LEGISLATION AND REGULATIONS

FDA will not regulate antibiotics for plant disease control . . . Considers them pesticides, usefulness up to USDA

"*The presence of antibiotic drugs in foods intended for human consumption, or the direct or indirect addition of such drugs to such foods, may be deemed an adulteration within the meaning of section 402 of the Food, Drug, and Cosmetic act . . .*" (Statement of policy of the Food and Drug Administration on the addition of antibiotics to processed foods. *Federal Register*, Feb. 1953, page 1066.)

The Food and Drug Administration has been intimately interested in the gradual developments of antibiotics in the areas outside the original applications to human therapy.

In February 1953 the statement above was issued as an indication of the official FDA policy toward application of research under way to add antibiotics to processed foods.

It seems unlikely that this position will be changed in the near future, unless there is evidence that the use of antibiotics as preservatives is safe and essential to the production of a given food.

Parallel with the research on antibiotics as preservatives has been the development of other nontherapeutic uses of these drugs (AG AND FOOD, Nov. 25, 1953, page 1096–1101). Since the statement of 1953 the agricultural use of antibiotics has created a number of unforeseen problems for the FDA.

Feed Supplements

The increasing use of antibiotics as feed supplements for pigs and chickens raised the very immediate problem of carryover. The question was raised regarding the attitude of the FDA to the presence of antibiotics in the meat, milk, and eggs of animals feed antibiotics for growth stimulation.

The carryover problem was a central topic of discussion at the antibiotics symposium sponsored in part by the FDA in Washington last fall (AG AND FOOD, Nov. 11, 1953). Research reported at that symposium indicated that it was not possible to detect antibiotics in the foods resulting when animals were fed at normal growth stimulatory levels. At high levels of feeding, however there was a detectable carryover, which was destroyed by cooking.

In the case of feed supplements the FDA may have modified its position in that it was a situation of indirect addition of the antibiotic to a food. However since the drug was not present in detectable quantities it would have been extremely difficult to challenge adulteration.

For the past 4 months the FDA has had up for consideration the question of the agricultural crop usage of antibiotics. The immediate cause for concern has been the request for approval of streptomycin and oxytetracycline for the control of pear, apple, and walnut blights.

Dr. Henry Welsh, Director of the Division of Antibiotics, FDA, addressed the recent meeting of the Potomac section of the American Phytopathological Society on the FDA's position on the use of antibiotics on crop plants (see page 281). He told the plant pathologists that the FDA is aware of the successful studies on control of bacterial diseases of plants through the use of antibiotics. And in effect he clarified the position of the FDA on the topic.

Plant Disease

The plant researchers have been concerned over the relationship of their work to the FDA statement of last year. They were also somewhat concerned over what regulations would be applied to the use of antibiotics in plant disease work. As drugs the materials would come under the experimental drug procedures of the FDA.

Dr. Welch told them that it was the opinion of the FDA that antibiotics intended solely for the control of plant diseases are not subject to the drug requirements of the Food and Drug Act. Even though the antibiotic drugs are primarily of value in the cure or treatment of disease, when they are used in agriculture as plant sprays or dusting powders they are more logically classified as pesticides and thus should be considered under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act.

According to the FDA the determination of the usefulness of antibiotics as pesticides rests with the USDA. And regulations of the use of these materials will be administered by the same department.

With the antibiotics for agricultural use declared to be pesticides the FDA is again faced with the problem of contamination of finished foods. Dr. Welch said that the policy on food contamination of antibiotics will still stand. The pesticide use of antibiotics for the control of blights would probably not result in significant quantities carrying over into the harvested fruit.

Preliminary studies, including some reported at the phytopathologists meeting where antibiotics were applied to apple trees during blossoming resulted in failure to demonstrate the drugs in the fruit. Similar assays following treatment of other trees and plants have yielded zero amounts of antibiotics under the test conditions.

Miller Bill

If there is widespread expansion of antibiotics in agricultural disease control programs, it may be necessary for the FDA to establish tolerences of carryover of these materials on the harvested fruit. Under the present food and drug act the establishment of tolerences for pesticides is an extremely cumbersome procedure. However if the Miller Bill (H.R. 7125) is passed to amend the present food and drug act the establishment of pesticide tolerences would be expedited.

Dr. Welch implied that if the FDA should be called upon to establish tolerances for antibiotic residues they might be "zero tolerances." This would be in line with the position on addition to food.

This new FDA policy statement by Dr. Welch may open up the application of antibiotic treatment of plant diseases. Chas. Pfizer, Inc., has announced that it is planning extensive field test programs of the agricultural antibiotic, Agramycin, a combination of streptomycin and oxytetracycline. If field tests prove antibiotics effective for control of bacterial infections of plants, then the application for registration of antibiotic preparations as agricultural pesticides may soon follow.

Michigan Legislature Considers Bill to Regulate Soil Conditioners

A bill, H.B. 214, has been introduced in the Michigan Legislature to include soil conditioners and trace element sources under the commercial fertilizer law.

Application for certification of a soil conditioner must be accompanied by authentic experimental evidence substantiating the claims made for it and the material must be approved by the Michigan Agricultural Experimental Station. Soil conditioners would be sold under the same inspection fee system as fertilizers, 8 cents per ton.