping carts used in the nation's food stores were lined up, they would reach from Chicago to Paris. The 365,000 checkout counters would form a line 425 miles long (1). Some 36 billion paper bags are used in the retail food stores in a year, and the register tape used for totaling customer transactions would reach to the moon and back twice, with a little to spare. Banking is an important aspect of food retailing. Food stores cash checks totaling about 150% of their gross sales; an amount second only to banks.

Food retailing is a big operation; for America has a big appetite. The average sized U.S. family of four persons consumes over 2.5 tons of food a year. (1). Of this amount nearly 1.75 tons are of a perishable nature.

Profit is the life blood of business. It is through profit that a company obtains the capital needed to enlarge facilities and update equipment and products. Profits for the retail food industry averages only about 1.0% net profit compared with 11% for the tobacco industry and 4.3% for the mail order houses. The

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