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September 1968

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THE ROLE OF FDA
IN ENVIRONMENTAL CONTAMINATION
AND SURVEILLANCE

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For me to talk about birds other than it pertains to the Food and Drug Act is somewhat like the fellow who got up and dressed in the morning, ate breakfast, and as he was kissing his wife good-by she took the dish cloth and slapped him on the side of his face. "What's that for?" he asked. "For being such a lousy lover," she answered. As he walked to work he couldn't figure out what had gotten into that woman. He pondered it all day. When he walked into the house in the evening, his wife ran up to him to give him a kiss. He took the newspaper he was holding and swatted her aside her head. "What's that for?" she asked. He replied, "For knowing the difference."

The Food & Drug Administration is concerned about birds in two areas. One is the direct contamination of foods, drugs and cosmetics by birds and the other is the possible contamination of these products by the chemicals used to control birds.

Since its conception, the Food & Drug Administration has been concerned about the contamination of foodstuffs by birds. Like all animals, they have both their good and bad points. The one bad point is that they are carriers of certain diseases. In addition, the consumer of today is not ready to accept products which have been contaminated by fecal material or feathers of birds.

Federal law prohibits the introduction or offer for introduction into interstate channels of any food, drug, cosmetic or device which is adulterated or the adulteration after receipt from interstate commerce.

Adulteration is defined as any food which consists in whole or in part of any filthy, putrid, decomposed or any substance which would make it otherwise unfit for food. While the act defines a number of other adulterants these would be the main ones of concern in dealing with this topic. Two areas where bird contamination has been particularly prevalent are grain elevators and warehouses. However, bird contamination has been found in most all types of food establishments. A review of the inspectors' observations and my own personal experience indicate that the major problem is associated with the premises surrounding the plant. Poor housekeeping practices outside of the plant attract the birds and open, unscreened windows and doors allow their entry. Our inspectors have

learned to be aware of the various signs of bird contamination such as droppings on rafters or bird feathers on the premises. Under federal law such products are subject to seizure and the individual in such an establishment would be subject to federal prosecution. In addition the law provides that food cannot be stored under conditions where it *may* become contaminated. So the very presence of a bird inside a food establishment would in itself be a violation of the law.

The evidence of bird feathers in a prosecution action against a firm was considered as some of the most substantial evidence in proving a case against a firm where the charge was that they were operating under conditions by which contamination with filth may have been possible.

In other words it is not necessary under the law to show that the actual contamination is in fact in the product if the evidence will sustain that the conditions are present whereby the contamination may take place. In this case, the court ruled that the presence of the bird feathers in the plant as well as bird nests indicated that these conditions existed for a considerable period of time.

Another thing of concern to us in dealing with a food establishment is the careless use of pesticides in a food manufacturing plant or warehouse. The careless use of pesticides which would be for either the repelling of birds or killing of birds once they gain entry. If they are used in a careless manner, not only the firm, but also the pest control operator, can be subjected to the penalties of the law. If you were to use some of the open bait boxes with some of the highly toxic chemicals, we would frown mightily heavily on this if we found it in a plant. And as I said, we would hold the firm responsible, and also the pest control company which put them there.

The establishment of a tolerance is a lengthy and costly procedure. The first requirement is that a need exists to use the product and that its use will serve a useful purpose. Next, the product must be subjected to acute and chronic chemical testing on two different types of animals.

The acute testing establishes the amount that can be used before an adverse effect takes place. The chronic testing establishes the lifetime effect upon an individual. Tests must also be submitted to show the minimum amount that can be used and still be effective.

These basic requirements are covered under both the pesticide and the food additive amendments. The pesticide amendment pertains to raw agricultural commodities; the food additive amendment pertains to that which is a manufactured product.

The general rule for establishing tolerances is the rule of 100. This rule is that 100 parts is a safety factor for the general population. Then an additional 100 parts is built in as a safety factor for those people who are more sensitive or allergic to such products. So you can see we are dealing with parts per million when we talk of establishing tolerances.

In addition, a method of analysis must also be submitted to determine the residues that would remain on a product after its use. The law also prohibits the inclusion of any chemical which is carcinogenic in nature.

Therefore, the use of a chemical to eradicate a bird may thus create a problem. In addition, the misuse of such chemicals may also create additional problems.

Since birds are disease carriers their presence in a food plant would be considered a danger to health problem, rather than an aesthetic problem. So, as a word of caution, if you do develop a bird problem, extreme care should be taken in determining the method of eradication or solution to the problem.

As you will probably hear throughout this conference, good sanitary practices such as keeping the surrounding area around the premises clean, refuse properly covered, and all windows properly screened and closed is still the best protection against possible bird entry and contamination.

DISCUSSION:

JACKSON: There seems to be some feeling among some people in Ohio that FDA is now looking for much stricter standards in sanitation than pest control, particularly where birds are concerned, especially in the last year or so. Does this represent any measured crack-down in sanitation?

SHANE: No, in fact for all intent and purposes during the last couple of years, and I can speak for Detroit and probably FDA in general, our major emphasis as far as manpower has been into the drug industry. In fact, this year we have thrown about 65% of our manpower into the field of drugs, primarily drugs for human consumption. Now there is in effect a good manufacturing practice regulations for the drug industry, and it would be a violation of the regulations if bird contamination would occur in the drug industry. Therefore I would assume that some of the drug people are much more concerned. In addition there is a proposed regulation covering the good manufacturing practices of food products. Of course these basic areas are spelled out as far as birds are concerned. We term this as a health problem rather than an esthetic problem.

SCHNEIDER: You said something about bringing both the pest control operator and the owner of the plant under charges. It is my understanding that the owner is primarily responsible for his plant.

SHANE: That's right, he is primarily responsible. Under the law he is totally responsible for his plant, but we could, under the law, charge the pest control operator for causing the violation. There are instances in the past where we have actually taken action against pest control operators. You're probably all aware of the injunction we placed on the pest control operator in Texas; we enjoined him from servicing food establishments. I'm sure that we are to a point that if we found 1080 and open bait boxes in conjunction with food that we would be tempted to take action pretty quick.

RUSSELL: Is the difference that the owner is responsible for the insect or rodent contamination and the pest control operator is responsible for possibly harmful contamination with the chemical that he uses?

SHANE: Right. In other words, the pest control operator we hold responsible for any poisoning they use in food establishments. Now we'd also hold the firm responsible for it. If you had gone to a plant and used 1080, we would not only hold the firm responsible for the fact that it was in there, but also the pest control operator.

RUSSELL: Right, but if you just find insects, rodents, or birds contributing to the contamination, then the owner is himself responsible?

SHANE: Correct.

SPITZ: What is the FDA feeling toward not using bait boxes for items other than 1080 in processing areas?

SHANE: Our general philosophy is that baits should be in a locked, anchored bait box. Now this depends on the situation, but this is primarily what we recommend. There is no official regulation to back it up, but it is our recommendation.

SPITZ: What is actually done when you go into a place and find cups all over the place; what is the FDA going to do?

SHANE: Well, the FDA agent upon seeing this would break out his camera and start taking pictures of the conditions. Then he would take a sample of the bait to determine the toxicity of the product and to establish its use in relationship to a food. Based on the findings, the decision would then have to be made whether or not to take legal actions. This falls under the provision of the law where you don't have to have direct contamination. It could happen; it's being done to some degree.

DALTON: Back to the use of 1080 and the federal regulations. We had a rat control program on a ship and the federal authorities came over and put the cups down. They counted every cup. We had the whole crew taken off the ship and the ship locked up.

SHANE: We have absolutely no restrictions against the use of 1080. Our law doesn't say that you can't use 1080, but we have to go back to the law that says, "if we find conditions by which. . ." If we find 1080 in a manufacturing area, like in an open cup somewhere where there's the possibility of contamination, then we would take an action. Some of the Fish and Wildlife people disagree over the toxicity of the product, but we consider it a very toxic substance.

HAYDEN: Even though 1080 is restricted, aren't municipalities able to purchase this, and have city authorities put out this product at city dumps or throughout a city?

SHANE: They may. We have no control over the purchase or sale of the product.

QUESTION: What is the definition of food—does it cover animal food?

SHANE: Food for man or animal. . .correct. In other words if you were using bird control measures in a feedlot where the food could become contaminated, then this could itself be a violation of the federal law, providing the product had moved in interstate commerce.

QUESTION: Even though it doesn't hurt the animal itself?

SHANE: There's a situation on establishing of tolerances, and as the fellow from the Department of Agriculture pointed out, you must have a tolerance established for any of these pesticide chemicals. If there is no tolerance established for a product and it is used per se it would be illegal.

SPITZ; Is this to say that if something is contaminated, and it is essentially for human consumption, and FDA says that it is no longer fit for human consumption, then it is no longer fit for animal consumption?

SHANE: Yes, that would be the general rule. We've tightened up drastically in our interpretation. We used to let a number of things go for animal consumption that we will not let go anymore. Thank you gentlemen.