CONTAMINATION OF MILK AND MILK PRODUCTS

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The Food and Drug Administration is responsible for the administration of the Food, Drug, and Cosmetic Act, which is intended to prevent interstate commerce in adulterated or misbranded foods, drugs, medical devices, and cosmetics. Applied to milk and milk products, the problems of contamination fall chiefly into two categories:

1. Contamination arising from use of filthy or decomposed milk, insanitary conditions in the production, storage, transportation or manufacture of milk products; or that caused by diseased animals.

2. Contamination with poisonous or deleterious substances which may be derived from pesticide residues on forage or feed, from fly sprays in dairy barns, drugs used in the treatment of animals or as growth promotion agents, sanitizing agents employed on premises or equipment of milk-handling or manufacturing establishments, or from preservatives deliberately added.

As to the first category, the Administration has vigorously pursued clean milk programs ever since enactment of “sanitary clauses” in the 1938 Act. First attention was directed to sanitation of dairy products manufacturing plants to eliminate any existing insanitary plant conditions that might contribute filth to butter, cheese, evaporated milk or other manufactured dairy products. Attention soon was directed also to the character of the milk or cream received by such plants. Pressure has been brought to bear on manufacturers to reject filthy or decomposed milk and cream for manufacturing use and thus encourage improvement in farm sanitation and in the handling and care of milk and cream all along the line. Such pressure is applied through regulatory actions — seizures, prosecutions or injunctions — based upon interstate shipments of the manufactured products. This has required extensive investigation including the development of special analytical procedures involving interesting and varied research projects. Time does not permit discussion of these here. Suffice it to say that legal procedures in this country properly require the Government to bear the burden of proof and to sustain by adequate evidence prosecution of a defendant or condemnation of merchandise. Among other things this means that we must be able to prove that a particular shipment in interstate commerce was “prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth . . . .” This we have been able to do through the development of methods that enable detection and identification of microscopic fragments of filth or the chemical breakdown products of decomposition.

We have sponsored and participated in educational programs with trade and industry associations and other Government agencies. Our objective is clean milk and clean milk products. We think it is not enough just to filter milk or cream to remove some of the evidences of insoluble filth. Our objective is “clean” rather than “cleaned” milk. Similarly, we think that the emphasis should be directed to proper handling and care of milk to prevent spoilage or decomposition. It is obvious that State and local sanitarians and the State and county agricultural agents, in encouraging better sanitation in the production and

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handling of milk to prevent filth contamination and decomposition, can directly accomplish that which we can do only by the rather indirect approach afforded by the Food, Drug, and Cosmetic Act on the products of interstate commerce.

As to the second category of contaminants, this discussion will be directed particularly to chemical contaminants that can be contributed to milk from pesticides or from treatment of dairy animals with drugs, such as antibiotics. In 1949 it was found that the use of DDT for fly control in dairy barns resulted in the appearance of that chemical in milk of exposed cows. Conferences between the Public Health Service, Food and Drug Administration, and the Department of Agriculture led to withdrawal of recommendations for use of DDT in dairy barns or on dairy cattle, and the issuance of warnings by the Department of Agriculture against such use.

The Food and Drug Administration has never sanctioned the presence of poisonous or deleterious substances in milk. We have felt that this important food commodity should be kept free of any amount of contaminants of this sort. Milk and milk products constitute the largest proportion of the average American diet. Based upon statistics compiled by the Department of Agriculture we have estimated that milk products make up about 29% of the average diet, that milk itself constitutes about 25%. This represents about a pint per person per day. No other one class of food forms a third as much of the diet. We have also had in mind that milk is the chief food in the diet of infants, small children, invalids and many persons on restricted diets. These represent population segments that are likely to be much more susceptible to injury than normal healthy adults.

Although we have never sanctioned residues in milk, recent surveys have indicated that some contamination has at times occurred. Several years ago limited surveys on market milk indicated the presence of antibiotics in some samples. A comprehensive sampling program was completed in 1956. Over 1700 samples, representing all of the States, were collected in the fall of 1955. Assays revealed that 5.9% contained penicillin, as confirmed by the penicillinase identity test. The concentration ranged from 0.003 up to 0.55 unit per milliliter. About 1% of the samples appeared to contain one of the tetracyclines, bacitracin, or a combination of antibiotics. Definite identity tests for these were not available. These facts were brought to the attention of an advisory panel of scientists and physicians knowledgeable as to antibiotics. The panel agreed that penicillin even in the very small quantities observed in these milk samples might cause allergic reactions in highly sensitive individuals. It seemed probable that the antibiotics observed in milk came from antibiotic-containing drugs used in the treatment of mastitis.

Preparations containing certain antibiotics including penicillin are subject to certification by the Food and Drug Administration. Certification is intended to ensure the safety and efficacy of the preparations when used in accordance with labeling directions. The first certified antibiotic preparation intended specifically for mastitis treatment contained 25,000 units of penicillin per dose. The evidence submitted showed the efficacy and safety of this product. Later when dosages were increased it was required that the labeling directions admonish that milk taken from treated cows within 72 hours after treatment should be discarded. In recent years it has been observed that the dosages in mastitis preparations have been steadily increasing. Some preparations have contained as much as 1,500,000 units of penicillin per dose. We think that is excessive and is likely to increase tremendously the probability of prolonging the appearance of residues in milk.

A program has been instituted which we believe will bring about immediate and substantial improvement. The antibiotic regulations have been revised to limit to 100,000 units the dosage of penicillin which is eligible for certification for single-dose mastitis preparations. We are also requiring more prominent display on labels of the warning statement against the use of milk for a definite time period after treatment. A vigorous educational and informational program is being carried out to emphasize to dairymen and farmers the importance of proper use of these drugs and the necessity for adhering closely to directions. The Federal Extension Service of the Department of Agriculture is taking the leading role in this program and trade associations in the dairy industry are participating.

Our surveys have also revealed evidence of the presence of minute quantities of pesticide chemicals in milk. The same samples collected for the antibiotic survey were also examined for presence of pesticide chemicals. Eight hundred of the samples of milk were so tested, using a sensitive fly-bioassay procedure. About 60% of the samples tested revealed positive results, chiefly for chlorinated hydrocarbons. No organic phosphates were detected. By applying chromatographic procedures to the samples exhibiting the highest toxicity to flies we were able to identify the presence of several chlorinated hydrocarbons, including DDT, DDD, DDE, BHC, lindane, and methoxychlor. The highest amount found was estimated at about 1% parts per million of DDT.

While the amounts of the contaminants revealed by this survey do not seem to be significant as a public
health hazard, the implications are startling and suggest the possibility that continuing and increasing amounts might lead to a public health problem. Furthermore, milk containing an added poisonous or deleterious substance is illegal for interstate shipment unless a safe tolerance has been established. No tolerance for such substances in milk has been established.

We postulated that the appearance of these pesticide chemicals in milk might be the result of ingestion by dairy cattle of feed containing residues of the chemicals or the result of the use of these pesticide chemicals in fly sprays on or around dairy cattle. We made additional follow-up investigations in four of our field Districts (San Francisco, Los Angeles, New Orleans, and Atlanta) where the contamination seemed to be most pronounced. These investigations were made between December 1956 and April 1957. No residues were found in any of the samples tested by three of the Districts at that time and only slight indications in one or two samples in the Atlanta District. Samples in this survey represented winter milk, whereas the assays made in 1956 were on milk collected in the fall of 1955. This suggests a seasonal factor and we are again repeating some of this work on late summer and fall milk this year.

The informational program of the Extension Service of the Department of Agriculture is also giving emphasis to the hazard of milk contamination through improper and careless use of fly sprays or pesticide applications on forage crops.

In setting tolerances for pesticide residues in forage crops we have required petitioners to present data showing whether or not residues appear in the food products derived from animals consuming such forage. If residues do appear, tolerances for forage crops are not granted unless at the same time a safe tolerance is requested and can be established for residues in the food products, such as meat, eggs, and milk. The misuse of pesticides either on forage crops or as insect-control agents on dairy animals or dairy premises may result in contamination of milk.

We are giving concentrated attention to these problems and we intend to pursue all possible avenues in coping with them. We shall employ educational, informational and regulatory programs to assure clean safe milk and milk products.