United States General Accounting Office

GAO

Report to the Ranking Minority Member, Committee on Commerce, House of Representatives

March 1995

SALVAGED FOOD

Lessons Learned From the Americold Fire

GAO/RCED-95-76

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-259724

March 8, 1995

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

Dear Mr. Dingell:

Every year, millions of pounds of food is damaged or contaminated as a result of mishandling, accidents, or disasters, such as floods or fires. Such a disaster occurred in December 1991, when an underground fire potentially contaminated about 245 million pounds of food in the Americold storage cave in Kansas City, Kansas. Concerned about the efforts made to salvage the food after the fire, you asked us to review federal and state regulation of the food salvaging industry.

As agreed with your office, we have (1) described the events surrounding the Americold fire, particularly the disposition of the food removed from the storage facility, and (2) identified lessons learned from this incident that could be used to improve federal and state regulation of food salvaging.

Results in Brief

Over half the food affected by the Americold fire was sent to landfills to be destroyed. The remainder, about 102 million pounds of food, was found to be salvageable by the Kansas Department of Health and the Environment and was released to the public. Of this total, about 3.7 million pounds was shipped to a Minnesota food salvager on the basis of laboratory results from a consultant to one of the food owners. It was later learned that this consultant had been under investigation for submitting false testing data to the Food and Drug Administration (FDA). All but about 100,000 pounds of this shipped food was eventually sold to the public.

In reviewing events following the Americold fire, we found opportunities for FDA to be more proactive in helping states manage food salvaging following major disasters. Although no illnesses were attributed to the food salvaged from the Kansas fire, the potential risk to public health was increased because of FDA's shortcomings.

Specifically, FDA did not adequately share important information it had about past problems it had experienced with the capability and

performance of the consultant discussed above and his laboratories. The consultant's laboratory test results were used to demonstrate to Kansas officials the safety of salvaged food later released to the public. In addition, FDA did not provide guidance on needed food sampling controls to the Kansas officials responsible for overseeing the salvaging.[1] FDA uses such guidance internally to ensure the credibility, accuracy, and reliability of analytical data from private laboratories.

Regulation of the Food Salvaging Industry

During the storage and distribution of the billions of pounds of food consumed annually in the United States, some food is damaged or contaminated because of mishandling, accidents (e.g., fires, explosions, or truck and train accidents), or natural and man-made disasters (e.g., earthquakes, hurricanes, floods, or riots). Food that is adulterated or contaminated is generally destroyed. However, if the food is determined to be safe, it may be salvaged and "reconditioned" for consumption.

Both FDA and the U.S. Department of Agriculture (USDA) are responsible for ensuring that all food shipped or received in interstate commerce is safe for consumption.[2] FDA enters into contracts or initiates cooperative agreements with state authorities to inspect food manufacturers and warehouses, including operations to salvage food. According to FDA officials, state and local authorities are the most effective regulatory bodies for monitoring such operations because (1) FDA has no authority to place an embargo on hazardous food;[3] (2) the states have intensive regulatory coverage of food warehouses and retail establishments, where most food salvaging operations occur; and (3) FDA has concentrated its resources on issues that pose a higher risk to public health, such as monitoring the blood supply and the safety of medical devices. USDA directly monitors meat and poultry salvaging operations using its own inspectors or designates states to perform inspections when they have inspection programs that meet requirements at least equal to federal laws.

When a major disaster occurs, states may contact FDA and/or USDA field offices for assistance and advice. However, FDA's operational procedures state that in unusual circumstances, such as those involving the interstate

[1]Food sampling involves selecting, securing, and preserving products for private laboratories' scientific analysis of levels of chemical residues.

[2]FDA derives its authority from the Food, Drug, and Cosmetic Act (21 U.S.C. 301). USDA is responsible for regulating the salvaging of meat and poultry products under authority of the Federal Meat Inspection Act (21 U.S.C. 601) and the Poultry Products Inspection Act (21 U.S.C. 451).

[3]An embargo is an order preventing further distribution of the product.

movement of merchandise or areas in which state or local political ramifications are anticipated, FDA may assume the primary role in overseeing salvaging operations.

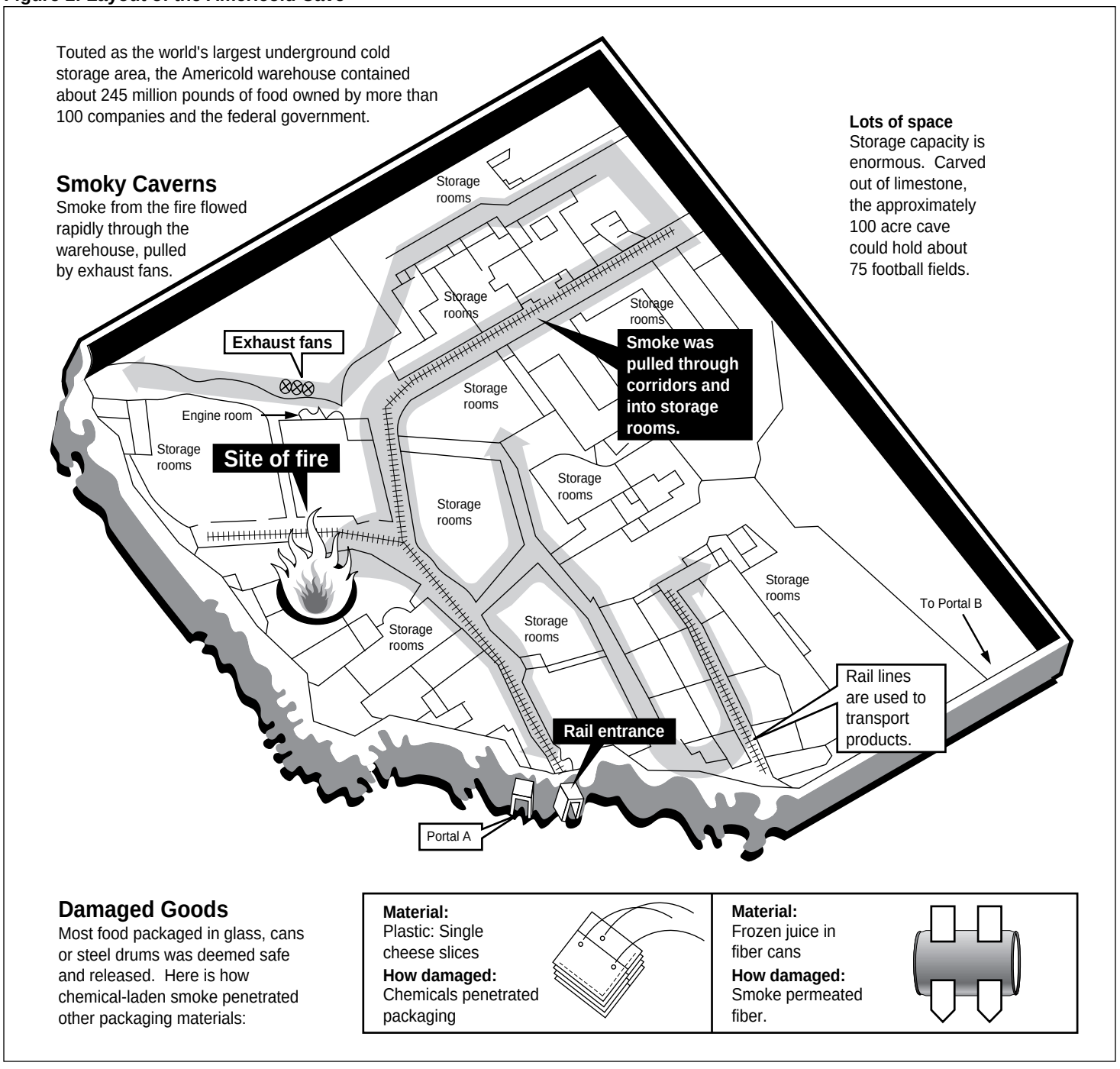
Events Surrounding the Americold Fire

On December 28, 1991, a major disaster occurred when a fire began in a storage cave of approximately 100 acres owned by Americold Services Corporation in Kansas City, Kansas. This man-made limestone cave is the largest underground food storage facility in the world, with freezers, coolers, and dry storage areas accessible by truck and rail. Figure 1 shows the layout of the Americold cave, including the location of the fire.

When the fire began, about 245 million pounds of food was stored in the cave. Of that amount, about 159 million pounds was owned by about 110 private food companies; USDA owned the remaining 86 million pounds. The products stored in the cave included dry milk, cheese, butter, fruit, nuts, and other dry goods, as well as canned and frozen meats, vegetables, and fruits.

The fire started in an area of the cave containing grocery items, including cleaning compounds, pesticides, paper goods, and cooking oil. The fire reached temperatures approaching 2,000 degrees Fahrenheit and, despite continuous fire-fighting efforts, burned for about 2 months. (See fig. 2.) The fire was confined to one section of the cave, but smoke flowed throughout the cave, exposing food to smoke residue for a prolonged period. According to FDA, this event was unique in that no other fire had involved such a large quantity of food that was exposed to smoke for such a long time.

Figure 1: Layout of the Americold Cave



Source: Based on an illustration in The Kansas City Star.

Figure 2: Smoke Coming From an Entrance to the Americold Cave

Source: The Kansas City Star.

Following the fire, the Kansas Department of Health and the Environment (KDHE) met with FDA and other federal, state, and local agencies to determine a course of action for protecting the public health and supervising the salvaging operations. It was decided that KDHE should take the lead in overseeing the salvaging, with assistance from FDA's district

office in Kansas City. Such an arrangement is typical in routine salvaging operations.

According to FDA's records, contaminants found in the air and on surfaces in the cave included toluene, benzene, and phenol—substances cited by the Environmental Protection Agency as being carcinogenic and causing genetic changes and mutations. Because of the potential risk to public health from these contaminants, KDHE, with advice from FDA, placed an embargo on all of the stored food. The embargo was to continue until the owners of the food presented KDHE with evidence, based on laboratory analysis, that the food was suitable for consumption.

In many instances, ownership of the food transferred to insurance companies and, ultimately, to food salvagers. The insurers and salvagers were eager to begin salvaging operations and, according to KDHE officials, placed pressure on KDHE to release the food. The salvaging operations began almost immediately and continued for over 2 years. Table 1 summarizes the final disposition of the food stored in the cave.

Table 1: Disposition of Food Stored in Americold Cave as of June 1994

Pounds of food in millions

Owner	Released	Destroyed	Total
Private	82.4	76.3	158.7
USDA	19.3	67.2	86.5
Total	**101.7**	**143.5**	**245.2**

Sources: KDHE's and USDA's records.

Over 143 million pounds of food was sent to landfills to be destroyed, and about 102 million pounds was released for reconditioning and consumption.

Most of the 102 million pounds of food salvaged from the fire was released to the public with little apparent controversy. However, in December 1993, about 2 years after the fire began, a series of articles in the Kansas City Star raised questions about the release of food to a Minnesota food salvager. About 3.7 million pounds of food was shipped to this salvager, and all but about 100,000 pounds was eventually sold to the public. Appendix I provides a chronology of the key events in the release of the food to this salvager.

Inadequacies in FDA's Assistance to KDHE: Need for a More Proactive Role for FDA

Our review of food salvaging activities following the fire—particularly those involving the shipment of food to Minnesota—found two problems from which lessons can be learned to improve future salvaging operations. First, FDA did not adequately share information with KDHE about past problems it had experienced with a food owner's consultant and his laboratories. This consultant's laboratory test results were used to demonstrate to KDHE the safety of food later released to the public. Second, FDA did not communicate its guidance on food sampling to the KDHE officials responsible for overseeing the salvaging operations. FDA relies on such guidance internally to ensure the integrity of analytical data from private laboratories. Both of these problems suggest the need for FDA to be more proactive in helping states manage food salvaging following major disasters.

FDA Did Not Adequately Communicate Important Information About Consultant and Laboratories

KDHE allowed several million pounds of food salvaged from the Americold fire to be sent to Minnesota on the basis of laboratory results submitted by a consultant to one of the food owners. KDHE officials subsequently learned from FDA that this consultant and his laboratories had been under investigation by FDA and that two of his laboratories were on FDA's "nonacceptance" list. However, FDA did not provide this information in a timely manner either to its Kansas City District Office or to the KDHE investigators overseeing the salvaging of the food.

In April 1992, KDHE asked FDA's Kansas City District Office for advice on the consultant's plans for sampling and testing food that had been stored in the Americold cave. The consultant had been hired by a food owner to sample and test the food for chemical and smoke residues. FDA's district office raised several concerns about the consultant's plans. However, it provided no information to KDHE about the past performance of the consultant or his laboratories. This information was known within FDA but was not shared with the FDA investigator advising KDHE.

FDA's Division of Field Science in Washington, D.C., maintains and periodically distributes to FDA district offices a "nonacceptance" list of some private laboratories. According to FDA officials, the list provides information about private laboratories that at least one FDA district office has found to be unacceptable for performing certain or all analytical tests. FDA's district offices may use this information in deciding whether to accept or reject analyses from a particular laboratory. Much of this information is based on enforcement activities in FDA's program for

monitoring imported food. FDA's information indicated that two of the consultant's laboratories were unacceptable for performing any analyses.

The investigator from FDA's district office said that he was unaware that such a list existed until June 13, 1992, when he learned of it from a visiting FDA scientist. A month later, he advised KDHE not to accept test results from the consultant's laboratories. However, the consultant informed KDHE that the analyses were being performed by another laboratory that KDHE, on the basis of discussions with the Minnesota Department of Agriculture, had determined to be reputable. This laboratory was not affiliated with the consultant. On the basis of this information and subsequent laboratory results indicating that the tested food was not contaminated, KDHE allowed the food to be shipped, under embargo, to a Minnesota salvager. KDHE officials later learned from FDA that the consultant himself was the subject of an ongoing FDA investigation concerning the falsification of laboratory data. They said that if they had known this earlier, they would not have allowed the food to be shipped to Minnesota.

After the food shipments to Minnesota began, the Minnesota Department of Agriculture asked FDA to test a truckload of cheese. Minnesota state food inspectors were concerned because the containers were covered with dust and smelled of smoke. FDA's test results showed that some hazardous chemicals, including toluene, were present in the cheese. However, according to an FDA official, the levels of chemicals found did not pose a health hazard. The remaining food held by the salvager was retested by a private laboratory, judged to be safe for consumption, and eventually sold to the public. Officials from KDHE and the Minnesota Department of Agriculture told us that no illnesses have been attributed to this food.

FDA Did Not Adequately Communicate Its Guidance on Food Sampling

FDA has published guidance on food sampling to ensure the credibility, accuracy, and reliability of analytical data from private laboratories. This guidance, which primarily concerns FDA's regulation of imported foods, was provided to KDHE's state laboratory[4] but not to the KDHE officials managing the food salvaging operations.

The food sampling processes KDHE used in the salvaging operations following the fire lacked some important controls, thereby creating the risk that unsafe food might be released to the public. For example, food

[4]KDHE's Health and Environment Laboratory is a separate department within KDHE, with its own director.

owners selected food samples without a KDHE official or other disinterested third party present. In addition, the consultant discussed earlier maintained control over food samples that were to be tested for chemical residues.

Although it has no legislative regulatory authority over private laboratories, FDA has internal guidance to help ensure that laboratories performing analyses of FDA-regulated commodities submit scientifically sound data. In March 1992, FDA provided Kansas with its Laboratory Procedures Manual, which spells out recommended sampling controls that FDA uses in monitoring imported foods. Among other things, the guidance recommends that scientific data supplied by private laboratories be obtained by using sound methods of sampling and analysis and that sampling be performed by a disinterested, objective third party.

The KDHE officials responsible for overseeing the food salvaging operations said, however, that they were not aware of this guidance because it had been provided only to KDHE's state laboratory. They also noted that the FDA officials assisting them had not brought this guidance to their attention. They said that if they had been aware of the guidance, they would have required all food owners to hire a disinterested third party to perform food sampling and ensured that the chain of custody over food samples was secured.

In discussing FDA's participation in overseeing the salvaging activities following the Americold fire, FDA officials said they viewed their role as limited to that of a consultant. According to one FDA official, FDA's role was limited to providing information to KDHE when requested, and FDA was not to anticipate what issues needed to be addressed.

Conclusions

KDHE had to make decisions about the release of potentially contaminated food under stressful conditions, including pressure from food owners to expeditiously release the food for salvaging. KDHE relied on FDA, which has considerable experience in dealing with food safety issues, for advice and guidance. However, although the Americold fire was a major disaster with potentially serious consequences resulting from the release of improperly tested food, FDA continued to view its role as that of a consultant—primarily responding to specific requests from KDHE for advice.

Such an interpretation may be appropriate for routine salvaging activities; however, this was not a routine operation. Over the years, FDA has

developed considerable nationwide experience and expertise in food safety. We believe that in future disasters of this magnitude, in which so much is at stake and improper decisions can adversely affect food safety, FDA should proactively draw upon this expertise and provide stronger leadership in working with states to maintain the safety of the food supply.

Recommendations

We recommend that FDA more actively assist states in managing food salvaging operations following major disasters. At a minimum, FDA should ensure that (1) the information it has about private food testing laboratories and key personnel is communicated to state officials responsible for monitoring food salvaging operations after a major disaster and (2) these state officials are made aware of FDA's guidance for maintaining the integrity of the food sampling process.

Agency Comments and Our Response

In commenting on a draft of this report, FDA disagreed with our conclusions and recommendations. FDA described the assistance it provided KDHE and said it had worked very closely with KDHE officials to ensure that the public health was protected and that unsafe food did not reach consumers. FDA stated that following a series of meetings, it was agreed that KDHE was the agency most suited to take the lead in the day-to-day supervision of the salvaging operations and that FDA's Kansas City District Office would support KDHE in any way required. Overall, FDA said it believed its actions in assisting KDHE were correct and appropriate.

With regard to our first recommendation, FDA stated that it would be inappropriate to routinely distribute its "nonacceptance" list of private laboratories to states, noting that (1) FDA does not have a regulatory mechanism for declaring a laboratory or analyst unacceptable, (2) the list could be misconstrued and used inappropriately, and (3) more aggressive distribution of the list could jeopardize FDA's ability to maintain and internally disseminate information about the laboratories' performance.

With regard to our second recommendation—ensuring that appropriate state officials are made aware of FDA's guidance on food sampling—FDA said it had provided KDHE with this guidance. FDA maintained that it is the state agency's responsibility to ensure that individual employees receive copies of pertinent FDA documents.

We recognize that FDA supported KDHE in dealing with the salvaging operations subsequent to the Americold fire and have added information

to the report to more fully describe the nature of that assistance. However, we continue to believe that lessons learned from the Americold experience can make FDA's support more effective in future disasters—the overall lesson being that FDA needs to provide stronger, more proactive leadership in assisting states in the aftermath of major disasters.

Our report notes that KDHE took the lead in overseeing salvaging operations, with FDA's Kansas City District Office acting in a consultant's role—primarily responding to requests from KDHE for assistance—and that such an arrangement was typical in routine salvaging operations. However, the Americold fire and the subsequent salvaging operations were not routine. As FDA itself noted, "this event was unique in that no other fire has involved such a large quantity of food that was exposed to smoke for such a prolonged period of time." It may be appropriate, in routine circumstances, for FDA to wait until states seek advisory information from it. However, in major disasters, we believe that FDA needs to draw upon its nationwide experience and expertise in food safety and more proactively provide relevant information to state officials responsible for dealing with such an event.

Regarding our recommendation that FDA share with states information about private laboratories and key personnel, we recognize that FDA's "nonacceptance" list is not intended to be a means of certifying a laboratory or declaring it unacceptable and that FDA believes it has no regulatory authority to do so. Furthermore, we understand FDA's concern that aggressive dissemination of the list could result in inappropriate use of the information on it. Nevertheless, as discussed in our report, the list may contain information of great relevance to state officials making critical decisions affecting the safety of the food supply.

To balance the risk of further disseminating FDA's list with that of withholding potentially important information on it, we have worded our recommendation to say that following major disasters, FDA should communicate information it has about private food testing laboratories and key personnel to state officials responsible for monitoring food salvaging operations. Thus, we are not recommending that the list itself be disseminated, but rather information on the list as well as any other relevant information about the performance of laboratories and key personnel. The form in which FDA wishes to convey this information, as well as any caveats attached to it, is left to FDA's discretion. Under these circumscribed conditions, we believe that FDA can maintain adequate control over the information to ensure that it is not inappropriately used.

With regard to our second recommendation concerning communicating FDA's guidance on food sampling to appropriate state officials, FDA explained that it had provided its Laboratory Procedures Manual, containing guidance on food sampling controls, to KDHE's state laboratory, which was not directly involved in food salvaging following the Americold fire. The KDHE officials who were overseeing the salvaging operations were unaware of this guidance, and FDA did not bring it to their attention. We believe that FDA officials assisting states in major disasters should take the initiative to ensure that state officials who are managing the food salvaging operations be made aware of key FDA guidance, such as that pertaining to the food sampling process.

Appendix II contains the complete text of FDA's comments, along with our responses.

Scope and Methodology

To obtain information on the food salvaging that occurred after the Americold fire and to identify the lessons learned, we interviewed FDA officials in Washington, D.C., Kansas, and Minnesota; USDA officials in Washington, D.C., and Kansas; and state health officials in Kansas and Minnesota. In addition, we interviewed a food salvager located in Minnesota. We reviewed FDA, USDA, and state records on the Americold fire at the locations listed above. We also reviewed laws and regulations applicable to food salvaging. We conducted our review from June 1994 through January 1995 in accordance with generally accepted government auditing standards.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 15 days after the date of this letter. At that time, we will provide copies to the appropriate agency heads and interested congressional committees. We will also make copies available to others upon request.

Please call me at (202) 512-5138 if you or your staff have any questions. Major contributors to this report are listed in appendix III.

Sincerely yours,

John W. Harman
Director, Food and
Agriculture Issues

Contents

Abbreviations

FDA	Food and Drug Administration
GAO	General Accounting Office
KDHE	Kansas Department of Health
USDA	United States Department of Agriculture

Chronology of Events Surrounding Food Shipments to Minnesota Salvager

March 1992	The owner of 3.7 million pounds of food hired a consultant to sample and test the food to determine if it could be salvaged.
June 10, 1992	The Minnesota Department of Agriculture agreed to accept food shipped under Kansas's embargo to a Minnesota salvager.
July 13, 1992	FDA's Kansas City District Office notified KDHE that the consultant's laboratories were on FDA's "nonacceptance" list and advised KDHE not to accept their results. KDHE agreed to accept laboratory results from the consultant after he told them that another laboratory had performed the analyses.
July 28, 1992	KDHE began allowing food shipments to a Minnesota salvager under KDHE's embargo after the laboratory results showed that the food was safe for human consumption. KDHE recommended that Minnesota's Department of Agriculture perform organoleptic (sight, smell, taste) evaluations when the food arrived and agreed to lift the embargo upon the Minnesota Department of Agriculture's recommendation.
August 8, 1992	The Minnesota Department of Agriculture placed a voluntary hold on a cheese shipment and asked FDA to test the cheese. However, the salvager sold the cheese before the laboratory results arrived.
October 10, 1992	FDA's laboratory results showed that the cheese had contained small amounts of chemicals, including toluene. FDA determined that the chemical levels were not sufficient to warrant action to seize the food.
December 1992	The Minnesota Department of Agriculture required the Minnesota food salvager to retest all the food from Kansas still in storage. The retested food was judged safe for human consumption.
August 1992 to Present	No illnesses have been attributed to the food shipped to the Minnesota salvager.

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

JAN 12 1995

Mr. John Harmon
Director, Food and Agriculture Issues
Resources, Community and Economic
Development Division
U.S. General Accounting Office
441 G Street, N.W.
Washington, D.C. 10548

Dear Mr. Harmon:

Attached are FDA's comments on the draft report entitled: "Salvage Food: Lessons Learned from the Americold Fire," GAO/RCED-95-76.

Sincerely,

Dennis T. Strickland

Dennis T. Strickland
Deputy Associate Commissioner
for Legislative Affairs

Enclosure

FDA COMMENTS ON THE GAO DRAFT REPORT ENTITLED, "SALVAGE FOOD: LESSONS LEARNED FROM THE AMERICOLD FIRE," GAO/RCED-95-76

GENERAL COMMENTS

FDA has reviewed the GAO draft and disagrees with the conclusions in the report. The Food and Drug Administration (FDA), particularly the Kansas City District Office (KCDO), worked very closely with the Kansas Department of Health and the Environment (KDHE) to ensure that the public health was protected and that unsafe food did not reach consumers. As previously discussed with the evaluators, immediately after the fire began FDA met with other Federal, State, and local government agencies to determine a course of action for protecting the public health and supervising the clean-up and salvage operations. Over the course of a few weeks of intensive evaluation of the situation, (i.e., what would be involved in the clean-up, what legal charges might be involved, whose authority was most applicable to the situation, which jurisdiction was most experienced at salvage operations, what role each jurisdiction could fulfill most effectively, etc.) the decision was made by all interested agencies that KDHE was most suited to the day-to-day supervision that would be required. It was further decided that KCDO would support KDHE in any way required. While the cave fire and resulting situation were unique, such cooperation between governments is not at all unusual. The KCDO is, in fact, in contact with Kansas regulatory agencies almost daily regarding situations of mutual interest.

The report states that FDA, "maintains and periodically distributes to FDA district offices a 'non-acceptance' list on some private laboratories." It also states that, "FDA did not provide this information in a timely manner either to its Kansas district office or to KDHE investigators overseeing food salvaging activities."

As was explained to the GAO evaluators, the "list" is comprised of private or commercial laboratories/analysts who have submitted analyses to FDA which the Agency has determined to be unacceptable for various reasons such as having submitted inaccurate results based on faulty analytical methodology, failure to permit site visits to confirm capabilities, suspected falsification of data, etc.. The primary purpose for the list is to assist FDA districts in deciding whether to accept analyses submitted to the agency for the purpose of demonstrating that a product offered for import meets FDA requirements for admission to the United States. While the list is routinely distributed to all district offices, many district office units are not usually involved in making decisions regarding admissibility of imported products. Therefore, individuals located in those district office units would have little reason to become familiar with the list.

See comment 1.

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FDA does not have a regulatory mechanism for declaring a lab or analyst "non-acceptable" and requiring a state not to use a particular laboratory. The "list" does not bar the laboratories on the list from submitting analyses or FDA from accepting them. It includes only laboratories that have submitted specific products using specific analytical procedures to FDA in support of the admissibility of a specific product. It does not make comparisons between the relative qualifications of laboratories in a local area or nationally. Nor does it include all laboratories that may be unable to perform analyses to support the admissibility of imported products, since FDA may not have had experience with all the laboratories that could conceivably do the analytical work needed. Furthermore, situations like the Kansas City fire are rare and would not justify circulating information outside FDA that could be misconstrued or cause an inappropriate denial of commerce to those laboratories on the list. For these reasons, we believe it would be inappropriate to distribute the list to States on a routine basis.

See comment 2.

Nevertheless, as was explicitly stated to the evaluators, on July 13, 1992, KCDO did, in fact, advise KDHE not to accept the consultant's lab results two weeks before KDHE released the product to the Minnesota Department of Agriculture (MDA) under embargo and KDHE seal. KDHE, therefore, knew the consultant was questionable before the product was shipped on July 28, 1992. It is FDA's understanding that the shipments from Kansas to Minnesota were made on the basis of lab results presented to MDA on the letterhead of a reputable Minnesota laboratory which was not on FDA's "list", and FDA did not have any information to indicate that the laboratory alleged to have done the work would be unacceptable. KDHE determined that there were problems with the data subsequent to shipment and notified FDA, which triggered a thorough FDA investigation and the possibility of further regulatory action against the consultant. This point should be clarified before the report issues. The chronology at appendix 1 also should be corrected to reflect the correct date on which KDHE was notified of FDA's concerns regarding the consultant.

See comment 3.

See comment 2.

Finally, the report should explicitly recognize that there were no illnesses resulting from the fire, that no dangerous product was consumed, and that FDA's analyses of the food tested by the consultant showed the levels of residues did not exceed levels of the same chemicals found in similar food that had not been subjected to the fire.

See comment 4.

GAO RECOMMENDATION

We recommend that FDA more actively assist states in managing food salvaging operations following major disasters. At a minimum, FDA should ensure that (1) information it has about private food testing laboratories and key personnel is communicated to state agencies and (2) state officials responsible for overseeing food salvaging operations are made

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aware of FDA's guidance for maintaining the integrity of the food sampling process.

FDA COMMENT

We do not concur. As discussed above, FDA was an active participant in the cleanup and salvage operations following the Kansas City fire. FDA's role in the cleanup and salvage operation was to assist KDHE in any way they needed assistance from the agency. Among the activities carried out by FDA were consultation about the adequacy of salvage plans submitted by salvagers, consultation regarding conditions in the cave that would require attention, laboratory analyses of products for contamination, review and approval of specific salvage plans submitted by salvagers, etc. FDA's activities regarding the fire cleanup and salvage operations continued as long as there was a need for participation. We believe FDA's actions were correct and appropriate to the event. It should further be noted that GAO visited other FDA district offices where disasters of a different nature (primarily natural disasters such as floods) had occurred and found no deficiencies in FDA activities, which generally were similar to those regarding the Kansas City fire. FDA consistently works closely with state and local governments when a disaster involving FDA-regulated products occurs. As was discussed with the evaluators, the lead role among regulatory agencies is usually determined on a case-by-case basis to best address each situation. We believe this to be the appropriate approach.

See comment 5.

We further believe the agency's practices with respect to disseminating information about individual laboratories/analysts is appropriate. In the specific case of the Kansas City fire, FDA notified KDHE of its concerns regarding the consultant well before the product in question was shipped under embargo to another state. We believe a more aggressive dissemination of such sensitive information could easily be misconstrued by those receiving it and result in inappropriate use of the information. Such use would be detrimental to the private laboratories over which FDA has no direct regulatory authority. It could also jeopardize FDA's ability to maintain and internally disseminate information about laboratory performance that would assist FDA districts in performing their task of import admission.

See comment 6.

The report implies that the Kansas City District Office did not adequately impress upon KDHE that the consultant was not "acceptable." In April of 1992, KDHE submitted the consultant's reconditioning proposal to KCDO, which rejected it because it was inadequate. In approximately the same time period, KDHE discovered that the consultant was airing product by driving it around in the back of a pick-up truck. It is FDA's impression that KDHE inspectors rejected the salvager's proposal because they believed the consultant was not acceptable. Certainly, both KCDO and KDHE had ample reason to question the ability of the

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consultant to perform at an acceptable level beginning at least as early as April.

As also noted in the draft report, FDA had provided KDHE with a copy of the Laboratory Procedures Manual which provides guidance to FDA districts and other interested parties regarding proper procedures for sample collection and maintenance of sample integrity. We believe it is the responsibility of the state agencies to provide to individual employees copies of documents they have received from FDA and not FDA's responsibility. Furthermore, as noted above, KDHE is very experienced in supervising salvage operations. Their inspectors are familiar with proper techniques for collecting and safe-guarding samples. KDHE followed acceptable practices in allowing the consultant to collect the sample. FDA's guidance regarding sampling does not require third-party sampling, but suggests that collection by a disinterested party would be "preferable." In this specific case, the laboratory under contract to the salvager qualified as a disinterested third party. However, the salvager was responsible for demonstrating to KDHE that the product in question was not contaminated before selling it or undertaking reconditioning. Submission of analytical results to KDHE was only one part of demonstrating that the product was not contaminated. KDHE had the responsibility of determining that the salvager had met all requirements for distributing the product for sale to consumers, not just the analytical results.

See comment 7.

See comment 8.

See comment 9.

TECHNICAL COMMENTS

1. Page 1, paragraph 1, sentence 2: Change to read, "Such an event occurred in December 1991, when an underground fire broke out in the Americold storage cave in Kansas City. Approximately 245 million pounds of food were stored in the cave at that time." Add, "This event was unique in that no other fire has involved such a large quantity of food 'that was exposed to smoke for such a prolonged period of time."

See comment 10.

2. Page 3, 7th line: Delete the word "health." FDA has contracts and cooperates with state agencies that are not health agencies as well as those that are called health agencies. There is no delineation among the state agencies on the basis of their being "health" agencies or not.

See comment 11.

3. Page 3, 1st full paragraph, 3rd sentence: Item (1) is incorrect. FDA has no embargo authority with respect to foods in domestic commerce. The statement should be deleted.

See comment 12.

4. Page 4, 4th line: The report states that FDA may assume responsibility for a salvage operation whenever "...state or local political ramifications are anticipated." We are unaware of any policy statement by FDA that would support

this statement. If the evaluators are referring to a particular document, it should be cited. Furthermore, FDA did not anticipate that KDHE would be unduly influenced by political ramifications as implied. The innuendo that state or local political ramifications in some way influenced the manner in which KDHE carried out its responsibilities with respect to the fire cleanup is a very serious statement that should be substantiated in the report or the statement should be deleted.

See comment 13.

5. Page 6, 2nd paragraph, last line: Delete "contaminating stored food."

See comment 14.

6. Page 6, 3rd paragraph: This paragraph needs to be expanded to more fully capture both KDHE's role and KCDO's role as discussed above.

See comment 15.

7. Page 6, last paragraph, 1st line: Change the word "contaminates" to "contaminants."

See comment 16.

8. Page 13, 1st paragraph, last sentence: This statement is incorrect. As stated above, FDA was fully supportive of KDHE and worked closely with the responsible KDHE staff to ensure that unsafe product would not be released for sale to the public. We would also question the characterization of this event as a "major disaster." While it certainly was a large and unique fire that negatively affected the firms storing food in the facility as well as the Americold firm, no unsafe product reached the public and there were no injuries.

See comment 17.

9. The report consistently refers to the Kansas City District Office as the Kansas district office. The proper name of the district is Kansas City District Office.

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The following are GAO's comments on the Food and Drug Administration's letter dated January 12, 1995.

GAO's Comments

1. FDA said the primary purpose of the "nonacceptance" list is to assist the agency's district offices in reviewing analyses submitted to demonstrate whether products offered for import meet FDA's requirements. FDA stated that many district offices have little involvement in decisions about imported products and therefore have little reason to become familiar with the list. We believe that individuals located in district offices, regardless of whether they are responsible for domestic or imported commodities, have reason to become familiar with the list, particularly when advising state agencies that may be using these same laboratories and analysts. Furthermore, FDA's guidance was updated in June 1994 so that laboratories and analysts who have submitted unacceptable analysis for both domestic and imported commodities are included on the list. Therefore, we made no changes to the report.

2. FDA's Kansas City District Office advised KDHE, on July 13, 1992, not to accept results from the consultant's laboratories but did not provide information about the consultant's past performance. KDHE subsequently learned that the consultant had been under investigation for submitting false testing data to FDA. We have changed the chronology to show the date that KDHE was notified about the consultant's laboratories.

3. Food was shipped to the Minnesota salvager on the basis of laboratory results presented to KDHE, not the Minnesota Department of Agriculture, as stated in FDA's comments.

4. Our report recognizes that no illnesses have been attributed to consuming food from the cave fire. However, we have no evidence to support FDA's claim that no dangerous products were consumed, nor have we been provided with test results showing that residue levels did not exceed levels of the same chemicals found in similar food that had not been exposed to the fire. FDA officials told us that they performed laboratory analysis on only two samples of food and did not perform the sampling and testing required by FDA's own procedures to ensure that the entire lot of food was safe for consumption. The food was sold by the salvager before the tests were completed.

5. GAO visited another FDA office to determine whether food salvaging had occurred following the 1993 Midwest flood. FDA noted that GAO found no

deficiencies in FDA's activities, which, it said, were generally similar to those following the Americold fire. We visited an FDA office in the area affected by the flood and were informed that no salvaging requiring the use of private food testing laboratories was performed. Therefore, this event was not similar to the Americold fire. We did not revise the report.

6. FDA stated that our draft report implied that FDA's Kansas City District Office did not impress upon KDHE that the consultant was not acceptable and notes that both FDA's district office and KDHE had ample reason early on to question the consultant's capability. We continue to believe that FDA did not adequately share information about the consultant's past performance. While the district office raised questions about the consultant's sampling and testing plan, it provided no information to KDHE reflecting its concerns about the consultant's past performance. This information was available elsewhere within FDA, but was not shared with the district office officials who were advising KDHE. In fact, KDHE officials later learned that the consultant was the subject of an ongoing FDA investigation. They said that had they known this earlier, they would not have allowed food to be shipped to the Minnesota salvager. We did not revise the report.

7. FDA contends that KDHE officials are familiar with proper techniques for collecting and safeguarding samples. KDHE officials agreed that this is true for samples collected by their own food inspectors. However, they said that they rarely use private laboratories in their routine food inspection activities and that FDA has much more experience in dealing with private laboratories. We have recommended in our report that following major disasters, FDA ensure that state officials responsible for overseeing food salvaging operations are made aware of FDA's guidance for maintaining the integrity of the food sampling process.

8. Our report acknowledges that FDA's guidance on third-party sampling is a recommendation, not a requirement. However, KDHE officials said that had they known of FDA's guidance, they would have required all food owners to hire a disinterested third party to perform food sampling and ensure that the chain of custody over food samples was secured.

9. We have added this sentence to the background section of our report.

10. We agreed with this comment and removed the word "health."

11. We agreed with this comment and have revised the report.

12. According to FDA's Investigations Operations Manual, subchapter 940, paragraph 942, "Except in unusual circumstances, FDA responsibilities are to assist the state and local health agencies in removing, destroying or reconditioning affected merchandise. In situations involving interstate movement of merchandise; large interstate firms; areas in which state or local political ramifications are anticipated; or when state or local health officials so request; FDA may assume the primary role in the operation." We included this statement to show that in major disasters, FDA may take on a stronger leadership role if it chooses to do so. We do not say, nor do we mean to imply, that KDHE was in any way influenced by political ramifications.

13. We agreed with this comment and have revised the report.

14. We agreed with this comment and have revised the report.

15. We agreed with this comment and have revised the report.

16. We believe that the Americold fire—an event that FDA described as "unique in that no other fire has involved such a large quantity of food that was exposed to smoke for such a prolonged period of time" and that resulted in the destruction of over 143 million pounds of food—can appropriately be described as a major disaster. Similarly, we do not question the fact that FDA supported KDHE. However, we believe that its support could have been more effective had it provided stronger, more proactive leadership.

17. We agreed with this comment and have revised the report.

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