

April 1998

FOOD SAFETY

Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors



**Resources, Community, and
Economic Development Division**

B-279328

April 10, 1998

Congressional Requesters

In May 1997, the Environmental Protection Agency (EPA) discovered elevated levels of dioxin in poultry samples analyzed as a part of its reassessment of the health risks of dioxin.¹ This discovery triggered a joint investigation to determine the source of the contamination. This investigation was undertaken by EPA, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), and the Department of Health and Human Services' Food and Drug Administration (FDA)—each of which has jurisdiction over some aspect of the food safety system. By mid-June, the agencies had traced the contamination to feed distributed to poultry, fish, hog, and cattle producers in several southern and southwestern states. At this point, FDA used its regulatory authority to halt the distribution of the contaminated feed and requested that the feed be disposed of by those holding it. Subsequently, FDA and FSIS required that the affected food products be tested to demonstrate that they did not contain elevated dioxin levels—defined by the agencies as levels above one part per trillion of 2,3,7,8 TCDD, one of the more potent forms of dioxin—before these products could be distributed. Because these elevated levels equated to the concentration levels in the animals, it was expected that the animals' growth would reduce the concentration levels over time.

By mid-September 1997, FDA and FSIS had determined that all the food products derived from the animals that had consumed the contaminated feed had only background levels of dioxin and approved them for commercial distribution. However, between July and September, large and small producers and state health officials questioned whether the levels at which dioxin was found in the food products warranted the actions taken. Producers and state officials also reported that the agencies sometimes issued multiple and unclear directives, resulting in confusion over the actions producers were to take.

Concerned about the performance of the federal agencies in handling this incident, you asked us to determine the (1) basis for the federal agencies' decisions to require producers to demonstrate that their food products did

¹Dioxins are a class of chemical compounds that are found throughout the environment at low levels (called background levels) and are known to be present in the food chain. The dioxin found in this incident included a high concentration of 2,3,7,8 TCDD, one of the more potent forms of dioxin. In 1997, the World Health Organization's International Agency for Research on Cancer classified this form of dioxin as a human carcinogen.

not contain levels of dioxin above one part per trillion; (2) federal agencies' effectiveness in working together to make decisions to address the problem of dioxin-contaminated feed and in communicating their decisions to the affected state agencies, producers, and processors; and (3) impact of the food safety system on the handling of this dioxin incident.

Results in Brief

The Food Safety and Inspection Service and the Food and Drug Administration requested the producers and processors to halt the distribution of food products with dioxin levels above one part per trillion because of their concern about the potential risk to human health that these products might present. While scientists have not yet determined the level of dioxin that poses a danger to human health, the Food and Drug Administration and the Food Safety Inspection Service believed that one part per trillion was an appropriate level to use for halting the distribution of these products. The Food and Drug Administration chose the one-part-per-trillion level to distinguish food products with elevated dioxin levels from those products with background dioxin levels.

The federal agencies worked cooperatively to identify the source of the dioxin contamination and to decide on the actions that might be necessary to address any health risks the contaminated food products posed to consumers. However, their guidance to the affected producers and processors was sometimes unclear and impractical, which left the affected producers confused about the actions they needed to take. For example, the Food and Drug Administration, which is responsible for fish products, told producers they had to test their products, but the agency did not tell them how to collect their samples for testing. In addition, the producers expressed concern that the agencies did not provide them with adequate time to comply with the agencies' testing requirements. For example, the Food and Drug Administration gave fish producers only a few days' notice that they could not market their fish unless the affected fish tested free of elevated dioxin levels. In some instances, the testing process took longer than the time allowed under the deadline. Although these regulatory actions delayed some food products from reaching the market, industry officials told us that the Food and Drug Administration's and the Food Safety and Inspection Service's actions did not result in the widespread destruction of affected food products.

In addressing the dioxin incident, the agencies involved had to overcome the inherent inefficiencies associated with the current food safety system,

which divides responsibility for ensuring food safety among several agencies. As we have reported on numerous occasions, this fragmented food safety system necessitates extensive coordination efforts to minimize wasteful duplication of effort, prevent gaps in regulatory coverage, and avoid conflicting actions.²

Background

While studies have shown that dioxin has an adverse effect upon some animals, the nature of the risk that dioxin poses to human health is not fully understood. In a 1990 FDA study, the agency concluded that the majority of the available epidemiologic studies on the association of cancer with exposure to dioxin provided little evidence that dioxin is a potent carcinogen in humans. Since that time, EPA, as part of its reassessment of dioxin in the environment, issued a draft report reconfirming its earlier position that 2,3,7,8 TCDD was a probable human carcinogen. Subsequently, in 1997, the World Health Organization's International Agency for Research on Cancer classified 2,3,7,8 TCDD as a human carcinogen. However, researchers from the Centers for Disease Control and Prevention (CDC) told us that science has not yet determined the level of exposure to dioxin that may present a danger to human health.

In early 1997, EPA, as part of its ongoing dioxin reassessment and its efforts to quantify dioxin levels in foods, analyzed 80 poultry samples collected from all over the nation to determine the background level of dioxin. In analyzing these samples, EPA found that two contained considerably higher levels of dioxin than the others. These samples were traced to two processing plants, one in Texas and one in Arkansas. Later sampling of poultry products from this same general area also revealed elevated levels of dioxin. The dioxin levels in these samples tested above 3.5 parts per trillion, while EPA had determined from the other 78 samples that the background level for poultry was about 0.14 parts per trillion.

When the final results for the tested products were received on May 20, 1997, EPA immediately notified the two principal agencies having regulatory responsibility for food safety of its findings: (1) FSIS, which is responsible for the safety of meat and poultry products, and (2) FDA, which is responsible for the safety of fish, shell eggs, and animal feed. FSIS and FDA have the authority to prevent adulterated products from reaching

²Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply ([GAO/RCED-92-152](#), June 26, 1992); Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry ([GAO/RCED-94-110](#), May 19, 1994); Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food ([GAO/RCED-94-192](#), Sep. 26, 1994); and Food Safety: A Unified, Risk-Based Food Safety System Needed ([GAO/T-RCED-94-223](#), May 25, 1994).

consumers.³ Together, EPA, FSIS, and FDA traced the contaminant to ball clay, an ingredient used as an anticaking agent in animal feeds sold to some poultry, fish, hog, and cattle producers in southern and southwestern states. The contaminated ball clay came from a single identified mine in Mississippi.

As a result of the dioxin contamination, FDA declared that the animal feed was adulterated. Subsequently, FDA and FSIS declared that food products derived from the animals that had consumed this feed were adulterated. On July 3, FDA acted to halt the distribution and use of the adulterated animal feed. Simultaneously, FDA's Health Hazard Evaluation Board, in consultation with FSIS and EPA, determined that the dioxin in the food products did not represent a severe or life-threatening health risk at these elevated levels.⁴ This determination was primarily based on its conclusion that the duration of consumers' exposure to the elevated levels of dioxin would be limited. FDA officials advised us that the Board, in reaching this conclusion, considered that exposure would be limited because the ball clay from the contaminated mine was no longer being used in animal feed, and products with elevated dioxin levels would be stopped from reaching the market.

Therefore, neither FDA nor FSIS requested a voluntary recall of any food products. However, both agencies told us they wanted to limit the public's exposure to elevated dioxin levels, in part because dioxin accumulates in the body over a lifetime. On July 8, FSIS and FDA informed producers and processors that the food products derived from the animals that had consumed the contaminated feed would need to be tested before being released into the market. The agencies used one part per trillion as a "practical discriminator," or a level of concern, to distinguish between the food products that they would allow into the market and those they would not. Three days later, FDA suspended its testing requirements for fish because of industry's and state officials' concerns with the implementation of its sampling and testing protocol. Subsequently, a revised implementation plan was agreed upon and a new deadline established. By mid-September 1997, FDA and FSIS had determined that all food products derived from the animals that had consumed contaminated feed had only background levels of dioxin and approved them for commercial distribution.

³Food is adulterated if, for example, it bears or contains any poisonous or deleterious substance that may render it injurious to human health.

⁴FDA's Health Hazard Evaluation Board is responsible for evaluating the risk (actual or potential) presented by contaminated products and for determining whether the risk warrants a recall.

Industry officials with whom we spoke informed us that FDA's and FSIS' actions did not, to their knowledge, result in the widespread destruction of beef, pork, poultry, or fish products, but some eggs had to be destroyed. We were also informed of several instances in which fish, poultry, and pork products were delayed in reaching the market while the dioxin levels in the animals' systems decreased or while producers awaited test results. These delays increased producers' costs. Furthermore, we were informed that the cost of testing for some companies totaled more than \$100,000.

One-Part-Per-Trillion Dioxin Concentration Level Chosen to Distinguish Elevated Dioxin Levels From Normal Background Levels

FDA and FSIS requested the producers and processors to halt the distribution of the affected food products with dioxin levels above one part per trillion because of their concern about the potential risk to human health. Although scientists have not yet determined the level at which dioxin may pose a risk to human health, the agencies chose a level of dioxin that is somewhat higher than the background level in food products to distinguish the food products affected by the use of adulterated feed from other food products.

The one-part-per-trillion level set by FDA, in consultation with EPA and FSIS, was a lower concentration level than FDA had used before. In an August 1981 letter to the governor of Michigan, FDA provided advice about the dangers of consuming fish from the Great Lakes tainted with dioxin. In this letter, FDA stated that if the dioxin levels in fish average less than 25 parts per trillion, "there is little cause for concern." Similarly, FDA's health advisory for fish stated that dioxin in concentration levels up to 25 parts per trillion posed "no serious health concerns."⁵ This advisory was included in a 1992 EPA study describing the physical and chemical properties of dioxin and the potential health effects associated with exposure to it. FDA officials said the 1981 guidance was written to apply to sports fish. They pointed out that the two situations differ because the recent dioxin incident involved multiple sources of food, and consumers might ingest more dioxin through these sources than they would from sport fish, which are consumed less frequently.

When FDA and FSIS notified producers and processors that their products could not be sold for human consumption unless the products had a dioxin concentration level below one part per trillion, industry representatives and the Arkansas Department of Health requested scientific evidence to support the need to restrict food products with these low dioxin levels because of the risk posed to consumers. According to

⁵National Study of Chemical Residues in Fish, Volume II, p. C-1.

these officials, FDA did not provide any evidence to support the decision to request that products with a dioxin level of one part per trillion be halted. Moreover, industry representatives were disturbed that FDA and FSIS had acted to halt the distribution of food products. They pointed out that neither agency had requested a voluntary recall of the adulterated products already in the market, even though these products had higher dioxin levels than the products they could not distribute and would potentially pose a greater risk to human health.

Both FDA and FSIS contend that since the dioxin came from a known, controllable source, they had the opportunity to reduce consumers' exposure to it, and therefore they acted to contain it. FDA officials informed us that they took these actions to fulfill their obligation to keep adulterated products from the market. Both agencies emphasized that the one-part-per-trillion level should not be construed as a new standard for dioxin. They stated that one part per trillion does not represent a general action level for dioxin in foods but only the federal government's response to this specific dioxin incident.

Federal Agencies Generally Cooperated During This Incident but Did Not Adequately Work With Producers and Processors to Overcome Their Problems

In response to an evolving situation, EPA, FSIS, and FDA worked cooperatively to identify the source of the dioxin contamination and to establish restrictions on the sale of adulterated food products. However, the agencies did not provide adequate guidance to producers. In addition, the producers expressed concern that the agencies did not allow enough time for them to comply with the requirements. As a result, some producers suffered hardships.

EPA, FSIS, and FDA Cooperated to Identify the Source of the Dioxin Contamination and to Decide on the Actions Necessary to Address Potential Health Risk

Once EPA confirmed that the dioxin levels in the poultry samples were higher than naturally occurring background levels, officials from FSIS and FDA were included in the investigation into the source of the dioxin. The agencies coordinated their efforts through daily conference calls involving numerous officials from the three agencies participating in the investigation. Through this arrangement, the agencies shared responsibility for leading the investigation as the focus evolved from identifying the source of the dioxin, to disposing of the adulterated animal

feed and, ultimately, to restricting the sale of adulterated food products. Because officials from these agencies were included from the beginning of the investigation, their decisions were well informed and coordinated. For example, they were able to agree on important issues, such as the concentration level of dioxin that would be used to distinguish food products with elevated dioxin levels from those products with background dioxin levels. In addition, the officials coordinated their efforts by sharing resources, such as laboratory testing facilities, and by undertaking joint efforts to collect samples.

Agencies Did Not Provide Adequate Guidance Nor Allow Sufficient Time to Comply With Testing Requirements

As the investigation into the source of the dioxin contamination evolved, the impact on producers' operations changed from simply stopping the use of contaminated feed to requiring producers to undergo a complex process for testing dioxin levels in the animals that had consumed the feed. Some producers had difficulty complying with these requirements because the agencies did not always provide guidance that was clear.

The confusion caused by FDA's guidance is illustrated by the agency's handling of the situation with the fish industry. On July 3, FDA began notifying fish producers that some of the feed they had been using was contaminated and that they should dispose of any remaining contaminated feed in accordance with appropriate regulations. However, FDA did not tell the producers to stop distributing their fish, nor did it tell them about the risk the fish might pose to consumers' health, even though we were informed that some producers had asked about these issues. Five days later, on July 8, FDA notified these same producers that their fish were subject to a testing requirement before they could be sold for human consumption. However, FDA recognized that it did not provide an adequate implementation plan for its sampling and testing protocol. Producers told us that FDA could not initially tell them whether all fish were subject to testing; nor did FDA give sufficient guidance on packing the fish samples for shipment to the laboratories for testing. Recognizing these concerns, FDA met with fish producers and discussed these and other matters. On July 11, realizing that its sampling and testing protocol for fish was impractical, FDA temporarily suspended its implementation. FDA then held additional meetings with state regulatory agencies and with industry officials and developed a revised protocol.

FDA officials informed us that between July 3 and July 8, they provided guidance only about the animal feed because, prior to July 8, they had not completed the guidance for the handling of food products. In agreeing to

revise its fish sampling and testing protocol, FDA officials said they had been flexible in working with industry to make its new protocol as effective as possible.

While the new sampling and testing instructions were clearer than the original instructions, the producers still were concerned that the instructions were impractical because they did not allow for a realistic period of time in which to complete testing. On July 16, FDA notified fish producers that any fish that had been fed contaminated feed could not be sold after July 20 unless the fish had been tested and shown to have dioxin levels below one part per trillion. Therefore, if producers who had used the contaminated feed wanted to sell their fish after July 20, they had 4 days in which to collect samples for testing, find a laboratory that could conduct the tests, send the samples to the laboratory, and receive the test results back. However, between July 16 and July 20, producers were free to market their fish products, regardless of the products' dioxin levels. Although many of the producers we spoke with said they received their results within 7 days, one fish producer informed us that his testing took 5 weeks to complete. During this time, his company could not sell its products. Furthermore, producers pointed out that the testing and sampling may have been unnecessary because their fish had not been fed contaminated feed since at least July 3, and the dioxin levels were diminishing as the fish grew.

FSIS allowed 5 days for poultry processors to meet its deadline. Although FSIS' testing requirements, issued on July 8, did not take effect until July 13, poultry processors were not always able to meet this deadline. For example, one poultry company was forced to shut down its processing plant for 2 days while it awaited the results of the dioxin tests. The inability to meet the deadline was partly due to the limited number of laboratories able to perform these very difficult tests.

The Current Food Safety System Resulted in Inefficiencies and Hardships for Some Producers and Processors

The agencies involved in addressing the dioxin incident had to overcome the inherent inefficiencies associated with the current food safety system, in which responsibility for ensuring food safety is spread among several agencies. As we have reported on numerous occasions, this fragmented food safety system necessitates extensive coordination efforts to minimize wasteful duplication of effort, prevent gaps in regulatory coverage, and avoid conflicting actions.

The large number of people that came together to make decisions and issue guidance in this situation illustrates the inherent inefficiencies in the current food safety system. For example, nearly every day during May, June, and early July, officials from EPA, FDA, and FSIS participated in conference calls to discuss the latest developments in the investigation into the source of the dioxin and to determine what actions, if any, the agencies needed to take to protect consumers. At times, over 40 officials participated in these discussions. While FDA and FSIS worked together to make decisions on the preferred course of action, each agency was responsible for communicating its decisions to producers or processors under its jurisdiction. However, complete information was not always communicated to all affected parties. For example, FDA, the agency responsible for regulating animal feed, sent field officials to inform the purchasers of the contaminated feed that they should discontinue the use of any remaining contaminated feed. When these officials met with meat and poultry producers, their primary concern was with the feed, not with the animals that had consumed the contaminated feed. Thus, the officials did not necessarily tell the meat and poultry feed purchasers of the actions they should take for their affected animals. FSIS, the agency responsible for regulating meat and poultry processors, sent word of the testing requirements to meat and poultry processors and to trade associations but also did not notify meat and poultry producers. FSIS has jurisdiction over processing plants, not producers.

In at least one instance, the fragmented nature of the system resulted in hardships for a producer because he was not informed in a timely manner about the actions he had to take to ensure that his animals could be marketed. This hardship occurred even though an FDA official had visited his farm on July 14, the day after FSIS' testing requirements for poultry and livestock went into effect. The producer told us that on this day the FDA official instructed him to stop using the contaminated feed but did not inform him about FSIS' testing requirement.

In the week following the visit by the FDA official, the producer, who told us he was still not aware of the testing requirement, shipped his hogs to a processing plant. While the hogs were in transit, the producer was informed by the processor that his animals would not be accepted for processing because his name had been included on an FSIS list of producers who had purchased feed contaminated with dioxin. The producer then had to unload his hogs en route at a receiving station while he tried to determine the actions he had to take. The producer told us that, despite numerous phone calls to the processor and to FSIS officials in

Washington, D.C., he was not initially told how to resolve this situation. After several days, FSIS told him the hogs had to be tested but agreed to bear the costs of testing. While awaiting the test results, the producer shipped the hogs back to his farm. The producer told us that at some point, his hogs contracted an illness that spread, resulting in a tenfold increase in the death rate normally experienced on his farm. Ultimately, the test results revealed that the levels of dioxin in the producer's hogs were below one part per trillion.

FSIS officials told us that this producer was the only beef or hog producer that they knew of who experienced a delay in bringing his animals to slaughter. In this instance, they stated that every effort was made to assist the producer, including purchasing three of his animals and arranging for their slaughter and testing. We agree that once the agency learned of the producer's problems, it was responsive to his needs. However, the producer's difficulties arose because he was not informed of the need for testing prior to his decision to ship his hogs for slaughter.

Agency Comments

We provided a draft of this report to the Food and Drug Administration, the Environmental Protection Agency, and the Food Safety and Inspection Service for review and comment. Subsequently, we met with officials from each agency to discuss the information in this report and to obtain their comments. The Food and Drug Administration also provided written comments, which, together with our responses, appear in appendix I.

In summary, the Food and Drug Administration commented that the draft, while factually correct, omitted significant aspects of the dioxin incident. The agency pointed out that the report did not completely discuss the work the agency did to identify and trace back the dioxin contamination. In addition, the Food and Drug Administration wanted to emphasize that it took action because of the health risk associated with dioxin. We believe the report describes the Food and Drug Administration's actions and adequately captures the agency's reasons for choosing to halt the distribution of food products with dioxin levels above one part per trillion.

In commenting on the draft report, the Director of the Environmental Protection Agency's National Center for Environmental Assessment expressed concern that the uninformed reader may underestimate the dangers associated with exposure to dioxin. He emphasized that while science has not yet determined the level of exposure to dioxin that may present a danger to human health, it also has not yet determined a safe

level of dioxin exposure. We believe we have adequately represented the known dangers of dioxin in the report.

In commenting on the draft report, the Acting Deputy Administrator of the Food Safety and Inspection Service's Office of Management expressed concern that the report's title and the emphasis given in the report to some producers' perceptions were misleading. The Food Safety and Inspection Service stated that the report did not adequately reflect the positive efforts the agencies made to quickly identify the source of the dioxin contamination; to protect consumers from any potential hazards; and to work effectively with processors and producers, given the large number of parties affected by this incident. In addition, the agency said the report was not completely accurate because it attributed the hardships producers experienced to the actions of the federal government and overemphasized one producer's "perceptions." We believe we have adequately captured the agencies' efforts to quickly identify the source of the contamination and to protect consumers from potential hazards. We agree with the Food Safety and Inspection Service that the dioxin-contaminated ball clay caused the incident. However, as we have stated, the Food Safety and Inspection Service's guidance to the affected producers and processors was impractical because it did not provide enough time for some processors to test and receive results before the agency's deadline and because it was not delivered to the producers in a timely manner so that they were aware of the steps that needed to be taken before they could deliver their products to market.

Officials from the Environmental Protection Agency, the Food Safety and Inspection Service, and the Food and Drug Administration also provided clarifying comments to the report that have been incorporated where appropriate.

Objectives, Scope, and Methodology

To address your concerns about the conduct of the federal food safety agencies, we spoke with, and obtained studies and other information from, officials at the U.S. Department of Agriculture's Agricultural Research Service (ARS) and FSIS, CDC, EPA, and FDA. In addition, we spoke with state officials from Arkansas and Missouri, representatives of trade associations and industry, and individual producers. To determine the basis for the federal agencies' actions to require producers to demonstrate that the dioxin levels in their food products were below a specified level, we spoke with officials from FDA and FSIS and reviewed appropriate statutes and regulations pertaining to their authority. We also met with officials from

EPA and CDC to identify and discuss any studies about the health risks associated with exposure to dioxin.

To determine federal agencies' effectiveness in working together on decisions to address the problem of dioxin-contaminated feed, we reviewed the records of interagency meetings and met with officials from FDA, FSIS, EPA, and CDC to discuss how frequently officials from the agencies met, whether officials from one agency took the lead on certain issues, and how the agencies coordinated their efforts. To determine the federal agencies' effectiveness in communicating their decisions to the affected state agencies, producers, and processors, we asked officials from the Arkansas Department of Health, the Arkansas Development Finance Authority, and the Missouri Department of Agriculture to describe their discussions with FDA, FSIS, and EPA. In addition, to discuss whether the federal agencies effectively communicated their decisions and the consequences of these decisions to the affected parties, we contacted officials from Tyson Foods, Inc.; Riceland Foods, Inc.; ARKAT Feeds, Inc.; Cal-Maine Foods, Inc.; Townsends, Inc.; the United Egg Producers; the Arkansas Cattlemen's Association; the Arkansas Pork Producers Association; and several individual fish and pork producers in Arkansas and Missouri. Finally, we met with ARS staff in Arkansas and with FDA staff from the Dallas District Office and the San Antonio Residence Post to determine how federal regulatory actions were conveyed to affected producers and feed mills.

To determine the impact of the current food safety system on the handling of the dioxin-contaminated feed situation, we discussed the structure of the current food safety system and its impact upon this situation with the federal and state agency officials, industry staff, and the producers listed above.

We conducted our work from September 1997 through March 1998, in accordance with generally accepted government auditing standards.

We are providing copies of this report to interested congressional committees; the Secretaries of Agriculture and Health and Human Services; the Administrator, Environmental Protection Agency; and other interested parties. Copies will be made available to others upon request.

If you have any questions about this report, I can be reached at (202) 512-5178. Major contributors to this report were Robert C. Summers,

John Nicholson, Natalie Herzog, Stuart Ryba, and Carol Herrnsstadt Shulman.

A handwritten signature in black ink, appearing to read "Robert A. Robinson". The signature is fluid and cursive, with the first name "Robert" being the most prominent.

Robert A. Robinson
Director, Food and
Agriculture Issues

List of Requesters

The Honorable Dale Bumpers
The Honorable Tim Hutchinson
United States Senate

The Honorable Marion Berry
The Honorable Asa Hutchinson
The Honorable Jay Dickey
The Honorable Jo Ann Emerson
The Honorable Roy Blunt
House of Representatives

Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

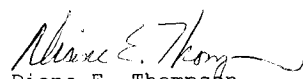
MAR 24 1998

Mr. Robert A. Robinson
Director, Food and Agriculture Issues
General Accounting Office
Room 2T23
Washington, D.C. 20548

Dear Mr. Robinson:

Enclosed are the Food and Drug Administration's comments on GAO Draft Report to Congressional Requesters entitled "Food Safety, Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors."

Sincerely,


Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

Appendix I
Comments From the Food and Drug
Administration

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors GAO/RCED-98-104

We appreciate the opportunity to review and comment on the draft report. The draft, while being factual in many respects, omits significant aspects of the dioxin incident.

See comment 1.

First, dioxin has long been recognized as one of the most toxic substances to which people can become exposed. Dioxin is a substance that poses risks at lower levels than other contaminants (e.g., parts per trillion versus parts per billion). It is ubiquitous in the environment, and unavoidable at background levels. It accumulates in the fatty tissue of humans and of animals consumed as food by humans. As of today, the level in humans at which adverse effects would occur has not been clearly identified. We must, therefore, be concerned about any additional exposure to dioxin, especially if it is avoidable.

See comment 2.

Second, under the Federal Food, Drug, and Cosmetic Act (FFDCA), food is adulterated if, for example, it bears or contains an added poisonous or deleterious substance, such as dioxin, which may render it injurious to health. Such food is unlawful, and therefore, is not permitted to be sold in interstate commerce. The 1 part per trillion (1 ppt) guideline represented a practical point at which a distinction between the background levels of dioxin and elevated levels could be made for the purpose of determining which products would be allowed to enter interstate commerce.

The nature of the Food and Drug Administration's (FDA or the Agency) response to any instance of adulteration is dictated by the seriousness of the potential threat to public health. In the dioxin incident, a determination was made that the adulteration extended to a large portion of the catfish, chickens and eggs for the southern and southwestern states and that the people of that region especially would be exposed to significant levels of dioxin if the problem were not contained. Upon reaching these conclusions, FDA further determined that it would be in the best public interest to stop the flow of adulterated products to the consumer while taking steps to reduce the potential impact of disrupting the marketplace for producers, processors, and consumers.

After the source of the contamination was identified, i.e., animal feed that contained contaminated ball clay, and actions were taken to stop further use of the contaminated clay and further distribution of animal feed containing the contaminated clay, the Agency took steps to minimize impact on the industry while protecting consumers from adulterated food. Working closely with state officials, The Catfish Institute, and the Catfish Farmers of America, FDA developed a sampling plan that could facilitate a steady flow of uncontaminated catfish to processors, while minimizing or nearly eliminating the release of contaminated catfish into commerce. By July 25, 1997, sampling results showed that dioxin levels for most fish fed contaminated meal had dropped below the level of concern due to the cessation of use of the contaminated feed and the rapid growth of catfish at this time of year. This finding permitted catfish growers and processors to return to normal operations, without having to destroy their stock.

Appendix I
Comments From the Food and Drug
Administration

See comment 3.

While it was clearly a challenge to the Agency to identify the source of contamination, the bigger challenge was communicating with the catfish industry. This industry consists of many small producers who are not centrally organized or represented by a single trade association that represents all catfish growers. This greatly affected FDA's ability to communicate with all of the producers. This was an unusual situation and the Agency made every effort to do the most reasonable thing to help the industry while meeting its obligation to protect the public health.

Finally, the four federal agencies involved in the dioxin incident worked very closely together, with each having a unique part in resolving the incident.

GAO's Comments

1. We believe we have adequately represented the known dangers of dioxin in the report.
2. The Food and Drug Administration (FDA) emphasized that it took its actions because of its concern that people in the southern and southwestern states would be exposed to higher levels of dioxin if the problem was not contained. We believe that in the report we adequately captured FDA's reasons for selecting the one-part-per-trillion level and choosing to stop the flow of adulterated products to the consumer, as well as FDA's efforts to work with the fish industry to develop the new sampling plan after the first plan was determined to be impractical.
3. FDA said it was difficult to communicate with the catfish industry because the industry consists of many small producers who are neither centrally organized nor represented by a single trade association. FDA said that, nonetheless, it worked closely with the industry to develop a sampling plan that could facilitate a steady flow of uncontaminated catfish to processors while minimizing or nearly eliminating the release of contaminated catfish into commerce. While we agree that FDA may have attempted to minimize the effects of their actions, the fact remains that catfish producers had difficulties complying with FDA's requirements because FDA's guidance was not always clear, leaving the producers confused about the actions they needed to take.

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GAO
Permit No. G100**

**Official Business
Penalty for Private Use \$300**

Address Correction Requested