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Report to Sen. Warren G. Magnuson, Chairman, Senate Committee on Commerce, Science, and Transportation; Sen. Adlai E. Stevenson, Chairman, Senate Committee on Commerce, Science, and Transportation: Science, Technology, and Space Subcommittee; Sen. Donald W. Riegle, Jr.; by Elmer B. Staats, Comptroller General.

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Contact: Human Resources Div.
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Organization Concerned: Department of Agriculture; Food and Drug Administration; Animal and Plant Health Inspection Service; Department of Agriculture: Agricultural Research Center; Michigan Chemical Corp., Saint Louis; Farm Bureau Services, Inc., Battle Creek, MI; Michigan: Dept. of Agriculture.
Congressional Relevance: Senate Committee on Commerce, Science, and Transportation; Senate Committee on Commerce, Science, and Transportation: Science, Technology, and Space Subcommittee. Sen. Donald W. Riegle, Jr.
Authority: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.). 21 U.S.C. 335. 21 C.F.R. 225-226.

In 1973, an industrial chemical containing polybrominated biphenyls (PPBs) was mistaken for magnesium oxide, a feed supplement, and mixed with animal feed in Michigan. The Department of Agriculture (USDA) and the Food and Drug Administration (FDA) are responsible for protecting consumers from such contaminated foods. Findings/Conclusions: Manufacturers of drugs and animal feeds and animal feed components are subject to FDA inspections. The Animal and Plant Health Inspection Services (APHIS) is responsible for administering the Federal Meat and Poultry Inspection Program. The Agricultural Research Service (ARS) is responsible for basic, applied, and developmental research in agricultural and related fields. APHIS and ARS were the two principal USDA agencies which were involved in the PBB incident in Michigan. Intrastate products that contained PBB in excess of applicable tolerance levels were recalled and voluntarily destroyed by the manufacturer or were seized by the Michigan Department of Agriculture (MDA). Survey results showed no evidence that nine States sampled had received any contaminated feed, and it was concluded that widespread contamination of livestock outside of Michigan had not occurred. USDA plans to continue its current practice of immediately notifying MDA when it finds meat that contains PBB residues above the tolerance level. At present,

APHIS has no written guidelines or procedures for dealing with future problems such as the PBB contamination incident in Michigan. (SC)

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02508

REPORT OF THE COMPTROLLER GENERAL OF THE UNITED STATES

Federal Efforts To Protect Consumers From Polybrominated Biphenyl Contaminated Food Products

Department of Agriculture
Food and Drug Administration

In 1973 an industrial chemical containing polybrominated biphenyls was mistaken for magnesium oxide, a feed supplement, and mixed with animal feed in Michigan. The report discusses what the Department of Agriculture and the Food and Drug Administration are doing to protect consumers from foods contaminated with polybrominated biphenyls.

HRD-77-96

JUNE 8, 1977

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

The Honorable Warren G. Magnuson
Chairman, Committee on Commerce,
Science, and Transportation
United States Senate

The Honorable Adlai E. Stevenson
Chairman, Subcommittee on Science,
Technology, and Space
Committee on Commerce, Science,
and Transportation
United States Senate

The Honorable Donald W. Riegle, Jr.
United States Senate

In your letter of March 14, 1977, you noted that the Committee on Commerce, Science, and Transportation was investigating the widespread contamination of food by the chemical polybrominated biphenyl. The potential for such contamination existed in Michigan in 1973 when an industrial chemical containing polybrominated biphenyl was mistaken for magnesium oxide, a feed supplement, and mixed with animal feed.

You requested that we obtain information relating to the activities of the Department of Agriculture and the Food and Drug Administration in protecting consumers from contaminated foods. Specifically you wanted information on the:

--Food and Drug Administration's authority to develop regulations for animal feeds and to inspect the Michigan Chemical Corporation and Farm Bureau Services. (See p. 1.)

--Actions taken by the Department of Agriculture and the Food and Drug Administration to identify the extent of the contamination problem. (See p. 13.)

--Statistical reliability of surveys conducted by the two agencies. (See p. 20.)

--Plans of both agencies to examine food products for polybrominated biphenyl residues. (See p. 32.)

--Plans of both agencies for dealing with similar problems in the future. (See p. 33.)

Appendix I contains the information you requested.

In accordance with instructions from the Subcommittee staff, we have not asked the Department of Agriculture or the Food and Drug Administration to formally comment on this report. The report's contents, however, have been discussed with officials of those agencies, and their comments have been incorporated in the report where appropriate.

A draft copy of this report was provided to you on April 29, 1977, for use in hearings held by the Subcommittee on Science, Technology, and Space on toxic substances control.

We will be in touch with the Subcommittee's office in the near future to arrange for release of the report to the Department of Agriculture and the Food and Drug Administration.

Comptroller General
of the United States

QUESTIONS AND ANSWERS ON FEDERAL EFFORTS TO PROTECT CONSUMERS FROM POLYBROMINATED BIPHENYL CONTAMINATED FOOD PRODUCTS

QUESTION 1

What legal authority does the Food and Drug Administration (FDA) have to develop good manufacturing practice (GMP) regulations for animal feeds? Has FDA developed GMP regulations for animal feeds and, in particular, GMPs relevant to the polybrominated biphenyl (PBB) contamination problem in Michigan? If such GMP regulations were in effect at the time of the Firemaster-Nutrimaster 1/ mixup, were Michigan Chemical Corporation or the Farm Bureau Service mills subject to FDA inspections to insure compliance with these GMPs? If they were subject to inspection, what inspection procedures did FDA develop, what were the dates of these inspections, and what were the inspection results? If deficiencies were noted during these inspections, has FDA followed up to determine what corrective actions, if any, were taken?

FDA INSPECTION AUTHORITY

Michigan Chemical Corporation, 2/ St. Louis, Michigan--a manufacturer of drugs and animal feed components--and Farm Bureau Services, Inc. (FBS), Battle Creek, Michigan--a manufacturer of animal feeds--are subject to FDA inspections.

Michigan Chemical also makes other products, such as industrial chemicals and magnesium compounds. One of the industrial chemicals, Firemaster, which is used as a fire retardant in the thermoplastic industry, is a mixture of several different PBBs, primarily hexabrominated biphenyl. One of the magnesium compounds--magnesium oxide--is used as an animal feed nutrient supplement. FBS-manufactured animal feeds include nonmedicated and medicated feeds and medicated premixes that are added to animal feeds.

1/Firemaster and Nutrimaster are Michigan Chemical's trade names for the PBB involved in the mixup and for magnesium oxide, respectively.

2/A March 23, 1977, FDA inspection indicated that the name of the corporation was changed to Velsicol Chemical Corporation.

Because Michigan Chemical manufactures drugs and medicated animal feeds and FBS manufactures medicated feeds and premixes, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 360(h), these firms are subject to FDA inspection at least once every 2 years.

Also under the FD&C Act, 21 U.S.C. 351(a)(2)(B) and 21 U.S.C. 371(a), FDA has authority to develop GMP regulations for medicated animal feeds. GMP regulations (21 CFR 225 and 226) for medicated feeds and for medicated premixes were issued on May 11, 1965, and November 1, 1967, respectively. These regulations provide criteria related to personnel, construction, and maintenance of facilities and equipment, product quality control, packaging, and labeling, and records and reports. The GMP regulations prohibit the carryover of medicants into nonmedicated feeds.

There are no GMP regulations for nonmedicated animal feeds. Animal feeds containing nutrients such as magnesium oxide are not considered to be medicated feeds and therefore are not subject to GMP regulations for medicated feeds. However, FDA has authority to inspect nonmedicated feed manufacturers under 21 U.S.C. 374, FDA's general inspection authority. FDA had no jurisdiction over Michigan Chemical's manufacturing of PBB because it was never intended as a food, drug, feed, or cosmetic ingredient.

MICHIGAN CHEMICAL CORPORATION INSPECTION HISTORY

FDA has made several inspections at Michigan Chemical that disclosed problems in its production and labeling of certain products.

Inspections before the PBB-magnesium oxide mixup

On November 7 and November 10, 1969, FDA made an inspection at Michigan Chemical. The inspection showed that Michigan Chemical's bulk salt operations, animal salt product operations, and magnesium hydroxide operations were

"In Compliance." 1/ The inspection showed, however, a lack of compliance with GMPs for the production and labeling of medicated trace-mineral animal salts. GMP deviations included the failure to use batch production records, failure to code medicated products, lack of written production and control procedures, and excessive dust residues in manufacturing areas. The medicated trace-mineral animal salt product operation was classified as "Official Action Indicated" because of the GMP deviations and because products did not contain the amount of drug ingredient specified in the labeling. FDA advised Michigan Chemical of its inspection findings by a letter dated February 2, 1970. On February 11, FDA's Detroit district office received a reply from Michigan Chemical stating that the firm had taken steps to comply with the recommendations about the GMP deviations.

On October 6, 1970, FDA conducted a followup inspection at Michigan Chemical of the medicated trace-mineral animal salt product operation and the GMP deficiencies noted in the November 1969 inspection. This inspection showed that the firm had set up appropriate manufacturing production and control procedures as specified in the GMPs and had eliminated the excessive dust residue problem. But it also showed that the company was still producing a medicated salt product that fell below the label claims for the active ingredient. In addition, the label for this product failed

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1/The terms "In Compliance," "Voluntary Action Indicated," and "Official Action Indicated" are used by FDA in the determination and reporting of the compliance status of an establishment following inspection. The general definitions for these terms follow.

Official Action Indicated--The firm has violated a provision of either the FD&C Act, other acts enforced by FDA, or FDA regulations, and FDA has recommended or performed one of a number of specific regulatory actions.

Voluntary Action Indicated--The conditions of the firm are such that they do not quite support a classification of Official Action Indicated but if they are not corrected within a certain time frame, they will likely support a regulatory action.

In Compliance--On the basis of a review of the inspection report, no action is indicated and/or conditions do not meet the criteria for Official Action Indicated or Voluntary Action Indicated.

to have adequate directions about continuous use of the product. Based on the inspection results, the medicated trace-mineral animal salt product operation was again classified as "Official Action Indicated" and official samples were taken for analysis. A followup inspection was contingent on the sample results.

As a result of the sample analysis, Michigan Chemical was charged with

--misbranding a medicated trace mineral animal salt containing less than the declared amount of medication,

--misbranding because the labeling had inadequate directions for use, and

--adulteration because the product was not manufactured in conformity with current GMPs.

By letter dated February 24, 1971, FDA requested Michigan Chemical to appear at an informal hearing pursuant to 21 U.S.C. 335 1/ to present its views on these matters. At the hearing held on March 10, 1971, Michigan Chemical submitted a letter dated March 5, 1971, summarizing the firm's program to correct the alleged deficiencies. A company official pointed out that each of the shipments listed in FDA's notice of hearing was made before the implementation of additional controls and the installation of new equipment. One Michigan Chemical official believed that the firm had acted promptly and responsibly to correct the conditions that resulted in the hearing.

Although we did not locate the establishment inspection reports, information in FDA's files indicated that Michigan Chemical was also inspected on May 24, 1973, and March 14, 1974.

The 1973 inspection covered the Magnesium Oxide N.F. 2/ production and laboratory records and the medicated trace-mineral animal salt operation. According to a May 25, 1973,

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1/This authority states that the person against whom a criminal proceeding is contemplated should be given appropriate notice and an opportunity to present his views, either orally or in writing, before any violation of the FD&C Act is reported by the Secretary of Health, Education, and Welfare to a United States attorney.

2/"National Formulary"--a book of standards for certain pharmaceutics and preparations which are not included in the "U.S. Pharmacopeia."

internal Michigan Chemical memorandum, FDA's inspection showed that the company's production records for the mineral salt were in very satisfactory condition. However, there were excessive dust and empty ingredient bags in the mineral salt premix area and there was heavy dust buildup in the Magnesium Hydroxide N.F. packing area. The memorandum indicated that action would be taken to correct these problems.

During its March 1974 inspection FDA found

1. residues on the floor and equipment in the premix, ingredient feeder, and mixer areas;

2. scales in the premix area covered with heavy buildups of residue; and

3. open containers of trace elements in the premix area allowing for potential cross-contamination.

An internal Michigan Chemical memorandum dated March 14, 1974, indicated the company would correct the deficiencies noted during the inspection and outlined the specific corrective actions that would be taken.

Inspections after the PBB-magnesium oxide mixup

After it was determined that the magnesium oxide supplier for FBS was Michigan Chemical, FDA inspected Michigan Chemical on April 26, 29, and 30, 1974. During those inspections, FDA obtained from Michigan Chemical information on its magnesium oxide and PBB manufacturing processes, the locations of these processes, the packing procedures for the products, and shipments of magnesium oxide to FBS. The FDA investigator found that the magnesium oxide and PBB were manufactured, bagged, stored, and distributed from buildings that were separated by a quarter of a mile and could not find any possible causes for the PBB-magnesium oxide mixup. Company officials could not explain how a labeling mixup, shipping mixup, or cross-contamination of the product could occur.

FDA made additional inspections at Michigan Chemical on May 1 and May 3, 1974. During these inspections the company was in the process of obtaining information on all shipments of Nutrimaster and Firemaster. The May 1, 1974, inspection was made to follow up on information indicating that a bag labeled "Firemaster" was found in a FBS feed mill in Mendon, Michigan. Michigan Chemical advised FDA that it would recall all "Nutrimaster" from the market and would

APPENDIX I

immediately telephone all customers informing them of the problem. Since the firm was in the process of obtaining product distribution data and setting up the recall format, FDA terminated its May 1 inspection.

FDA's May 3, 1974, inspection was made to obtain additional information about the product recall as well as checking on the status of the recall. The inspection showed that Michigan Chemical had completed telephone contacts to all Nutrimaster customers and was mailing out a followup recall letter. As of May 3, 1974, the only known product mixup was confined to FBS feed mills. None of the other Nutrimaster customers reported any livestock injuries or any bags labeled Firemaster.

A May 13, 1974, FDA inspection provided information on the distribution of the PBB involved in the mixup. According to the inspection report, Michigan Chemical shipped the entire production of this PBB to Cincinnati Chemical Processing Company for granulation. Cincinnati Chemical sent granulated PBB back to Michigan Chemical. In addition, Cincinnati Chemical sent 19 shipments of granulated PBB directly to Michigan Chemical customers. FDA classified this inspection as "Voluntary Action Indicated" since FDA was still obtaining information on Michigan Chemical's recall of Nutrimaster.

On May 23, 1974, FDA reexamined Michigan Chemical's manufacturing operations to determine if any areas of cross-contamination or potential cross-contamination might exist between the magnesium oxide and PBB operations and to document shipments between Cincinnati Chemical and Michigan Chemical. FDA found that the shipments of bulk flake PBB from Michigan Chemical to Cincinnati Chemical were returned to Michigan Chemical in granulated form. The inspection report does not contain information on the reexamination of Michigan Chemical's manufacturing operations.

According to FDA's August 30, 1974, summary of the Nutrimaster recall, none of the Nutrimaster was returned to Michigan Chemical.

In August 1974, an FDA investigator responding to a request from FDA's Detroit office visited Michigan Chemical to obtain detailed information on the responsibilities of Michigan Chemical employees at the St. Louis, Michigan, plant and at corporate offices in Chicago.

Other FDA inspections of Michigan Chemical

On July 11, 1974, FDA inspected Michigan Chemical's activities related to the manufacture of salt for human consumption. Information was obtained on the source of raw materials, equipment and manufacturing procedures, quality control records, sanitary conditions, and product distribution records. The inspection revealed no objectionable conditions, and the company's salt operation was classified as "In Compliance."

On May 30, 1975, an attorney representing Michigan Chemical reported to FDA that Michigan Chemical had discovered a misshipment of the drug, Magnesium Hydroxide N.F., and an industrial chemical with the trade name Akron Chemical Retarder. On June 12 and June 20, 1975, an FDA official visited Michigan Chemical to obtain information on this misshipment and to collect samples of products to see if there was PBB cross-contamination. FDA found that Michigan Chemical had received as part of a shipment of Magnesium Hydroxide N.F., from Cincinnati Chemical Processing Company 19 drums stenciled "Akron Chem. Retarder." Some of the 19 drums were also labeled Magnesium Hydroxide N.F. Consequently, Michigan Chemical contacted all customers of Magnesium Hydroxide N.F. and determined that only three of the drums contained Akron Chemical Retarder and these were in the possession of Michigan Chemical.

On August 12, 1975, FDA visited Michigan Chemical to obtain additional samples of Magnesium Hydroxide N.F. FDA files that we reviewed did not contain information on the results of the sample analysis.

On March 16 and 18, 1976, FDA made a routine surveillance investigation of Michigan Chemical's medicated animal feed and Magnesium Hydroxide N.F. operations. The inspection also covered trailer trucks that carried the company's salt products and Michigan Chemical's food salt production. Coverage of the human salt production was included because of a complaint by a United States Department of Agriculture (USDA) inspector to FDA's Chicago office that a Michigan Chemical shipment of salt contained black specks. The inspection found that Michigan Chemical had ceased all production of Magnesium Hydroxide N.F. and magnesium oxide for drug use in November 1975. This inspection noted some objectionable conditions related to poor housekeeping practices and weak or nonexistent quality control procedures. Michigan Chemical officials said corrections would be made immediately. In addition, the inspection of the company's production of salt for human consumption disclosed no problems with specks.

APPENDIX I

FDA INSPECTIONS AT FARM BUREAU SERVICES

FDA's first inspection of FBS' Battle Creek, Michigan, plant, made in December 1971, showed that nonmedicated feeds were cross-contaminated with medicated feeds containing Diethylstilbestrol (DES). FDA attributed the contamination to improper manufacturing controls and inadequate cleaning of equipment between batches of different feeds. FDA advised FBS of its findings in writing and classified FBS' medicated feed operation as "Voluntary Action Indicated" and FBS' nonmedicated feed operation as "Official Action Indicated." As a result of the inspection, FBS (1) closed its plant to clean all processing equipment and all bins that contained DES feeds and (2) improved its procedures for equipment flushing between medicated and nonmedicated feed production runs. Also, lots of finished feeds were quarantined and analyzed for DES before being released for marketing.

FDA's February 25, 1972, followup inspection showed that nonmedicated feeds were still contaminated with DES. A private laboratory used by FBS confirmed this finding. The FDA inspector noted, however, that FBS' testing procedures appeared adequate to make a timely determination as to whether feeds were contaminated so as to prevent them from being marketed. FBS also improved its equipment flushing procedures. FDA's inspection classified the medicated and nonmedicated feed operations as "In Compliance."

Inspections related to the PBB-magnesium oxide mixup

On March 14, 1974, a farmer notified FDA's Detroit district office that he was having problems with his dairy herd and that he suspected lead poisoning. On March 15, 1974, FDA collected samples of feeds used at the farm, but was not able to immediately identify the source of the problem. A USDA scientist who also examined samples of the feed found that it was contaminated with PBB. A USDA official notified FDA of this finding on April 24, 1974.

FDA initiated a compliance inspection at FBS on April 26, 1974, after PBB had been identified in a feed manufactured by FBS. This inspection was completed on May 9.

FDA's inspection found that:

--Between September 1973 and January 1974, FBS had received several complaints from farmers concerning the use of FBS' Formula 402 dairy feed. FBS had also

received complaints from other feed mill customers. The complaints noted that milk cows consumed insufficient quantities of feed, milk production fell, and the animals developed generally poor health.

--On about January 15, 1974, FBS initiated a recall of all Formula 402 feed and discontinued manufacturing this formula.

--Between January and March 1974, FBS collected and tested numerous samples of animal feed with inconclusive results.

--In February 1974, FBS concluded that all complaints were related to feed mixed with magnesium oxide.

--FBS received assurances that Michigan Chemical's manufacturing practices were adequate to prevent mixups or contamination of magnesium oxide with other chemicals Michigan Chemical manufactured.

During its inspection, FDA checked all bags of magnesium oxide in FBS' inventory and noted that each bag containing magnesium oxide was properly labeled. Also, FDA took samples from recalled lots of Formula 402 feeds and submitted them to its laboratory for analysis to determine if they contained PBBs.

On April 26, 1974, FBS initiated a recall of all feed containing magnesium oxide. FDA reviewed FBS' January 15 and April 26, 1974, recalls. According to FDA's report on the January recall, FBS manufactured approximately 535 tons of Formula 402 between March 1973 and December 1973, and about 45 tons of it was returned. The report points out that FDA was not informed of this recall at the time it was undertaken. A FBS official told an FDA inspector that FBS had data that indicated the problem was due to molds and toxins in the feed and that FBS did not consider this an FDA matter, believing that only a few herds were affected. The FDA report further states that all the returned Formula 402 was destroyed under State of Michigan supervision on about July 1, 1974.

An FDA inspection report states that the FBS April 26, 1974, recall included all magnesium oxide and all feeds containing magnesium oxide distributed from three FBS locations--Carrollton, Jenison, and Battle Creek, Michigan. Distribution from these locations was to retail feed mills owned by FBS.

FDA requested FBS to put a voluntary hold on all its magnesium oxide from Michigan Chemical and to hold all magnesium oxide returned under the recall at a central point until FDA could examine it.

As a result of the contaminated feed and the recalls, FDA conducted a GMP inspection at FBS on May 15, 16, and 17, 1974. FDA also inspected FBS' nonmedicated feed operations. FDA noted the following deficiencies:

--FBS did not take adequate measures to avoid cross-contamination of nonmedicated feeds with medicated feeds.

--FBS' equipment design allowed a build up of residual materials in various pieces of equipment.

--Open bags of antibiotic drugs were in the raw material storage area.

--Unlabeled bags of ingredients were in the storage area.

--Inventory records for one drug contained discrepancies.

As a result of this inspection, FBS' medicated and nonmedicated feed operations were classified as "Official Action Indicated." The inspection report indicates that FBS management promised to take corrective action to eliminate some of the GMP deviations.

On January 31, 1975, FDA requested FBS officials to appear at an informal hearing to discuss problems related to medicated and nonmedicated animal feeds and other food products that contained PBB. At this hearing the history of the PBB-magnesium oxide mixup was discussed. In the hearing record an FBS official says that he believed there was absolutely no reason to suspect willfulness in this case but that he recognizes intent is not required in FDA cases. He said, however, he hoped that FDA did not wish to prosecute someone just for the sake of prosecution. This official also said that no one could be punished anymore than FBS had been for the past year.

In March 1975 FDA rejected FBS' January 15, 1975, application to manufacture six medicated feeds, saying that the controls at the Battle Creek plant were not adequate to assure suitable examination or testing of the components used to manufacture medicated feeds. The 1974 GMP

inspection results were also mentioned as a reason for disapproval. FDA told FBS that it would be necessary to correct the deficiencies noted during the 1974 inspection and that reconsideration of the applications for producing medicated feeds could be made upon receipt of a favorable inspection report.

Inspections after the PBB-magnesium oxide mixup

On March 27, 1975, and April 3 and 4, 1975, FDA conducted an inspection at FBS to determine if FBS was complying with the medicated feed GMP regulations. The following deviations were noted:

--Master formula records for medicated feeds did not include (a) manufacturing instructions including mixing steps and times, (b) appropriate control instructions including sampling procedures and procedures to be observed to avoid contamination of the medicated feed with other feed or drug components, and (c) endorsement of the master formula records by a responsible company official.

--No documentation was available to show that a production formula record was made and kept for each specific batch of medicated feeds.

--No records were available to show the performance of each step in the process of producing animal feeds.

--Metal cans used to store certain drug components and vitamins and feed additives were labeled only on their removable lids.

--Sweepings from the pellet mill could result in the cross-contamination of a nonmedicated feed with a medicated feed.

--The feed conveying system between different pieces of equipment was not designed to prevent low level contamination of feeds.

--Certain inventory records were not properly maintained.

On the basis of the inspection findings, medicated and nonmedicated feed operations were classified as "Voluntary Action Indicated." FBS officials indicated that they would correct all of the objectionable conditions except the

problem with the conveying system. They believed that this was due to faulty equipment design and that it was an industry problem. FDA planned to reinspect FBS after the corrections had been made. FDA's inspection report also indicated that Michigan Department of Agriculture (MDA) officials were visiting FBS at least once a week and were taking samples from various parts of the production equipment for PBB analysis. A FBS official told the FDA inspector that Michigan officials had not discovered any violative level of PBB lately.

On June 24 and 25 and July 1, 1975, FDA made a followup inspection at FBS. According to FDA's inspection report, FBS made corrections to bring its records systems, related instructions, and guidelines into agreement with the requirements of GMP regulations for medicated feeds. FBS had also established an independent Quality Assurance Department. As a result of this inspection, FBS' medicated and nonmedicated feed operations were classified "In Compliance."

On July 21, 1975, the FDA Detroit district recommended that FDA's Bureau of Veterinary Medicine approve FBS' applications for producing medicated feeds. On October 31, 1975, the Bureau informed FBS that based on (1) a review of FBS quality control procedures, (2) the inspection completed in July 1975, and (3) the Detroit district office's advice that since the Battle Creek plant was substantially in compliance with regulations for medicated feeds, consideration would be given to approval of FBS' applications for producing medicated feeds. In November 1975, FDA began approving FBS applications for producing medicated feeds.

On September 22 and 23, 1975, FDA inspected FBS to obtain information on FBS' recall of a nonmedicated swine feed that had been comingled with a dairy feed. FDA learned of the recall from a newspaper account. During the inspection FDA learned that MDA and Michigan State University were investigating the mixup and the reported injuries to dairy cows. Also, FDA learned that the feed returned because of the recall was seized by the State of Michigan. The inspection indicated that FBS had made corrections to prevent a similar mixup in the future.

On March 1 and 2, 1977, FDA conducted an inspection of FBS' compliance with GMPs for medicated feeds. With two exceptions, FBS was generally in compliance with the GMPs. Problems were noted in FBS' (1) procedures for sampling products and (2) labeling practices. FBS indicated they would correct these problems, and FDA classified the company as "In Compliance."

QUESTION 2

Describe the actions taken by USDA after it became aware of the PBB contamination problem in Michigan. Specifically, what actions were taken to identify the extent of PBB contamination in meat and poultry in Michigan and other parts of the country? What actions, if any, were taken (a) when USDA found that meat and poultry contained PBB residues in excess of the tolerance level established by FDA and (b) to prevent such meat and poultry from being distributed to consumers? Similarly, what were FDA's actions with respect to other food products?

DEPARTMENT OF AGRICULTURE

The Animal and Plant Health Inspection Service (APHIS) and the Agricultural Research Service (ARS) were the two principal USDA agencies which became involved in the PBB incident in Michigan. APHIS is responsible for controlling or eradicating plant and animal diseases and pests and for administering the Federal Meat and Poultry Inspection Program. ARS is responsible for basic, applied, and developmental research in agricultural and related fields.

How USDA identified the contaminant

In January 1974 USDA's National Animal Disease Laboratory at Ames, Iowa, and other laboratories began working with MDA to help identify possible causes of an illness in a Michigan dairy herd. Feed samples were analyzed and various probable causes were eliminated. Late in the winter (sometime after January 1974), the Wisconsin Alumni Research Foundation laboratory detected a halogen (a compound containing bromine or chlorine) in the feed.

In April 1974 a National Animal Disease Laboratory research scientist discovered the same halogen and was able to identify the molecular weight of the compound. This information and the feed samples were turned over to an ARS animal scientist who had previously been involved with research on PBB. This scientist identified the compound as PBB on April 24, 1974.

The research on PBB had been conducted in conjunction with research on polychlorinated biphenyls. Experiments were conducted on cows and hens that were fed PBB to determine if the effects of PBB were similar to polychlorinated biphenyls. The hens were fed 20 parts per million (ppm)

of PBB for 9 weeks and observed for the following 7 weeks. The results showed a reduction in egg production and feed consumption and a slowdown of chick growth.

In February and March 1973, four cows were fed 10 milligrams of PBB per day for 60 days. Within 30 days the level of PBB in the milk fat reached 3.07 ppm. In May 1975, the ARS scientist conducting the research concluded that there were no long-term effects of PBB on the animals' milk production, reproduction, or physical health or on the health of their offspring.

USDA's efforts relating to the PBB problem

After PBB was identified as the contaminant, APHIS requested that FDA establish a guideline for PBB in meat. On June 7, 1974, FDA established a guideline of 1 ppm on a fat basis in meat and on June 21, 1974, FDA established a guideline of 0.1 ppm in eggs. Prior to that FDA had established PBB guidelines of 1 ppm on a fat basis in milk and milk products on May 10, 1974, and 0.3 ppm in animal feeds on May 29, 1974.

In November 1974 FDA lowered the PBB guidelines (tolerance) that had been established in May and June 1974 to 0.3 ppm on a fat basis in milk, meat, and poultry and 0.05 ppm in eggs and animal feed.

APHIS concentrated most of its efforts on determining whether PBB was a problem in States other than Michigan and in helping Michigan to evaluate the effectiveness of its identification and quarantine program by collecting samples from livestock and analyzing them for PBB levels.

APHIS tested for PBB in slaughtered cattle by obtaining fat tissue samples from the kidney and intestinal areas. According to USDA officials, the highest concentration of PBB would occur first in these areas and then spread to other fat areas. Live animals can be tested for levels of PBB by analyzing milk samples or by taking fat biopsies from the tailbone area.

Although data was not available at USDA on the comparability of these three testing methods (meat fat, milk fat, and fat biopsies), an ARS scientist who performed some tests comparing individual milk fat and meat fat samples taken from animals destroyed concluded that the approximate level of PBB in the meat fat could be determined by applying a

mathematical formula to the test results of the milk fat samples. Also, an APHIS scientist told us that fat tissue samples from slaughtered animals and biopsies from live animals should yield similar results. She said, however, that because dairy cows are usually thinner than beef cattle, it is sometimes hard to get an adequate fat tissue sample from a live dairy cow.

Nine-State survey

After discussions with MDA and FDA officials, APHIS concluded that proper actions were being taken in Michigan to prevent contaminated meat products from reaching the consumer and that it should concentrate its efforts on determining if PBBs were in the meat supply in other States.

In May 1974, APHIS performed a survey on dairy cows slaughtered in nine States--California, Georgia, Illinois, Indiana, Kentucky, Michigan, Missouri, Ohio, and Wisconsin. In addition to Michigan, seven of the States were selected because of the possibility that they had received shipments of PBB-contaminated feed. California was selected as a control State. One hundred and seven meat fat tissue samples--each from a different dairy cow--were gathered from animals slaughtered at federally inspected plants. Laboratory analysis of the samples did not detect any traces of PBB. The sampling was limited to dairy cows because it was originally assumed that PBB had been mixed only with dairy cattle feed. Subsequently, however, it was found that cross-contamination had occurred in feeds for other animals.

Based upon the survey results and the fact that there was no evidence that the States sampled had received contaminated feed, USDA concluded that widespread contamination of livestock outside Michigan had not occurred. See p. 21 for discussion of the statistical reliability of the survey.

October-November 1974 survey

In October 1974, USDA took a national sample of livestock to determine whether there was any serious PBB residues in the meat supply of the United States. Two hundred and fifty-three samples, including 25 from Michigan, were collected at federally inspected slaughter plants in 34 States. Although 10 samples showed traces of PBB, none exceeded 0.11 ppm. The States where traces of PBB showed up in the samples were Alabama, Indiana, Iowa, Mississippi, New York, Texas, and Wisconsin. Since the samples were analyzed in the early period of familarization with the method for identifying PBB, USDA questioned whether the samples really contained PBB because the

the levels were so low. Based on the sampling results, APHIS again concluded that it was unlikely that livestock outside of Michigan contained PBB. See p. 22 for discussion of the statistical reliability of the survey.

Monitoring efforts in Michigan

In November 1974, after FDA lowered the PBB tolerance level from 1 ppm to 0.3 ppm, APHIS reevaluated its monitoring efforts. After discussion with MDA officials, it was agreed that APHIS' monitoring of the Michigan meat supply at slaughter plants would best supplement Michigan's identification and quarantine program of milk sampling, feed testing, and tracing contaminated feed distribution. Throughout the program Michigan identified and quarantined contaminated herds.

APHIS initiated sampling of cattle and swine for PBB in January 1975 at State and federally inspected slaughter plants in Michigan. Initially, 300 samples per month, divided equally among beef cattle (steers and heifers), dairy cows, and swine, were allocated to the program. Three fourths of the samples were to be collected from State-inspected plants and one-fourth from federally inspected plants. The results of all sampling were to be turned over to MDA, who, in turn, was to investigate all violations (instances in which PBB exceeded the tolerance level of 0.3 ppm) and place the farms from which the animal came under quarantine.

Although APHIS sent out instructions to its inspectors to take 100 samples a month from each species, it did not always obtain results from that many samples. According to APHIS officials, some of the reasons for obtaining less than 100 samples per month from each species were (1) spoilage of samples, (2) inability of an inspector to obtain a sample from a particular species on a particular day, and (3) an inspector forgetting to send the sample to the laboratory. One official also noted that APHIS had trouble with samples not being sent to the laboratory immediately after they were collected. At times, samples from State-inspected slaughter plants were sent to the laboratory as late as 4 months after collection.

APHIS discontinued swine sampling in May 1975. According to APHIS, this action was taken because of an apparent decline from January to March in the number of violations and the number of positive samples. In addition, APHIS believed that swine marketed in June 1975 would not have been

exposed to PBB because swine are marketed at 6 months of age and most of the contaminated feed had been recalled by the fall of 1974. Testing results on 301 swine samples during January through April 1975 showed 4 PBB violations.

APHIS discontinued sampling of Michigan beef cattle and dairy cows at the end of July 1975 because the results indicated a decline in the level of PBB and the number of animals contaminated. Also, APHIS concluded that Michigan's traceback, identification, and quarantine procedures were effective. Test results for 555 dairy cows sampled during January through July 1975 showed 9 with PBB violations. In addition, test results for 644 beef cattle sampled during the same period showed 10 with PBB violations.

In September 1975, Michigan requested APHIS to resume cattle testing because of the increased public concern over PBB contamination. APHIS agreed to resume testing through December 1975 and then reevaluate the situation. In January 1976 APHIS evaluated the sampling data and concluded that beef cattle as a group were no longer a public health concern but that dairy cows should be tested through 1976.

Testing of dairy cattle was resumed in February 1976 and continued through December 1976. Test results for 824 dairy cattle sampled during this period showed 3 PBB violations. Two of the violations, found in August, were animals which had been kept for replacement stock and apparently had been exposed to PBB as calves. It was determined that they would not reproduce, and they were sold for slaughter.

In January 1977 APHIS agreed to collect and analyze samples from 100 slaughtered dairy cows each month for 3 months beginning February 1 and then discontinue sampling if the data showed that the percentage of animals with PBB below the tolerance remained constant or declined. As of April 8, 1977, APHIS had received the results on 64 samples collected in February and 22 collected in March and found only one violation. The farm from which the contaminated animal was shipped was placed on quarantine on March 10 and MDA began testing the milk of the individual cows for PBB.

Hamburger survey, May 1975

In April 1975 a Michigan State Senator requested USDA to conduct a hamburger survey to determine the degree of PBB contamination in meat sold at the retail level in Michigan. Hamburger was selected since it is composed chiefly of muscle from dairy cows, the animal type known to contain the highest level of PBB at that time.

Samples were taken from 130 retail stores in Michigan. Of the 130 samples, 115 showed no traces of PBB and 15 showed traces of up to 0.12 ppm. See p. 26 for discussion of the statistical reliability of the survey.

APHIS efforts to prevent PBB contaminated meat from reaching consumers

APHIS did not take any direct action to prevent PBB-contaminated meat from being distributed to consumers. Of the 2,927 head of livestock monitored for PBB in Michigan between January 1975 and March 1977, APHIS found 16 dairy cows, 10 beef cattle, and 4 swine with PBB levels above the FDA tolerance of 0.3 ppm. All carcasses sampled were released into commerce before it was known whether they contained PBB levels above the tolerance level. According to the APHIS Administrator, USDA does not have authority to retain carcasses at slaughter plants without some suspicion of the presence of a violative residue. Also, APHIS officials said that violative levels of PBB would not normally be identified through the regular ante mortem and post mortem inspections at slaughter plants. APHIS told us they reported all residue findings to MDA, who, in turn, investigated all violations and placed the farms from which the animals were shipped under quarantine, thereby preventing future shipments of possibly contaminated animals from these farms.

APHIS relied upon MDA's identification and quarantine program, but no formal evaluation was made of the effectiveness of the program except for APHIS' continued residue monitoring at State and federally inspected slaughter plants, which began in January 1975. The statistical reliability of this monitoring is discussed on page 24. Also, APHIS did not perform any followup on the Michigan animals found with violative levels of PBB to determine why the State had not identified the animals before they were slaughtered. Generally, APHIS was not aware of the results of Michigan's followup on violations. However, one APHIS official stated, that according to MDA officials, none of the violations APHIS found came from quarantined herds. The APHIS official said she did not know whether any of the violations came from herds which the State had tested and not quarantined.

APHIS did not sample poultry in Michigan because:

1. The State of Michigan was tracing the contaminated feed to poultry producers and destroying the flocks.

2. FDA was monitoring poultry through egg sampling.

3. Poultry has a short life span from birth to slaughter.

FOOD AND DRUG ADMINISTRATION

On April 26, 1974, 1 day after FDA's Detroit district office was notified that PBB was the cause of the problem, FDA initiated investigations at FBS and Michigan Chemical. Soon thereafter, FDA's Detroit office and the MDA agreed to coordinate their investigation of the problem. The State focused on milk operations and feed mills and FDA concentrated on sampling manufactured dairy products, investigating FBS and Michigan Chemical, and following up on injury or illness reports.

FDA employees visited each farm quarantined by the State to interview the owner. The interview covered such areas as: human and animal health problems, source of animal feeds and formulas, disposition of dead or sick animals during the suspect feeding period, milk production data, and the disposition of contaminated milk, eggs, and other products. From these interviews and from information obtained from the State, FDA determined that some of the animals that had died or were ill before the PBB problem was discovered had been sent to rendering plants in Michigan. FDA and State officials subsequently followed up at these plants and found that the PBB residues in samples of rendered animal by-products were below the tolerances that had been established by FDA.

FDA obtained information on possible interstate shipments of PBB contaminated products from manufacturers of dairy products, the State of Michigan, and others, and, according to an FDA official, FDA followed up on every lead. FDA found the following PBB-contaminated products outside of Michigan and specifically traced these products back to their Michigan sources.

--Twenty lots of an FBS animal feed in Indiana, Ohio, and Pennsylvania. However, no PBB was detected in the milk collected from dairy farms which used the feed in those three States.

--Three lots of cheese shipped from a Michigan cheese manufacturer to Chicago on May 20, 1974, contained up to 1.5 ppm PBB. The cheese was marketed and was not recovered. Additional lots were sampled at the Michigan manufacturer's plant and were found to contain only trace levels of PBB.

--Three lots of evaporated milk shipped from Michigan to Indiana and Ohio contained up to 2.53 ppm PBB. These lots were recalled by the manufacturer.

--Samples of two lots of butter shipped to Georgia about May 22, 1974, showed that the PBB in the butter was below the tolerance level at the time these samples were collected. No regulatory action was taken against the butter.

An FDA official told us that intrastate products that contained PBB in excess of applicable tolerance levels were recalled and voluntarily destroyed by the manufacturer or were seized by MDA. In February 1977, MDA reported to FDA that about 865 tons of feed, 17,950 pounds of cheese, 2,650 pounds of butter, 34,000 pounds of dried milk, and 4.8 million eggs were destroyed.

Also through its national pesticide surveillance program, FDA found a number of products in States other than Michigan containing PBB. (See p. 31.) Because the levels of PBB found in these products were lower than the FDA tolerance levels, no action was taken to prevent them from being distributed to consumers or to trace them back to their Michigan sources.

QUESTION 3

Describe the sampling procedures followed by USDA in determining PBB levels in meat and poultry in Michigan and in other parts of the country. Do USDA officials consider the samples statistically valid and, if so, what was the level of reliability? Detail the USDA rationale for their sampling program and to what extent the data provides a basis for conclusions about the likely exposure of the public to meat and poultry contamination with PBBs above the FDA tolerance levels. Did FDA sample for PBBs in other food products, and, if so, do FDA officials consider the samples statistically valid and reliable? If FDA carried out this sampling program, detail FDA's rationale for the program and to what extent the data provides a basis for conclusions about the likely exposure of the public to food products contaminated with PBBs above FDA's tolerance level.

DEPARTMENT OF AGRICULTURE

As discussed previously, USDA made a nine-State PBB survey, a nationwide PBB survey, and a PBB survey of hamburger

sold in Michigan retail stores. In January 1975, USDA also began monitoring the levels of PBB in cattle slaughtered at State and federally inspected slaughter plants in Michigan. Our analysis of the sampling procedures used in these surveys and the statistical reliability of the results follows.

Nine-State survey, MAY 1974

The objective of APHIS' nine State survey was to determine whether a PBB contamination problem existed in States other than Michigan or if it was confined to Michigan. In addition to Michigan, the States of Kentucky, Missouri, Ohio, Illinois, Indiana, Georgia, and Wisconsin were selected because of the possibility that they had received shipments of the contaminated feed. California was also selected to serve as a control State, because APHIS believed that the State had not received contaminated feed. The sampling was limited to dairy cows because, based upon the information available at the time, it was assumed that the PBB had only been mixed with dairy cattle feed.

The sample was taken by first determining how many sampling units (animals being sampled) APHIS' laboratory could handle. In this case, the laboratory could handle 107. Second, while the sampling units were divided somewhat evenly among the States, some adjustments were made to account for the relative number of cattle slaughtered in each State. Third, the selection of the slaughter plants within a State was left up to APHIS' field offices, but they were instructed to select as many federally inspected plants as possible. Fourth, the inspectors who collected the samples were not given any specific instructions about how to select the dairy cows except that the selections should be unbiased and each animal selected should be from a different herd.

APHIS stated that

> "Taking the eight States as a single unit (as far as we knew, all had the same source of exposure), the data from this survey indicated that not over 3 percent of cows potentially exposed to PBB-contaminated feed contained PBB above 1.0 ppm, at the 95 percent level of confidence."

However, this statement is correct only if the sampling units were selected without any bias.

Because of the methods used in this survey, it is highly unlikely that this could be considered a simple random sample

since the individual sampling units would have to have an equal probability of selection. Also, the survey was based on a judgment sample because:

1. Selection of the plants was left to the judgment of the APHIS field office staffs.

2. The dates for the sample collection were not specified, i.e., they were left to someone's judgment.

3. The inspector used his judgment to determine which sampling unit was selected.

The following steps or other acceptable alternative steps would have been necessary to select a valid statistical sample which would have served as a basis for the type of conclusion APHIS reached.

1. Because the objective of the survey was to determine if the PBB problem was confined to Michigan, the sampling plan either (1) should have excluded Michigan and covered the remaining eight States only or (2) enough sampling units should have been selected in each State to make individual State estimates.

2. Assuming that alternative (1) above had been selected, the plants at which samples were to be taken should have been randomly selected from the total universe of plants in the eight States by the use of valid statistical techniques (i.e., each plant in the eight States should have had equal probability of being selected).

3. The date the sampling unit was to be collected at each of the selected plants should have been randomly selected by the use of valid statistical techniques.

4. The sampling units (animals) should have been randomly selected by the use of some statistical method such as a table of random numbers. That would have removed all elements of judgment from the sample selection.

October-November 1974 survey

The objective of this survey was to determine whether there were any serious PBB residues in the meat supply of the United States. Also, the survey was to include all species

of livestock because USDA had obtained additional information after the May 1974 survey that feed for livestock other than dairy cattle might have been contaminated. Again, the number of sampling units to be collected was based on the amount of available laboratory time.

Two hundred twenty-eight sampling units were analyzed for PBB by the APHIS National Residue Laboratory from the samples collected for chlorinated hydrocarbon analysis under APHIS' National Residue Monitoring Program (NRMP). No specific time period was established for the laboratory to select the samples to be tested for PBB; the dates on the selected sampling units ranged from late September to early November. The laboratory was (1) instructed to randomly select a specific number of samples from each species to be analyzed for PBB and (2) given the areas of the United States to be covered by the sample. However, the laboratory manager told us that after receiving notice to analyze samples from all animal species for PBB, they began analyzing every sample as it came into the laboratory until the number of samples for each species from each area was reached. The sampling units were selected only from federally inspected plants.

In addition to the 228 NRMP sampling units selected for PBB testing, 25 sampling units were selected from cows and steers slaughtered at federally inspected plants in Michigan. The only instructions given to inspectors collecting the samples, other than the number of dairy cows and steers to sample, was that each sampling unit should be from a different Michigan producer.

In commenting on the validity of the results of the 253 samples, APHIS stated:

> "Since these samples were randomly selected from samples collected under our National Monitoring Program, we consider them statistically valid samples and representative of livestock slaughtered in the United States."

This was a judgment survey, not a valid statistical survey, because:

1. The laboratory did not select the sampling units from the sampling units collected under NRMP on a random statistical basis.

2. The selection of the plants in Michigan from which the 25 additional sampling units were collected was left to the APHIS field office staff's judgment.

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3. The selection of the 25 sampling units was left to APHIS inspectors' judgment.

4. The results of the two sample groups cannot be presented as results of a simple random sample, as USDA did, because they were selected from two universes with unequal probabilities of selection.

The following steps or other acceptable alternative steps would have been necessary to select a valid statistical sample which would have served as a basis for the type of conclusion reached by APHIS.

1. Within a given timespan, determine the universe of sampling units collected under the NRMP for each animal species of interest.

2. From each universe, randomly select a sample of sampling units for each species.

3. For the Michigan sampling units, randomly select the plant and date for each unit and then randomly select the sampling unit by some statistical method, such as a table of random numbers.

Monitoring efforts in Michigan

In January 1975 APHIS began monthly monitoring of PBB levels in cattle and swine slaughtered at State and federally inspected plants in Michigan. The objectives of the monitoring were to (a) determine if PBB contamination above the 0.3 ppm tolerance level was occurring in Michigan livestock at a rate greater than 3 percent, (b) assist MDA in evaluating the effectiveness of its control efforts, and (c) monitor the levels of PBB in marketed animals in Michigan to detect trend changes.

A sampling program was designed to identify PBB violations (PBB level exceeding 0.3 ppm) in cattle and swine slaughtered in Michigan. Initially, 300 samples a month, divided equally among beef cattle, dairy cows, and swine, were allocated to the program. In addition, the animals must have been raised in Michigan and one-fourth of the sample units were to be selected from federally inspected plants and three-fourth from State-inspected plants.

The sampling procedures were as follows.

1. A list was obtained of State and federally inspected slaughtering plants with monthly slaughter rates by

animal species. From this list, individual plants were judgmentally selected, using the slaughter rates as a factor in selecting both large and small plants. A larger number of samples were collected from the large plants than from the small plants. Samples were generally collected from the same large plants each month, although the number of samples collected varied. In the early stages of the survey, however, samples were collected from different smaller plants each month. After about a year of this method of sampling, the sample plants and the number of samples collected monthly from each plant remained the same.

2. Once the plants were selected and the number of units to be sampled at each plant was determined, the information was fed into a computer, which randomly selected the dates the samples were to be taken and which printed forms for each sample. These procedures were repeated monthly.

3. After the forms were printed, they were distributed to Federal and State plant inspectors. The inspectors were not given any detailed instructions on how to select the animals to be sampled on a particular day other than to randomly select the animals. The inspectors were instructed, however, to collect the sample of fat on the date indicated on each form and if the requested species was not slaughtered on the scheduled sampling date, to collect a sample on the first subsequent day the species was slaughtered.

In commenting on the sampling results, APHIS stated: "The sampling is considered statistically valid for the objectives stated above, and the data was analyzed using a 95 percent level of confidence."

This survey was not statistically valid but rather was a judgment survey because:

1. The plants were selected on a nonrandom basis.

2. The number of species sampled at each plant was judgmentally selected based upon slaughter rates.

3. The inspectors determined which sampling units were to be selected based on their judgment.

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In addition to randomly selecting the sample collection dates, the following additional steps or other acceptable alternative steps would have been necessary to select a valid statistical sample which would have served as a basis for the type of conclusions reached by APHIS.

1. The plants at which samples were to be taken should have been randomly selected from the total universe of plants in Michigan.

2. The sampling units (animals) should have been randomly selected by the use of some statistical method, such as a table of random numbers that would have removed all elements of judgment from the sample selection.

Hamburger survey, May 1975

In May 1975 APHIS surveyed PBB levels in hamburger meat at retail stores. The objective of the survey was to determine the degree of PBB contamination in meat sold at the retail level in Michigan. Hamburger was selected because it is composed chiefly of muscle from dairy cows, the animal type known to contain the highest level of PBB at that time, rather than beef cuts which generally come from beef breeds.

The sampling unit was defined as a 1-pound package of ground beef purchased from retail grocery stores. The sampling procedures were as follows:

1. A list of cities in Michigan was compiled using 1970 census data.

2. The cities were weighted by their population so that the number of samples to be taken in each city would reflect each city's relative population size.

3. Giving appropriate recognition to the population of the cities, a systematic sample of cities was selected.

4. Each sampling unit was to be collected from a different store.

5. The names of the stores were randomly chosen from the city's yellow pages.

6. The cities for which yellow pages were not obtained were assigned either a large or small store from which the sampling unit was to be collected. The determination of small or large stores was made by going down the list of cities and arbitrarily assigning a small or large store. At these locations the store was selected by the APHIS sampler.

7. The instructions provided for the collection of a 1-pound package of hamburger from the meat display case. If there was no hamburger in the display case, the APHIS sampler was to ask the butcher for 1 pound of hamburger. If for any reason the sampling unit could not be obtained from the selected store, the sampling unit was to be collected from the next grocery store down the street.

In commenting on the survey results, APHIS stated:

"Statistical analysis of the data obtained indicated that 81.6 - 93.4 percent of hamburger sold in Michigan contained no detectable PBB, and that 99.8 percent contained less than 0.3 ppm at the 95 percent level of confidence."

The statement made by APHIS has two major problems. First, it gives no indication of the time frame during which the sampling was done and to which the statement is applicable. Second, the survey was judgmental for the following reasons:

1. In cities where the yellow pages were not obtained, APHIS arbitrarily designated that the sample should be obtained either from a large or small store. The actual selection of the store was left to the judgment of the person collecting the sample.

2. The sampling unit was judgmentally selected.

3. If there were no sampling units available at the selected store, the APHIS sampler was to go to the next grocery store down the street, which was not selected in the plan but judgmentally selected.

In addition to selecting the cities from 1970 census data, the following additional steps or other acceptable alternative steps would have been necessary to select a valid statistical sample which would have served as a basis for the type of conclusions reached by APHIS.

1. Obtain a list of all stores in Michigan which sell hamburger.

2. Randomly select the stores from this universe by some statistical method.

3. By some statistical method, select the date for collection at each store.

4. In some fashion, establish a random selection procedure for the collection of the sampling unit.

Value of a judgment sample

A common fault of all the USDA surveys is that judgment sampling was used in one or more of the selection steps required for each survey. Judgment sampling precludes making statistical inferences about the universe and does not permit statements of confidence and precision about survey findings.

There really is no way to assess the value of a judgment sample. This is even truer when a large number of people are exercising their individual judgments in numerous sampling situations.

On the subject of the value of judgment samples, W. Edwards Deming in his book "Sample Design in Business Research" on page 28 states:

> "Probability sampling is NOT the substantive expert's selection of 'representative' or of 'typical' cases, areas, or farms, or of weeks or months from the year. Instead, the selection of the sampling units is accomplished by means of a standard tool known as a table of random numbers. When the selections are made by judgment, inferences may be made only by judgment, not by the theory of probability. True, one sometimes sees unjustifiable calculations of standard errors and unjustifiable inferences in papers on medicine and agricultural science, in accounting, and in marketing and opinion research, when the samples are not random. Such calculations have no meaning; and if they lead to a correct answer, it is so only by luck.
>
> "Expert knowledge, judgment, sincerity, and honesty, are all necessary ingredients of any

science, but they are not sufficient to make a sample. There is no substitute for the use of statistical theory."

Again on page 31, he states:

"A judgment sample is one in which an expert in the subject-matter makes a selection of 'representative' or 'typical' counties or other areas or business establishments. For an evaluaton of the reliability of such a survey, we must rely on the expert's judgment: we can not use the theory of probability. In contrast, the precision of an estimate made from a probability sample is never in doubt, as the probabilities associated with any given margin or error one estimates by formulas directly from the sample itself."

Morris H. Hansen, William N. Hurwity, and William G. Madow on page 9 in their book "Sample Survey Methods and Theory, vol. I" state:

"When the determination of the individuals to be included in a sample involves personal judgment, one cannot have an objective measure of the reliability of the sample results, because the various individuals may have differing and unknown chances of being drawn. We shall refer to such methods as nonmeasurable or judgment designs."

APHIS comments

We discussed with APHIS officials the matters covered in our response to question 3 as they relate to USDA. They stated that the term judgment survey used throughout the report, while accurate, tended to obscure the efforts USDA made to obtain a reasonable cross section of animals slaughtered in the United States and hamburger sold in Michigan. They also stated that, while sampling methodology similar to that which we outlined would assure scientifically representative results, such methodology was not, and probably is not, possible to implement for the PBB program. They added that the time constraint and the lack of readily available data on the sampling universes precluded the use of valid statistical sampling techniques.

The APHIS official in charge of the Residue Evaluation and Planning Staff that was responsible for these surveys also noted that often there is not enough time or money to

collect all the sampling units necessary to be reasonably certain a problem does or does not exist. As a result, specialists, such as an epidemiologist and a toxicologist, must often make judgment decisions as was done in the decision to stop testing outside of Michigan.

FOOD AND DRUG ADMINISTRATION

FDA's sampling of food products for PBB was divided into two phases. Phase one consisted of identifying all suspected PBB-contaminated products. During this phase, which took place in the early stages of the investigation, FDA collected and analyzed samples of dairy products manufactured in Michigan and followed up on all interstate shipments of products suspected of containing PBB. FDA also collected samples of animal feeds from farmers, Michigan Chemical, and FBS. State inspectors were responsible for inspecting milk collection centers and animal feed mills. FDA officials believed that there was followup on 100 percent of the suspected products. Information on the products that FDA identified as being contaminated with PBB is contained on page 19.

Phase two of FDA's investigation was initiated in November 1974 as a part of its fiscal year 1975 food pesticide program. This program is designed to detect pesticide residues in the Nation's food supply. Specific objectives included in the fiscal year 1975 pesticide program were

--to determine the pesticide levels of individual food commodities on a geographic basis through the use of gathered intelligence on pesticide use and misuse and a statistically based sampling plan and

--to survey selected food commodities on a nationwide basis to obtain an overview of the pesticide residue levels in these foods.

Since samples collected under the program would not normally be analyzed for PBB, the 1975 pesticide program was modified on November 10, 1974, to include an examination for PBB in all samples of milk, eggs, fish, and cheese collected. The purpose of the modification was to determine if foods were contaminated with PBB from environmental or other indirect sources or if a problem similar to that in Michigan existed in other parts of the country. In addition, in January 1975 FDA's Bureau of Veterinary Medicine similarily modified its program for monitoring the levels of pesticides, including PBB, in animal feeds.

According to FDA records under these programs 597 samples from 35 States, excluding Michigan, were analyzed for PBB. FDA found the following PBB-contaminated samples, each with residues below the FDA tolerance levels in effect at the time the samples were collected:

--Nine samples were from Indiana. (FDA learned that two of these samples came from Michigan sources.)

--One sample was from Pennsylvania. (An FDA chemist told us that he suspected that the PBB found was due to contaminated laboratory equipment. Other samples later taken from the same place showed no PBB.)

--One sample was from Ohio. (FDA learned this sample came from a Michigan source.)

In addition, a feed sample collected in Michigan was traced to a manufacturing plant in Illinois.

Statistical validity of sampling

FDA's fiscal year 1975 pesticide surveillance program was based on surveys of selected commodities from specific geographic areas. Each survey consisted of 12 samples.

An FDA official told us that even though the FDA district offices use their judgment in determining specifically which grower or processor is to be sampled, certain inferences can be drawn from these 12 samples. Factors such as volume, location, and prior inspectional history are often considered when collecting these samples. These inferences are generally valid only for the specific geographic area from which the 12 samples are collected. This official also said that, based on the results of each survey or on other information which identifies a potential pesticide residue problem, the FDA district office may collect additional samples from the specific geographic area to determine if regulatory actions are warranted. We believe that it is appropriate for FDA's district offices to use this data in making general judgments concerning the extent of pesticide problems within a specific geographic area.

FDA officials believe the following pesticide surveillance program findings provide an adequate basis to support a conclusion that the PBB problem was limited to the State of Michigan:

--Five hundred eighty-six of the 597 samples from States other than Michigan did not contain PBB.

--The PBB residues found in the samples were all below FDA tolerance levels in effect at the time the samples were collected.

--The positive PBB findings were in States adjacent to Michigan.

--No other evidence was found which would indicate that the manufacturing and industrial use of PBB had contaminated the Nation's food supply.

An FDA official told us that (1) the objective of the pesticide surveillance program was to determine if a PBB contamination problem existed outside of Michigan and (2) FDA did not intend to attribute any particular degree of statistical confidence to the program findings. He believed, however, that, if a sizeable PBB problem was identified outside of Michigan, FDA would have followed up to determine the cause of the problem.

We believe that FDA's conclusion concerning the extent of the PBB problem was reasonable.

QUESTION 4

What are USDA's plans for future monitoring of PBB levels in meat and poultry in Michigan and in other parts of the country? What future actions will USDA take (a) when it finds that meat and poultry contain residues in excess of the tolerance level established by FDA and (b) to prevent such meat and poultry from being distributed to consumers? Does FDA have plans for future monitoring of PBB levels in other food products and, if so, what actions will FDA take if PBBs are found?

DEPARTMENT OF AGRICULTURE

In March 1977, APHIS stated that it plans to continue monitoring Michigan dairy cows for PBB residues for the next several months. USDA has no plans for further testing of livestock for PBB outside of Michigan, unless FDA lowers the PBB tolerance or new evidence of exposure occurs. If this should happen, USDA plans to reevaluate the data and determine the need for additional testing both inside and outside of Michigan.

USDA plans to continue its current practice of immediately notifying MDA when it finds meat that contains PBB residues above the tolerance level. According to APHIS, MDA investigates by tracing the animal back to the herd from which it came, quarantines the herd, and tests or requires testing of each animal before it is released for slaughter. APHIS told us that it lacks authority to retain an animal carcass at a slaughter plant without some suspicion of the presence of a violative residue; therefore, the carcasses sampled for PBB residue are released into commerce before it is known whether they contain residues above the tolerance level.

FOOD AND DRUG ADMINISTRATION

FDA officials told us that FDA has no plans to further monitor PBB in foods in States other than Michigan. Milk produced in Michigan will be periodically checked for PBB. These officials believe that since the fiscal year 1975 pesticide surveillance program did not disclose any PBB residues above FDA's established tolerance levels in States other than Michigan, any further FDA expenditures of resources to monitor PBB would be unwarranted. According to FDA, MDA is also continuing to collect and analyze samples of milk, animal tissues, eggs, animal feeds, and miscellaneous products in Michigan for PBB.

FDA will continue to assist Michigan by exchanging complaints or other information concerning the PBB problem.

QUESTION 5

What plans does USDA have for dealing with future problems such as the PBB incident in the event that meat and poultry becomes inadvertently contaminated with other toxic substances? Has FDA established any special procedures for dealing with similar problems in the future?

DEPARTMENT OF AGRICULTURE

At present APHIS has no written guidelines or procedures for dealing with future problems such as the PBB contamination incident in Michigan. For those chemicals which are not tested for under NRMP, APHIS relies upon the States to inform it of problems or accidents when they occur. In addition, APHIS has requested the support of national veterinary organizations in identifying problems encountered by field practitioners when the cause appears to be something other than an animal disease. Also, because of the recent episodes involving environmental contamination or accidental

inclusion of undesirable chemicals in animal feeds, USDA and the Environmental Protection Agency are considering developing a memorandum of understanding. APHIS believes this would enhance cooperation in investigating residue problems and would permit more rapid and effective control of the residues, thereby reducing exposure of people, livestock, and the environment.

In testimony before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science, and Transportation in Lansing, Michigan, on March 31, 1977, the APHIS Administrator stated that Federal authority and funds are needed to enable State and Federal resources and universities to assist in the diagnosis of sickness or death due to unknown causes. He also said that when evidence indicates that more than one herd is affected and when certain other criteria are met, a team of experts from various Federal agencies should be sent to work with their counterparts within the State until the problem has been resolved.

APHIS believes that authority similar to that which permits it to quarantine geographic areas to prevent the movement of animals afflicted with various infectious diseases is also needed for proper control of residue contaminated livestock. According to the APHIS Administrator, USDA intends to include in its legislative program for the 95th Congress a proposal which would give it authority for regulatory measures relating to identification, control, and disposition of animals adulterated with violative levels of chemical residues.

FOOD AND DRUG ADMINISTRATION

FDA officials told us that FDA has not established any new or special procedures for dealing with problems of this type specifically because of the PBB problem. They said that the factual situation for each chemical contamination problem that FDA has investigated has been different and they believe the key to investigating any unusual situation is remaining flexible and being able to adapt to rapidly changing events.

Chapter 9 of FDA's Inspector Operations Manual contains information dealing with food-borne disease outbreaks and disaster investigation procedures. FDA officials believe that the information contained in chapter 9 provides FDA personnel with adequate guidance for reacting to problems similar to the PBB incident.

Information contained in the chapter relates to

--how FDA is informed of problems;

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--coordinating with local, State, and Federal agencies in conducting the investigation;

--identifying the nature and the extent of the problem;

--forming a factual basis for establishing responsibility for the problem; and

--obtaining sufficient information during the early stages of the investigation so that FDA district or headquarters officials can determine if further followup is warranted.

Other activities

In addition to FDA's routine inspections and testing of foods for chemical contaminates, FDA initiated in 1971 a formal program to search for and identify chemicals and metals which contaminate foods. An FDA official told us that this program is intended to identify and assess the health risks of chemicals such as PBB before they actually become a contaminant. Under this program, FDA analyzes food products to determine the levels of chemical contaminates, such as pesticides, polychlorinated biphenyls, and metals in food.

In addition to its chemical contaminates program, FDA has a formal memorandum of understanding with USDA that sets forth the working arrangements which enable each agency to discharge, as effectively as possible, its responsibilities relative to the problem of illegal drug, pesticide, and industrial chemical residues in meat, poultry, and feeds for food-producing animals. Although this agreement was finalized in April 1975, FDA officials told us that the agreement was being developed prior to the PBB incident.