# History

of the

# U. S. Food and Drug Administration

Interviewee: Walter R. Moses

Interviewer: Robert A. Tucker

Date: August 28, 1995

Place: Springfield, Virginia

# DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Walter R. Moses

As a conditional gift under section 2301 of the Public Health Service Act (42 U.S.C. § 300 cc), and subject to the terms, conditions, and restrictions set forth in this agreement, I, Walter R. Moses [redacted] do hereby give, donate and convey to the National Library of Medicine, acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at my residence on August 28, 1995 and prepared for deposit with the National Library of Medicine in the form of recording tape and transcript. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

Title to the tapes and transcripts shall pass to the National Library of Medicine upon their delivery and the acceptance of this Deed of Gift by the Chief, History of Medicine Division, National Library of Medicine. The Chief, History of Medicine Division shall accept by signing below.

I place no restrictions upon the use of these tapes and transcripts by the National Library of Medicine.

The National Library of Medicine may, subject only to restrictions placed upon it by law or regulation, provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, description, exhibition, display and servicing of the tapes and transcripts as may be needful and appropriate.

Copies of the tapes and transcripts may be deposited in or loaned to institutions other than the National Library of Medicine including the U. S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The National Library of Medicine may dispose of the tapes and transcripts at any time after title passes to the Library.

Date: _____ Signed: _____

I accept this gift on behalf of the United States of America, subject to the terms, conditions and restrictions set forth above.

Date: _____ Signed: _____

Chief, History of Medicine Division
National Library of Medicine

# INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 2

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Administration

DATE: August 28, 1995 PLACE: Springfield, VA LENGTH: 80 minutes

| INTERVIEWEE | INTERVIEWER |
|---|---|
| NAME: Walter R. Moses | NAME: Robert A. Tucker |
| ADDRESS: [redacted] | ADDRESS: U. S. Food & Drug Administration |
| [redacted] | Rockville, MD 20857 |

FDA SERVICE DATES: FROM: July 27, 1937 TO: May 1, 1970

TITLE: Chief, Food Case Branch, Division of Case Guidance, Bureau of Compliance
(Last FDA position)

INDEX

Attachment:

Reprint - SYMPOSIUM: Imitation Products and the Future of the Dairy Industry - Imitation Dairy Products - Federal Laws and Regulations; Walter R. Moses.

RT: This is another in the series of FDA oral interview recordings. Today, this will be a supplemental interview with Mr. Walter R. Moses in his home in Springfield, Virginia. This supplements the earlier interview which was conducted here on May 21, 1987. Today is August 28, 1995. In addition to Mr. Moses, Robert A. Tucker is here conducting the interview.

Walter, we had an extensive coverage of your career and many activities you were engaged in in the previous interview. However, we're aware that you also worked with a number of laws, regulations, and programs that may be less known than those that were previously covered. So would you just share with us some of the experiences you had with those earlier laws and regulations?

WM: When I reported to the Baltimore station of the Food & Drug Administration in 1938, the chief activity of the Food & Drug Administration was enforcement of the Food and Drugs Act of 1906. However, there were other laws that were being given attention that had received far less public attention and not well known, even to a great many people who have worked in the Food & Drug Administration.

For instance, among the laws that were still on the books and that we had to learn about was the Naval Stores Act. This was a very old law dealing with naval stores: that is turpentine, tar, and other products that were of value at the old sailing ships. I never conducted any inspections or collection of the samples under the Naval Stores Act, but I was given some training by some of the older inspectors.

Next to the Food & Drugs Act, the act that was given the most attention at that time was the Insecticide and Fungicide Act (I & F Act). At that time, principal attention was given to household packages of various pesticides. The more potent chlorinated hydrocarbons and organophosphates came shortly thereafter. But before that time, Congress passed an act replacing the I & F Act with the Insecticide, Fungicide & Rodenticide Act. This act was given to another branch in the Department of Agriculture to enforce.

Most of my experience was with the collection of household samples, household packages of insecticides and fungicides. Older inspectors had had to deal with adulteration of bulk insecticides. For instance, in the south, it was not uncommon for the inorganic substances used to fight boll weevil on cotton to be adulterated with flour. In the Baltimore District area, the assignment most dreaded by Food & Drug inspectors was collection of lime-sulphur compound, which was used as a dormant spray on apple trees. I was warned that if I ever had to collect a sample of lime-sulphur to take my oldest clothes and shoes and throw them away, because it would be impossible to ever get the smell out of the clothing.

RT: Walter, before we go on too far, I should have perhaps asked earlier--coming back to your first referred act, the Naval Stores Act--now this, I suppose, is one that dated way back early in the history of the country. Did it not?

WM: Right.

RT: So . . .

WM: I don't know how far back, but . . . I no longer have a copy of that act.

RT: Yes. And then it was the Department of Agriculture, in which FDA was then located, where the work we're speaking of now had occurred. Is that right? That was before it got separated out.

WM: Right.

RT: OK. Thank you.

WM: Next in the amount of time given to enforcement was the Caustic Poisons Act.

RT: That was in 1926 wasn't it, or about that?

WM: I think it would be around there. I don't remember the exact year.

RT: And the Insecticide Act, was that passed earlier than the Caustic Poisons Act?

WM: Yes, it was passed not too long . . . I don't know how long after the Food & Drugs Act of 1906, but somewhere in that area it had been enacted.

The Caustic Poisons Act was the result of a crusade by one man. I do not recall his name. He was a pediatrician who saw many children whose throats were severely burned by strong acids or alkalies or other caustic substances. He set out on a personal crusade and was able to get Congress to pass the Caustic Poisons Act. This act required that caustic poisons bear labeling that had the word "poison" in large letters, which had the skull and cross bones, which had the common or usual names of the caustic poison, such as hydrochloric acid or sodium hydroxide, more commonly labeled as lye. It also required that the labeling bear antidote directions. This, of course, was before the establishment of poison centers.

The appropriations at that time were made specifically to the enforcement of the individual act--so much money that was given for each. One year shortly after I was sent to Baltimore, some weeks before the end of the fiscal year, the Food & Drug had practically used up its appropriations for foods and drugs, and the only money left was for enforcement of the Caustic Poisons Act. So we spent a lot of attention on the Caustic Poisons Act for a short time. The first establishment inspection I ever made was not of a Food & Drug establishment, but it was an establishment that was putting out test kits that included a number of caustic poisons. I believe the name of the firm was Mott, but I'm not sure.

RT: Now you mentioned they were test kits. What do you mean by the term "test kits"?

WM: To test the various elements in the soil for nitrogen, potassium, and phosphorous, and to test the alkalinity or acidity of the soil.

RT: I suppose in conducting inspections of that industry some care had to be exercised on the part of the inspector? What kinds of activities were involved in inspecting? Was it primarily for labeling compliance, or were there other aspects?

WM: I . . . Inspection involved finding what chemicals were being included in the test kits and whether the packages of these individual chemicals bore the labeling required by the Caustic Poisons Act. We normally did not take samples but relied on the labeling of the bulk materials, such as hydrochloric acid, sodium hydroxide, acetic acid, whenever they were in a strong concentration. We collected samples of all their labeling to determine whether the labels did comply with the act.

Among the acts that have at one time been considered important, but are not widely known, even within the Food & Drug Administration, were those dealing with dairy products and imitation dairy products. One of those was the Import Milk Act.

RT: Do you happen to know about the time of enactment? About what year that might have been passed?

WM: I don't believe I have it. It was in the 1920s. I know that.

RT: That's good. That's fine.

WM: At that time, New York City needed more milk, and they'd gone to the farmers in the St. Lawrence River Valley who had dairies producing a great deal of milk. And at one time the Food & Drug Administration established a station at Rouses Point, which was intended solely to make the inspections, examinations, and so forth required under the Import Milk Act. This act required that all cows be

tuberculin tested, that they be otherwise healthy, that the farms or dairies where the cows were milked be found sanitary, although the sanitary standards were somewhat limited.

WM: I do not know exactly how long the Rouses Point Station operated, but at the time I started working at Food & Drug Administration, there were still inspectors or veterinarians in the Food & Drug Administration who had worked at Rouses Point.

The Import Milk Act didn't receive much attention then for a number of years. There were no enforcement actions, and no import milk permits were issued until 1942.

RT: Now for a point of clarification, Walter, we have been discussing now the Import Milk Act, and this related to examination of milk shipped to the United States from other countries. Is that correct?

WM: From other countries.

RT: So I wanted to just clarify, as perhaps the earlier discussion may have related more to the Filled Milk Act, because I think you mentioned that the farm sanitation and so on was an important element of overview. And, of course, we wouldn't be in a position to do that in a foreign country, would we?

WM: By arrangement with Canada, those inspections of the farms and dairies and the inspection of the cows could be done either by qualified inspectors and veterinarians from the U.S. Food & Drug Administration or by qualified veterinarians and inspectors of the Canadian government. The law permits the secretary to accept inspections and tests from qualified personnel of the foreign government.

RT: OK. Then I would like also to clarify, was this act primarily related to imports of milk and milk products from Canada?

WM: That was the only source from which large quantities of milk were imported. Yes, Canada was the only source. And when the demand lessened, and probably the Canadians found other outlets, the station at Rouses Point was closed, and there was no further activity under the Import Milk Act for some years.

However, the law remained on the books and the regulations remained on the books. Then in 1942, early in World War II, the United States Air Force built a flying field at Del Rio, Texas. This field was isolated from any American dairies that could supply milk. In fact, the nearest dairies were supplying milk to San Antonio Texas. The officers of the flying field approached the Food & Drug Administration about purchasing milk from a large dairy across the Rio Grande River in Mexico. The Mexican government was not very cooperative. However, arrangements were finally made whereby they would permit the veterinarians from the flying field to cross over and make the necessary examinations of the cows, test for tuberculosis and other health conditions, and check on the sanitation.

RT: That would include checking milk producers, as well as processing facilities.

WM: No, it wouldn't be processed. This is raw milk. Just milked and came across as raw milk. Under the law, the raw milk crossing into the United States had to be sampled and checked for bacteria, and the maximum count that was allowed was 300,000 in milk, 750,000 in cream. So after the veterinarian had made the required inspections and examination of the cows, and certified on the forms prescribed by the Secretary, actually the administrator of the Federal Security Agency . . . ?

RT: The administrator maybe?

WM: Yes, the administrator. The Food & Drug Administration accepted these reports, a temporary permit was issued that would allow for a short time the importation of the milk. At that time, Del Rio was under the supervision of New Orleans District of the Food & Drug Administration. I was stationed in San Antonio as resident inspector, and New Orleans sent a microbiologist, Jimmy Hyndman, and shipped the needed equipment for sampling and for examination to the flying field at Del Rio, where arrangements had been made to utilize the laboratories of the hospital for making the bacterial examinations and for sterilizing the equipment used in sampling.

RT: Was that the U.S. Air Force hospital, then, at Del Rio?

WM: Yes. Jimmy Hyndman had had polio and was largely confined to a wheelchair, although he could get about enough that he was a very good microbiologist, and he had shipped out the equipment from New Orleans that the hospital could not furnish. In the hospital laboratories, they had the autoclaves for sterilization and had incubators for incubation of the bacteria. But they didn't have the petri dishes and the special pipettes necessary to sampling. We used a metal pipette so there wouldn't be danger of breaking pipette and having glass fragments in the milk. Each had to be used only in one can of milk and then resterilized.

Jim and I were unpacking this equipment in the storage room near the hospital. These storage rooms were side by side, one story, no opening to each room except a single door. No windows. And as we were unpacking the equipment, I glanced up and coming through the door was a bear. We had an inspectors manual about three inches thick, but there was not a word in there about what to do when you came face to face with a bear. I was frozen trying to figure it out, doing what I could do to help Jimmy, and then saw that the bear had a metal collar and a chain was attached. At the other end of it, there was the person responsible for care of the bear.

RT: Mascot for the flying field.

WM: . . . the man who was responsible for taking care of the mascot. But that was one frightening moment.

RT: An unusual experience for a food and drug inspector.

WM: Yes, the one and only such experience. All of our samples came within the microbiological limits, so a one-year permit was issued.

RT: Now that, of course, was under the management of the military. So the Public Health Service commissioned people wouldn't have been involved in that, the milk program people. Is that correct?

WM: Once the milk was turned over, it was the responsibility of the flying field.

RT: So where was the raw milk sent for processing, then, in the United States?

WM: They had to put in pasteurizing equipment.

RT: There at the Air Force base.

WM: I am not sure where the pasteurization was done. By the end of the year, the Air Force had been able to make arrangements for transportation of milk from distant American dairies. So they were no longer particularly interested in continuing. But, again, we made bacteriological tests, and the counts were way out of line. So the permit was not renewed.

RT: At that time, transporting milk long distances, did they use tankers?

WM: They didn't have these stainless steel refrigerated tankers, and they didn't have, even on the trains, any way of refrigerating the bulk milk.

RT: Was this sent at ambient temperature?

WM: What they had to do was to get dairies that packaged the milk and then shipped it in refrigerated cars. That was the last permit ever issued under the Import Milk Act.

In the 1960s, there was consideration given to whether we should apply the Import Milk Act to some milk being imported from Holland, the Netherlands. This was evaporated, canned evaporated milk, but there was a technical question as to whether it was sufficiently "sterilized" to escape the provisions of the Import Milk Act. Discussions were held with the representatives of the Netherlands government.

(Interruption)

RT: OK. We're ready now.

WM: We discussed at length the technical aspects of whether this did meet the "sterilization" requirements of the Import Milk Act, and also discussed the feasibility of the inspectors and veterinarians of the Netherlands government making the required inspections and examinations.

At that time, a man by the name of Pieters was commercial attachè. I recall in one of our conferences, Mr. Pieters was protesting this. He says, "You're hurting our pocketbook, and when you hurt a Dutchman's pocketbook, you've hurt him." (Laughter) Although the regulations under the Import Milk Act were revised or amended June 28, 1968, they were not utilized.

RT: Now those amendments or changes, were they made with regard to the Netherlands problem, the concern about the canned evaporated milk?

WM: No. Mainly to make corrections to bring the procedures in line with the changes in organization due to transfer of FDA from the U.S. Department of Agriculture to the Federal Security Agency, then to the Department of Health, Education and Welfare.

RT: Recodify. I see.

WM: Yes, to make changes as to who was responsible for various parts of the enforcement.

RT: You mentioned that after 1968, apparently, there was not too much attention to this.

WM: If there's been any attention at all to it since the time, I don't know of it.

RT: But as far as you know it has never been repealed. It's still on the books?

WM: No. As far as I know, it's never been repealed. It's just been neglected like it was from the time of the closing of Rouses Point until Del Rio.

RT: The current attention of this political administration to reinventing government; I think a part of the initiative is to clear the books of old antiquated requirements. So it may be--I'm not sure--it may be the Filled Milk Act or, pardon me, the Import Milk Act may be included in that review. I don't know.

WM: Probably I'd say that both acts have served their usefulness.

RT: It's kind of hard to . . .

WM: The technology of the dairy industry has come a long way since then.

RT: Oh, it has. It's interesting in terms of individual health care now, there's many recommendations to avoid butter and concentrated fats, whereas a number of years ago the concern was just the opposite that substitute products be avoided.

WM: That's why we got the Filled Milk Act. (Laughter)

The Filled Milk Act was passed in the 1920s. Filled milk is milk in any form from which the butter fat has been extracted and the foreign oil or fat substituted. The two cases under the Filled Milk Act were against Carolene Products Company of Litchfield, Illinois. The first court case in 1938 was appealed to the Supreme Court. One of the observations of the court was that the Filled Milk Act was intended to prevent the competition of a coconut grove with the American cow. (Laughter) There was a section of the public health which they thought that the foreign fats were inferior. As you have mentioned, today we might consider some of the fats better from the health standpoint than the butter fat. But then the chief product used to replace the butter fat was coconut oil which is even more saturated than the milk fat.

The second trial was in 1942. Carolene Products Company had flooded West Virginia with shipments of their filled milk product which was distributed under two labels, Carolene and Milnot.

RT: Milnot is still a product that you see, isn't it? Isn't Milnot a product that's still marketed with that trade name?

WM: Well, I don't know. I really don't know. I collected a number of samples while I was a resident at Charleston, West Virginia, and I was called to testify in the

case at Wheeling, West Virginia. This was a hotly contested case in which there was a great deal of testimony, both legal and nutritional.

The judge was very hard on the government lawyers. The member of the Food & Drug Administration General Counsel that was sent out was a man named Murphy that worked with the United States attorney, whose name I do not remember. But the judge insisted on making them back up every point they made. He would hammer his gavel and say, "I don't want Murphy and so-and-so on this point! Quote me some authority." And they would have to go get the citations. He insisted on everything being proved out.

The case was being tried without a jury. He found the corporation, and each individual officer guilty, and fined each of them the limit, $1,000 each, and gave each of the responsible officers of the corporation a one-year prison sentence. That's the maximum that could be given. The Filled Milk Act had no provision for seizure, only for prosecution. So the case was carried to the Circuit Court and then on to the Supreme Court and upheld, and the prison sentences were upheld. But the individuals were granted a presidential pardon.

RT: Oh, is that right? What President? Was that President Franklin Roosevelt?

WM: Let's see. Yes. Roosevelt died in 1945.

However, since the law and the sentence had been upheld by the Supreme Court, apparently the individuals did not wish to risk a second prison term, and so far as I know, there's been no action under the Filled Milk Act since then.

RT: Well, that sort of demonstrated that real enforcement had a deterrent effect on further violations. Now the Filled Milk Act, like the Import Milk Act, is apparently still on the books.

WM: As far as I know, it's still on the books. It would take an act of Congress, of course, to repeal it.

A frozen dessert was developed comparable to filled milk, which instead of being made with milk fat had the milk fat removed and other fat substituted. At the time I was resident inspector in Houston, a firm in Texas developed a product, which they called Mellorine. This was apparently intended as a substitute for ice cream. The maker of it or the person who developed it claimed two benefits. One was price. He could sell the Mellorine much cheaper than ice cream. Also, he claimed that he could control the flavor much better using the pure vegetable oil rather than the cream, which varied in taste from time to time.

Along with Texas Department of Health inspectors, I inspected this operation. The manufacturer told me that he was going to be very careful to not violate the Federal Food, Drug & Cosmetic Act, that he would keep his product entirely within the state until such time as he could persuade the government to establish a standard for his product. He apparently kept his word. The state of Texas eventually did set up a state standard. I believe Arkansas set up a state standard. I don't remember for sure what other states. Several states established standard for Mellorine.

Had he shipped the product in interstate commerce under the Food, Drug & Cosmetic Act, the FDA would probably have required that it be labeled "imitation ice cream." This would be in line with the court decision in the Chill Zert decision. A firm was manufacturing and shipping a product called chocolate Chill Zert. This was made with no dairy ingredients. It was a non-dairy product, and the firm argued that they did not have to label it as imitation ice cream. But the courts held that they would have to label it imitation ice cream because it was so similar in appearance and use and taste and every other way that it clearly imitated ice cream. So had the Mellorine been shipped in interstate commerce it probably would have required imitation labeling.

Let's see. We've discussed the Filled Milk, Import Milk Acts, and Mellorine.

Back in the 1930s and earlier, there was a product called renovated butter.

This was subject to the Renovated Butter Act which was enforced by another bureau of the Department of Agriculture. It was produced under their supervision.

RT: What was the legislative intent with regard to this particular act, the Renovated Butter Act.

WM: What I'm getting at is although the Food & Drug did not have jurisdiction over the renovated butter, we made a seizure of the packing stock butter which was used to make this, and that was hard fought. The case went to the Fifth Circuit once, this circuit up to the Supreme Court, back to the lower courts. Then it's again appealed, went to the Fifth Circuit and to the Supreme Court. Then the third time, it appealed to the Fifth Circuit, and the theory was that Food & Drug held that the packing stock butter was adulterated food under the Food, Drug & Cosmetic Act.

RT: That's what I meant by my earlier question. What is really renovated butter?

WM: I'll get to that in . . . I'll explain it in a minute. Then they . . . Mr. Kidd, Clover Leaf Butter Company, claimed that it was not a food subject to the Food & Drug Act, but it was solely subject to the Renovated Butter Act, which would give us no authority to make the seizure.

RT: But the product itself really . . . What is the product itself?

WM: OK. When . . . I can start explaining what renovated butter is now.

RT: Sure.

WM: Renovated butter was made from what was called packing stock butter. Packing stock butter was obtained from housewives and farmers who would churn a

few pounds of butter and take it into a country store, where it would be weighed, tested for butter fat content, and they would be paid on the butter fat content. Then that butter would be put into a milk can. And then another housewife or farmer would bring in another lot. That would be weighed, tested for butter fat, they'd be paid, and then it would be thrown in on top of this first, and keep on until they got a can full of what was called packing stock butter. Much of this was prepared under very insanitary conditions, and then it was held under insanitary conditions.

Although the Food & Drug Administration did not have authority, for some reason I had occasion to inspect a renovated butter plant in Baltimore in the 1930s. The renovated butter was made thus: first they would take this packing stock butter, and they'd put that in a vat and run steam through it until they broke down the emulsion and separated the oil from the milk solids, and you had the layer of butter fat and the layer of water that has a layer that had the milk curd, along with all kinds of insects and rodent filth and all that kind of thing. They had a layer several inches thick of this material, and they would skim that off. Then they would take the butter oil, which was usually quite rancid and treat it chemically to remove its acidity. Then that clarified butter oil would be mixed with some milk and some coloring matter and some salt and maybe some artificial flavor and churned back into butter, which was "renovated butter."

Most of the plants that had been making renovated butter had closed by about 1940. But one man in Birmingham (Alabama), a man by the name of Kidd, operated the Clover Leaf Butter Company. The New Orleans District sampled and seized a quantity of the packing stock butter with all this filth. Well, Kidd claimed we had no jurisdiction. He appealed to the Fifth Circuit Court of Appeals. When he lost there, he took it to the Supreme Court. The Supreme Court remanded it to the lower court, and the . . . Again, he appealed to the Fifth Circuit. Again, he was overruled. Again, he appealed to the Supreme Court. Again, he was overruled. He appealed again to the Fifth Circuit. And they remanded the case for a trial on its merits.

By that time I was assistant chief in New Orleans. So I went over to Birmingham several times to work with the United States Attorney.

RT: All that litigation covered what number of years? Several years then, didn't it?

WM: I don't remember how many years that had taken us, but it had taken several years.

RT: Now during the time that this matter was before the courts, was he continuing to produce this product or was that terminated?

WM: Oh, yes. He was still operating his renovated butter plant. We couldn't do anything until we proved that we had jurisdiction over the packing stock butter. So he was continuing to make renovated butter all this time.

Makers of renovated butter would claim that the processing, given the packing stock butter and make it into renovated butter would purify the butter fat, and there wouldn't be any filth with the finished product. Well, in connection with our work at that time on sour cream butter made by the creameries, the chief chemist of the New Orleans District had developed analytical methods to demonstrate that when there were maggots in the cream that the maggot fat went on into the butter. So we had a way of showing that the filth was never removed by this. As severe as the process was, it couldn't remove maggot fat.

RT: Who was the chief chemist there, did you say?

WM: Vandaveer. I don't remember his first name. We always just called him Van. He was a very sharp soil chemist. He left FDA and became an official in Frito Lay. So you know he knew his chemistry.

After we were all prepared for trial, Mr. Kidd decided to agree to destroy this butter or to take it down under bond and make it into soap stock. That was a very expensive lot of soap stock.

RT: I was going to ask you, do you recall the approximate value of the butter that was under question in this case?

WM: I don't remember.

(Interruption)

WM: Mr. Kidd contested the seizure so strongly, because he had to win this case if he was going to continue in business, because if we started seizing all the filthy packing stock butter, he'd be out of business. So he agreed to take the seized product down under bond and make it into soap stock. It wasn't the value of the butter itself, the packing stock butter itself, that was the main point, but his business depended on winning. After the passage of the Oleomargarine Amendment in 1950, he converted his plant to an oleomargarine plant. And that was the last of the renovated butter.

RT: Now the Oleomargarine Act was again, as I recall, driven by economics, wasn't it? Wasn't that primarily an economics piece of legislation? Was that sponsored by the butter industry?

(Interruption)

WM: The first act defining oleomargarine was enacted by Congress on August 3, 1886.

RT: And at that time was the legislation to require it not to be colored? In the early days, you added the color.

WM: No. There was a great deal of controversy, particularly with regard to oleomargarine, whether the oleomargarine could be shipped in interstate commerce. When I first started work for the Food & Drug Administration, colored oleomargarine could not be shipped in interstate commerce. The oleomargarine being shipped at that time was perfectly white, but they would include in the package a small packet of the coloring that the housewife could mix with the margarine.

RT: Coloring packet?

WM: . . . packet of color, and you would have to take a spatula and stir and mix and mix and mix, which was a kind of messy operation.

RT: Yes, as it was, that was my job as a child, and I remember that.

WM: Oleo was subject to tax. The tax collection was in the hands, of course, of the Treasury Department. And in some states, such as Wisconsin, it was totally prohibited.

RT: So it was based on economics, not health reasons at that time.

WM: It was the dairy industry which opposed legalization of colored margarine. But the Oleomargarine Amendment of the Food, Drug, & Cosmetic Act was sponsored by Congressman W. R. Poage from central Texas. There were a number of cottonseed oil mills in his district. This amendment specified the conditions under which oleomargarine could be shipped in interstate commerce, but it didn't have to be shipped in interstate commerce to be subject to the act. This amendment is

different from any other part of the Food, Drug, & Cosmetic Act. It is based not on interstate shipment, but on the theory of placing a burden on legal products shipped interstate.

RT: I see. That's a different wrinkle, all right.

WM: Let's take a break, and I'll read you the statement. "Colored oleomargarine or colored margarine which is sold in the same state or territory in which it is produced shall be subject in the same manner and to the same extent to the provision of this act as if it had been introduced in interstate commerce. . . . So the Congress hereby finds and declares that the sale or the serving in public eating places of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of the Federal Food, Drug, & Cosmetic Act depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded."

RT: Well, as I recall, when I first began working in the Food & Drug work at the state level and working with FDA people primarily from Chicago, one of the plebe or beginning assignments which most FDA people didn't like was to go around and do some restaurant surveillance. I remember going with persons from FDA, and they needed to determine there was either a very visible sign in the establishment and that the patties were triangles rather than squares. In one place in Redkey, Indiana, the fellow had divided the patty of butter into triangles but pushed them back together, and it seemed to be kind of a trivial type of enforcement project. Most of the FDA inspectors didn't like it.

Then as I recall there was a field test kit. I think John Guill developed this oleomargarine test kit--critical temperature dissolution (CTD kit)--to do field tests in the cars while one traveled on field assignments.

WM: Another of the provisions about this amendment is that packages of colored oleomargarine can be no larger than one pound, and it has to be clearly identified and letters as large as any other labeling on the package as "oleomargarine" or "margarine." As to serving them in public eating places, it had to be labeled oleomargarine either by a wrapper or by the dish on which it's served, or it had to be in triangular form. In addition, there had to be a clear public declaration that the establishment served oleomargarine or margarine. This could be done by a prominent sign or by prominent statement on the menu, printed menu.

As far as the Food & Drug Administration was concerned, generally they did not give great priority to enforcement of the oleomargarine amendment. But inspectors were instructed to, when we ate at an establishment, make an observation on whether the law was being complied with.

RT: What penalty, if any, would be imposed on violators?

WM: Same as any other misbranding of food.

RT: Were there ever any of these persons who were prosecuted?

WM: So far as I can recall, I don't remember any actual prosecution under this. The one case that I know of that was sent forward to the U.S. Attorney was when I was resident inspector in Houston; I visited an eating place, and I made a report to the Food & Drug that they were serving oleomargarine. It was not in triangular form, nor labeled, the patty was not labeled, and that they did not have a declaration on the menu. However, I had not collected a sample, I hadn't collected the menu, there had been no analytical work to show that it was actually margarine instead of butter. I never understood why it was sent to the U.S. Attorney in Houston. Of course, when he found there was no evidence, except my hearsay evidence, he never filed the case.

One experience I had after the passage of the Oleomargarine Amendment, the Food & Drug Administration decided to make a national survey of the degree of compliance, and they worked out a system to assure that the places inspected would be chosen randomly. They worked out a system using the listings in the Yellow Pages of the telephone directories in the various cities. It happened that the two as selected in San Antonio, one turned out to be a beer establishment where they had their food permit, but it was for finger food that they could give to the people with their beer, and they didn't say butter or oleomargarine. They didn't serve any spread.

RT: Well, I think as I recall working with FDA people in the field as a state person, most of those regarded it as not a very important activity, feeling that that wasn't protecting people very much from real filth. And I know at one time there was a proposal that this be delegated to state people for enforcement. Well, it was a federal act. Most state people I think were not interested. Well, I recall that the critical dissolution kits--they were going to give those to the states--most of the states declined to share that interest. So it didn't really work out.

WM: The other establishment in San Antonio turned out to be a Chinese family restaurant operated by a Chinese family. The husband could speak no English at all. The wife could speak a few words, and we were kind of at a standstill until she figured what to do. She went to the phone and called her attorney. And then she talked to him in Chinese. Then she motioned for me to take the receiver, and he talked to me. I explained who I was, what I wanted, what we were doing. The husband then got on the phone, and the lawyer told him. So they eventually got it across to him that he should show me their menus and their supply of oleo. Though he couldn't speak any English, his oleo was in triangular form, and there on the menu, all the rest was Chinese, it said, "We serve oleomargarine."

RT: So he was in compliance anyway, wasn't he? Well, that's good.

WM: He couldn't speak English, but he got a good lawyer.

But actually, you're right. Neither the states nor the FDA took this act as being of great importance. Poage's purpose in getting it through, of course, was to benefit the makers of cottonseed oil, and other vegetable oils, and to provide consumers with a cheaper spread.

RT: When the agency in their new food regulations--of course, they have been promulgated since your retirement--but at one time, anything that was an imitation was really looked at with great regulatory concern. But today, even some of the butter companies are in the margarine business. So health awareness, I think, has changed our enforcement perspective as well.

WM: Right. There are some other acts that I don't know whether they've ever been repealed by Congress or not. One of them is the Filled Cheese Act. The Filled Cheese Act was strictly a revenue measure, so it was enforced by the Treasury Department. I've had no experience with it. But the labeling had to comply with the Federal Food, Drug, & Cosmetic Act and the Fair Packaging and Labeling Act.

RT: Was the Filled Cheese Act passed by Congress about the time of the Filled Milk Act?

WM: No, even further back than that. I don't know how far back. Then there was another act that as far as I know is still on the books is the Adulterated Butter Act. The Adulterated Butter Act was passed in May 1909. It also is administered by the Internal Revenue Service (IRS), because adulterated butter is any butter to which some foreign fat has been added, and that's subject to the high tax under the Internal Revenue.

RT: So that is probably the one that is pretty much antiquated now, isn't it?

WM: As far as I know no one wants to make adulterated butter. There wouldn't be much point. Real butter brings a much higher price, and oleo is competing for the cheaper markets. So the economic conditions are such that probably there would be no market for an article labeled "adulterated butter."

RT: But in the case of adulterated butter, this would not have been a concern about filth, merely the substitution of the natural oils or whatever for a foreign oil.

WM: Well, the Adulterated Butter Act dealt with economics rather than filth adulteration. It was actually butter, but it had some added foreign fat.

RT: That would offend the sensibilities of anybody, I think, the way it sounds.

Well, does that pretty well cover those additional statutes that you intended to discuss, Walter?

WM: Of course, the enforcement of dairy laws by the states has helped a whole lot to do away with the sources of such things as the packing stock butter, the filled milk, filled cheese, et cetera.

RT: Well, the Conference on Interstate Milk Shipments which is, you know, a national organization comprised of milk control officials at the county, even city in some cases, state and federal levels has also helped I'm sure to bring a uniform level of product and sanitation into being, and that's something that all the states are very committed to. In fact, this matter of reciprocity you mentioned with regard to the Import Milk Act--reciprocity of accepting inspection results between Canada and the United States--the Interstate Milk Shipments Conference has certainly done that for the state, because in the early days, New York wouldn't accept milk from New Jersey

unless New York people went to New Jersey to look at it themselves and vice versa. It was a tremendous and unnecessary waste of resources and of no real benefit, because it was primarily an economic barrier measure. If they didn't want milk from one state, they'd just keep it out that way.

Walter, if that pretty much covers our subjects . . .

WM: When I check the transcript I find something that I've left out, I'll add it.

RT: Sure. I really appreciate your thoughtfulness in letting us interview you further on this. You had a wealth of experience in just about everything FDA did for many years.

WM: I guess I've had experiences more with laws enforced by the Food & Drug Act than anybody else.

RT: I think you have, because you were in the Bureau of Regulatory Compliance for so many years, and you developed interpretations for industry and the states and everybody that had an interest in FDA's regulatory program. So thank you very much, Walter.

WM: You're welcome.

RT: I will add one thing at the end here that I don't think we did at the beginning. At the time of your retirement, Walter, you were chief of--what was it?--the Food . . . ?

WM: Chief of the Food Case Branch, Division of Case Guidance, Bureau of Compliance.

RT: At the headquarters of FDA. OK. Well, thank you very much, Walter.

Reprinted from the JOURNAL OF DAIRY SCIENCE, Vol. 25, No. 5, Pages. 748–751

# SYMPOSIUM: Imitation Products and the Future of the Dairy Industry [1]

## Imitation Dairy Products—Federal Laws and Regulations

**WALTER R. MOSES**

Food Case Branch, Division of Case Guidance, Bureau of Regulatory Compliance
Food and Drug Administration, Washington, D.C. 20204

You are concerned about the impact of imitation and dairy product substitutes on the dairy industry. Regulatory 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 their obligation these officials must, of course, act in accordance with applicable laws and regulations presently in effect or which may be enacted to deal with new problems.

One of the laws to be considered is the Federal Filled Milk Act passed by Congress in 1923 to close the channels of interstate and foreign commerce to filled milk.

Another is the Federal Food, Drug, and Cosmetic Act, particularly the specific provisions of this Act which relate to establishing food standards, the prohibition of false or misleading representations in the labeling of foods, and the labeling of imitations.

In administering these Federal Acts, the Food and Drug Administration (FDA) must also consider related State laws and regulations, particularly those based upon the Grade A Pasteurized Milk Ordinance recommended by the Public Health Service. In applying the labeling provisions of the Food, Drug, and Cosmetic Act the FDA generally accepts and uses the definitions in the 1965 revision of the Ordinance.

### The Filled Milk Act

Certain substitutes fall within the prohibitions of the Filled Milk Act, which states that, "The term 'filled milk' means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated." Any product made in imitation or semblance of milk or cream in any form is a "filled milk" if made from skimmilk, part skimmilk, nonfat dry, or any other form of milk or cream combined with fat or oil other than milk fat. Any person or firm who ships filled milk in interstate or foreign commerce is liable to prosecution. Persons convicted of violating the Act may be fined up to $1,000 or imprisoned for up to one year, or both.

It may be interesting to note the following statement about the purpose of the Filled Milk Act made by the Court in the case of Carolene Products Company of Litchfield, Illinois v. Wallace, tried in the District of Columbia in 1939: "The purpose of this chapter was to forbid the competition of a cocoanut grove with the American cow; to prevent the practice of frauds on the consuming public; and to avoid harm to the public health through the substitution of inferior fats for butterfat in an important food product."

The last reported case decided under this Act was that of U.S. v. Carolene Products Company, tried in Wheeling, West Virginia, in 1943. Conviction of the corporation and its officers was upheld by the Circuit Court of Appeals and by the U.S. Supreme Court.

The FDA has thus far encountered no interstate shipment of any of the substitutes for fluid milk or fresh cream which fall within the definition of "filled milk." Should they encounter shipments of such articles in interstate or foreign commerce they would be obligated to initiate regulatory action against the responsible firm or persons. The Filled Milk Act contains no seizure provision.

### Not all Nondairy Products Subject to Filled Milk Act

There are so-called nondairy products made without milk or cream in any form, using instead sodium caseinate or other protein materials combined with oils or fats other than milk fat. Unless these articles consist in part of

[1] Presented at the Sixty-third Annual Meeting of the American Dairy Science Association, The Ohio State University, Columbus, June 1968.

some form of milk or cream, they have been held not subject to the Filled Milk Act. The FDA was recently asked to reconsider its position on this. Their experts in the field of dairy science were asked to review the available *data and comment on whether sodium caseinate* could be considered "milk" as that term is used in defining "filled milk." Their decision was that sodium caseinate is not milk though it is usually derived from casein in milk. The process involves precipitation of the casein with acid, then its treatment with sodium hydroxide to form the chemical substance, sodium caseinate.

Their comments confirmed the earlier conclusion that the Filled Milk Act does not apply to imitations of milk or cream made by combining sodium caseinate with oil or fat other than milk fat, emulsifiers, and other nondairy ingredients. Such articles may, therefore, be shipped interstate provided they are not adulterated or misbranded in violation of the Federal Food, Drug, and Cosmetic Act.

#### Imitations Must Be Labeled as Such

Several provisions of that Act apply to these imitation products. The first is Section 403(c) under which a food is deemed to be misbranded if it is an imitation of another food, unless its 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 these in 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. Federal authorities exercise no jurisdiction over such articles, which are marketed solely in intrastate commerce.

There are some who believe that there should be a distinction between the designation of these filled milks and the so-called nondairy products. If the nondairy substitutes are, in fact, imitations, the FDA is 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 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 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 to advise the public that his product was not ice cream; that Congress had specified the method of advising the public that a product is not in fact the one which is imitated.

In applying this section, the first step is to determine whether the article is, in fact, an imitation of another food. The best guidelines *thus far given by 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.

#### Proposed Standards for Imitation Milk and Cream

As mentioned earlier, regulatory officials are concerned with protecting consumers against substitutes which are nutritionally inferior or which do not bear informative, non-misleading labeling. The FDA decided these problems could best be solved by establishing, in accord with Section 401 of the Act, standards of identity and of quality for imitation milks and creams. The proposed standards were published in the Federal Register of May 18, 1968. The proposed standard for imitation half-and-half is being amended to included the frozen form.

The proposed standards of identity are intended to 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.

Because the ingredients used in imitations of milk or cream, and the finished imitation products are capable of supporting rapid bacterial growth, it is essential that adequate sanitation and temperature controls be maintained.

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

There are unresolved and controversial questions about the physiological role of various fats in the human diet. The standards require only that the fats be suitable and that the quantity of fat used equals levels prescribed for dairy counterparts. The FDA still considers a food misbranded if claims are made in its labeling that the food is of special value in the prevention, cure, or mitigation of heart or circulatory disease because of its fat content.

The purpose of the proposed standards of quality is to assure consumers the imitations will either be nutritionally equivalent to milk 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." They specify not only the minimum amount of protein, but require that this be of a biological value equivalent to casein. The standards prescribe levels of calcium, phosphorus, vitamin A, and riboflavin. Addition of vitamin D is optional, but if added there must be 100 USP Units per 8-fluid-ounce serving.

### Other Imitation or Substitute Dairy Products

The Courts have not yet decided whether imitations of sour cream made from milk and vegetable fat are subject to the Filled Milk Act. Several years ago manufacturers were advised that FDA would not seek a decision on this if their products were labeled as "Imitation Sour Cream" and otherwise comply with the Food, Drug, and Cosmetic Act. Should the Courts decide such article is subject to the Filled Milk Act, manufacturers whose products comply with the Food, Drug, and Cosmetic Act will be so advised before action is initiated under the Filled Milk Act.

The frozen dessert sometimes called "Mellorine" is definitely considered 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."

### Margarine Is an Exception

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 statute, 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." The first definition of margarine by Congress was by Act of August 2, 1886.

The most recent ruling concerning the 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. The government 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 provisions 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 the contention that there could not be an imitation of what was really an imitation butter; the ruling was that an article not complying with the standard could be labeled and sold as "Imitation Margarine."

### Adulterated Butter and Filled Cheese

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, "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 tolerances having been allowed for." Any butter in interstate commerce found to contain less than 80 per cent milk fat is subject to seizure. Some have asked whether a low-fat butter might be marked as "imitation butter." Such article would probably be subject to the taxes, licensing provisions, and other requirements of the Adulterated Butter Act of May 9, 1902, administered by the Internal Revenue Service. The definition of "adulterated butter" in that 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."

Questions have been asked about the butter substitutes recently marketed in Wisconsin. The Internal Revenue Service presently has under consideration the question of whether these come within the definition of "adulterated butter." The FDA is withholding any action pending that decision. If the article, instead, should be found to come within the definition of margarine, it is subject to the provisions of the Federal Food, Drug, and Cosmetic Act even if the margarine is not shipped out of the state where it was produced, since Congress has declared that the sale and serving of adulterated or misbranded margarine depresses the market in interstate commerce for butter and margarine which are neither adulterated nor misbranded, irrespective of whether such margarine originates from an interstate source or from the state in which it is sold.

There are on the market many products which imitate standardized cheeses or cheese products. Most of these are properly labeled as imitations. The addition of any vegetable or other fat or oil to cheese brings it within the definition of "filled cheese," making it subject to the Filled Cheese Act administered by the Internal Revenue Service 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.