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The Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) share responsibility for insuring that raw meat and poultry do not contain illegal residues of drugs, pesticides, or environmental contaminants. Residues of many substances which have been found to cause adverse effects including cancer in test animals have been found in raw meat and poultry at levels exceeding established tolerances. USDA reported that illegal residues were found in only about 2% of samples tested. However, the testing methods were questioned, the results did not accurately indicate consumer exposure, and the incidence of illegal residues was higher. Generally, neither USDA nor FDA can locate and remove from the market the products found to contain illegal residues. A tagging system for identification of slaughtered animals does not seem to be feasible. A capability needs to be developed for a timely sample analysis before the carcass leaves the packing house. Efforts to prevent future shipments of contaminated animals have not been effective because of ineffective follow-up by FDA, avoidance by growers of USDA pretest requirements, inadequate residue detection methods, and difficulties involved in using strong regulatory actions such as the lack of case histories to support prosecution and FDA's lack of authority to seek civil penalties. (HTW)

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Statement of
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before the
Subcommittee on Oversight and Investigations
House Committee on Interstate and Foreign Commerce
on
Federal Efforts to Regulate Toxic Residues
in Raw Meat and Poultry

Mr. Chairman and Members of the Subcommittee, we are pleased to appear here today to discuss the results of our review of Federal efforts to control the marketing of food-producing animals containing illegal and potentially harmful residues. We are currently preparing a report to the Congress on the results of our review.

Food-producing animals including cattle, sheep, swine, chickens, and turkeys, are exposed either intentionally or unintentionally, to a wide variety of drugs, pesticides, and environmental contaminants. Residues of some of these substances may be present in meat and meat by-products and may pose hazards to consumers.

Our review has been directed to determining (1) the extent to which consumers are exposed to illegal and potentially harmful residues in raw meat and poultry, (2) the effectiveness of Federal efforts to identify and remove from the market raw meat and poultry containing illegal residues, and (3) the effectiveness of Federal efforts to prevent future shipments of residue-contaminated animals from a violative grower.

BACKGROUND

The Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (USDA) share responsibility for insuring

that raw meat and poultry does not contain illegal residues of drugs, pesticides, or environmental contaminants.

FDA is responsible under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for (1) insuring the safety of drugs given to food-producing animals, (2) setting a limit, or tolerance, on the amount of an animal drug or environmental contaminant allowable in food, and (3) preventing the marketing of raw meat and poultry containing residues that exceed established tolerance levels.

EPA is responsible for regulating the introduction into the environment of pesticides and toxic substances. Under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, as amended, EPA must approve pesticide products for safety and effectiveness before they can be marketed. In addition, under the FD&C Act, EPA establishes safe tolerance levels for pesticides likely to leave residues in food. The introduction of toxic substances into the environment is regulated by EPA under the Toxic Substances Control Act of 1976.

USDA is responsible under the Federal Meat Inspection Act and the Poultry Products Inspection Act for preventing the marketing of adulterated raw meat and poultry, including that containing residues in excess of tolerances set by FDA or EPA.

USDA operates a two phase residue monitoring program. Under the first, or monitoring phase of the program, a random sample of animals is identified and USDA inspectors collect samples from them at slaughtering plants. While the sample is being analyzed at a USDA laboratory, the carcass continues moving through the slaughtering and marketing process. About 18,000 to 20,000 animals are sampled annually under this program.

Under the second, or surveillance phase of the program, samples are collected because USDA has reason to believe the animal carcass is violative. Because the animal is suspected of containing illegal residues, USDA can detain the animal carcass for up to 20 days. Samples may be collected under the surveillance phase (1) if there are outward signs, such as injection lesions, that the animal may contain illegal residues, (2) if the grower has previously shipped animals containing illegal residues, or (3) as part of special surveys.

If the laboratory analysis indicates that residues are present in raw meat or poultry at levels in excess of tolerance, USDA refers the case to FDA for investigation. FDA inspectors investigate at the grower level to determine the cause of the residue problem and to take regulatory action, if warranted. If FDA's followup indicates that

the illegal residue resulted from misuse of a pesticide, FDA refers the case to EPA for regulatory action.

Under the FD&C Act FDA may initiate, through the Department of Justice, action to (1) prosecute an individual who violates provisions of the act, (2) enjoin a grower from violating the act and FDA regulations, and (3) seize raw meat and poultry that is adulterated or misbranded.

In cases of minor violations, FDA generally issues information letters notifying the alleged violator of the problem and requesting that corrective action be taken.

CONSUMERS EXPOSED TO HAZARDOUS RESIDUES

Many of the drugs, pesticides, and environmental contaminants to which food-producing animals are exposed have been found to cause long-term adverse effects in test animals including cancer and birth defects. Residues of many of these substances have been found in raw meat and poultry at levels exceeding established tolerances.

There are at least 143 drugs and pesticides and an unknown number of environmental contaminants likely to leave residues in food-producing animals. USDA's monitoring program tests for only 46 of the 143 drugs and pesticides, and 8 environmental contaminants.

The extent to which the public is exposed to illegal residues has not been accurately estimated by USDA. On the basis of data developed under its residue monitoring program, USDA reports that it found illegal residues in only about 2 percent of the raw meat and poultry samples tested. USDA arrived at a 2 percent violation rate by dividing the number of violations identified by the number of animals tested.

The results of this calculation, in our view, do not accurately estimate overall consumer exposure to illegal residues of the drugs, pesticides, and environmental contaminants included in the monitoring program because each meat and poultry sample was not tested for each of the substances. Instead, each sample was tested for only one substance or class of substances. In order to use USDA's 2 percent violation rate as an overall estimate of the incidence of illegal residues, a mathematical assumption must be made that there is no illegal residue of a substance in a sample if the sample was not tested for that particular substance. For example, USDA tested approximately 8,600 swine, but tested only about 2,100 for sulfa residues. Even though USDA's tests showed that about 10 percent of the 2,100 swine contained illegal sulfa residues, the assumption would have to be

made that none of the remaining 6,500 swine contained illegal sulfa residues.

In our opinion, a more appropriate assumption would be that samples not analyzed for a particular substance or class of substances would generally contain about the same percentage of illegal residues as did the samples that were analyzed for the substance. On this basis the overall violation rate would more closely approach the sum of the violation rates for each of the substances or class of substances included in the monitoring program assuming that those violation rates were statistically valid. Accordingly, further analysis of the data developed under USDA's monitoring program indicates that the actual incidence of illegal residues of the drugs, pesticides, and environmental contaminants covered by the monitoring program between 1974 and 1976 may have ranged from as high as 2.6 percent in sheep and goats to almost 16 percent in swine.

Because USDA does not test for most drugs and pesticides likely to leave residues in food-producing animals, the actual incidence of illegal residues was probably even higher. Drugs and pesticides not included in the monitoring program include:

--Chlorophenoxy herbicides, including 2,4-D, 2,4,5-T, and Silvex, which are suspected of causing birth defects.

--EBDC (Ethylene bis dithiocarbamate) fungicides, whose decomposition product, ethylene thiourea, has been shown to cause thyroid cancer in laboratory animals.

--Furazolidone, an animal drug shown to cause cancer in rats and mice.

Although some of the drugs and pesticides are not included in the monitoring program because methods to detect their residues are not available, methods do exist for detecting many of the drugs and pesticides not included.

Toxic effects of residues

Of the 143 drugs and pesticides identified as potential sources of residues, 40 are suspected of causing cancer and 18 are suspected of causing birth defects.

However, residues of some pesticides suspected of causing cancer are unavoidable due to the persistence of the chemicals in the environment. Therefore, residue tolerances or action levels have been set for them even though safe exposure levels cannot be established. For example, both DDT and dieldrin were banned by EPA for agricultural uses because they were suspected to cause cancer, yet residues are still in meat and poultry as a result of prior usage of these chemicals. USDA tests for DDT in 1976 showed that 82 percent of the about 900

chickens tested had measurable residues; none contained residues above tolerance. Similarly, 52 percent of the about 1,800 cattle tested for dieldrin during 1976 had measurable residues; only 13 cattle contained residues above tolerance.

PROBLEMS IN IDENTIFYING AND REMOVING CONTAMINATED ANIMALS FROM THE MARKET

With few exceptions, neither USDA nor FDA can locate and remove from the market raw meat and poultry found to contain illegal residues. Most raw meat and poultry identified under USDA's monitoring program as containing illegal residues was sold to the public.

The Government is unable to prevent the marketing of the contaminated animals because:

--USDA does not have the authority to detain raw meat and poultry pending results of sample analysis unless it has reason to believe the animal is violative.

--Meat and poultry are generally marketed within 48 hours after slaughter, and sample analysis usually takes between 6 to 25 days to complete.

--Meat from violative animals cannot be identified once the animal has been slaughtered.

In order to remove raw meat and poultry containing illegal residues from the market, USDA must either

(1) develop a "tagging" system whereby the carcasses of slaughtered animals will be marked for future identification, or (2) develop the capability to complete the sample analysis before the animal carcass leaves the packing house.

Tagging system not feasible

A tagging system does not appear feasible because the animal would have to be tagged at least four times in order to maintain the identity of the animal through to the retail level. Specifically:

--An ear tag, brand, or other external tag would be required when the animal is sent from the grower to an auctionhouse or slaughterhouse.

--Separate tagging would be required for the carcass and the edible by-products, such as liver and kidney, when the animal is slaughtered because external identification is lost.

--Separate tagging of each cut would be required when the packing house divides the carcass into wholesale cuts.

--Each cut would have to be tagged when the wholesaler or retailer divides the carcass into retail cuts.

According to one packing house official, one animal may yield several hundred retail cuts.

Thus, before meat from an animal found to contain illegal residues could be identified and removed from the market, USDA would have to trace through the voluminous paperwork involved in maintaining four separate tagging processes. By the time USDA could identify the locations to which meat from a violative animal had been shipped, the meat would probably have been purchased by a consumer.

More timely analysis needed

The FD&C Act requires animal drug manufacturers to develop "practicable" methods for detecting drug residues in raw meat and poultry. FDA defines a practicable method as one that is suitable for routine use in a Government laboratory and consistent with regulatory objectives such as monitoring and compliance.

Because it is not feasible to locate and remove from the market meat from animals containing illegal residues, sample analysis must be completed before the animal is divided into wholesale cuts at the packing house if USDA is to prevent the marketing of meat containing illegal residues. Because animals are generally divided into wholesale cuts about 24 hours after slaughter, a practicable method would appear to be one that can be completed at the packing house within a 24-hour period.

Several methods, including testing on live animals, are available or are being developed which would enable USDA to complete sample analysis on some drugs and pesticides within 24 hours. However, a USDA official told us that USDA does not have the laboratory facilities or equipment to use such methods. Even if USDA develops the capability to complete sample analysis at the packing house, the consumer protection afforded will be minimal because only about 1 out of every 8,000 livestock and 1 out of every 700,000 poultry slaughtered are sampled.

PREVENTING FUTURE SHIPMENTS OF CONTAMINATED ANIMALS

Because of the problems in identifying and removing residue-contaminated raw meat and poultry from the market, a major part of FDA, EPA, and USDA efforts concerning residues must be directed to preventing future shipments of residue-contaminated raw meat and poultry from violative growers. However, our review indicates that the Government's efforts in this regard have not been effective because:

--FDA does not follow-up on most residue violations to identify the cause of the violation and the corrective action needed.

--USDA's pretest program to determine whether residue violations have been corrected can easily be avoided by growers.

--Residue detection methods adequate to support regulatory actions do not exist for many drugs and pesticides.

--FDA generally issues information letters because of difficulties in using stronger regulatory alternatives.

--USDA's monitoring program is not designed to enable FDA and EPA to develop case histories to support prosecution.

--FDA cannot seek civil penalties against violators; its authority is limited to criminal penalties

Ineffective followup

After USDA identifies illegal residues in a sample of raw meat or poultry, followup should be performed (1) by FDA to determine the cause of the violation, and (2) by USDA to determine whether needed corrective actions have been taken. However, neither agency's followup efforts have been effective.

During the 4-year period ended December 1976, USDA reported about 3,100 residue violations to FDA for followup. FDA district offices reported followup investigations on only about 37 percent of the cases.

An FDA official told us that FDA does not follow-up on some residue violations because the data the agency receives from USDA are too old. In an effort to speed the reporting of residue violations to FDA district offices,

USDA, in July 1976, began reporting the results of its sample analysis directly to the appropriate FDA district office in addition to reporting the violation to FDA headquarters.

However, the new procedure has not resulted in an increase in the number of residue violations investigated. During the first 6 months after the new procedure became effective, only about 20 percent of the violations reported to FDA were investigated.

The pretest portion of USDA's surveillance program provides for USDA to test animals from growers previously identified as marketing animals containing illegal residues. Before shipping additional animals to slaughter a violative grower is asked to provide a small lot from the herd or flock for residue analysis. If the sample analysis shows that residues are within tolerance levels, the remainder of the herd or flock is approved for slaughter.

Many growers, however, do not comply with USDA's pretest requirements. Our review at three USDA regional offices indicated that pretest had not been completed by about 800 of the approximately 1,300 growers required to submit animals for pretest between January 1973 and November 1976.

USDA officials acknowledge that growers can easily avoid pretest by shipping animals to an auction house

or to a different slaughterhouse. Because USDA lacks authority to require growers to "tag" their animals for grower identification the identity of the owner cannot always be determined. Our review of 31 open cases at the three USDA regional offices indicated that at least five of the growers may have shipped additional animals to market without going through pretest.

USDA officials believe quarantine authority would strengthen the pretest program. Such authority would enable USDA to prevent the movement of animals from a grower's farm until pretest has been successfully completed.

Factors limiting the effectiveness of enforcement efforts

According to an FDA official, FDA generally issues information letters to growers even if the violation was caused by the grower's deliberate misuse of drugs. Several factors make it difficult for FDA to initiate stronger regulatory actions. Specifically:

1. USDA's monitoring program is not designed to enable FDA to develop the case histories needed to support stronger regulatory actions. FDA officials told us that FDA generally will not prosecute a grower for the first violation. Because animals sampled under the monitoring program are randomly selected it is unlikely that a

grower will be sampled frequently enough to enable FDA to develop a case history.

2. Raw meat and poultry from animals found to contain illegal residues generally cannot be identified for seizure action.

3. Residue detection methods adequate to support FDA regulatory actions do not exist for 22 of the 25 animal drugs we identified as being included in the monitoring program. An FDA official said that many animal drugs do not have residue detection methods suitable for regulatory purposes because, FDA has strengthened its requirements regarding detection methods and some methods that were once considered acceptable may no longer be valid. This official said that while better methods have been developed for most of the older drugs, FDA is in the process of requiring updating of detection methods for all drugs to meet current standards.

4. Misuse of an animal drug is not a violation of the FD&C Act, thus FDA must prove that misuse resulted in the marketing of adulterated raw meat or poultry. Residue violations frequently occur because growers fail to adhere to established withdrawal times or fail to clean feed bins when switching from medicated to nonmedicated feed. If misuse of an animal drug were a violation of the FD&C Act, FDA could establish a

monitoring program designed to identify and correct conditions which could cause residue violations.

Another major cause of residue violations is misuse of pesticides. Although use of a pesticide in a manner inconsistent with its labeling is a violation of the Federal Insecticide, Fungicide, and Rodenticide Act, EPA does not have authority to inspect a grower's premises without the grower's permission unless it has reason to believe a violation has occurred.

5. The marketing of raw meat and poultry containing illegal residues is punishable by criminal penalties under the FD&C Act. However, for the reasons cited earlier, criminal penalties are not assessed for most residue violations. One alternative that could help FDA enforce the provisions of the FD&C Act would be the authority to assess civil money penalties for residue violations. In 1972 the Administrative Conference of the United States stated that civil penalties are an important and useful enforcement tool that should enable agencies to (1) obtain quicker corrective action for violations, and (2) demonstrate greater consistency in their judicial reviews.

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Mr. Chairman, that completes my prepared statement. We will be happy to answer any questions that you or other members of the Subcommittee may have.