

The players in foodborne illness recalls

Science: Identifying a foodborne illness that prompts a product recall

When food manufacturers are involved in a potential product recall, one key question is: how do we really know if it is our product that is causing people to get sick? This article discusses various science-related issues relevant to the food recall process. Technological advances have dramatically changed the ability of government agencies to identify and investigate outbreaks of foodborne illness. These advances have also dramatically improved the tools food manufacturers can use to effectively complete an internal investigation, supplement, corroborate, or dispute the results of a government investigation, and anticipate or even deflect further government action. (For a brief discussion of experts that a company involved in a recall may consider hiring, see sidebar.)

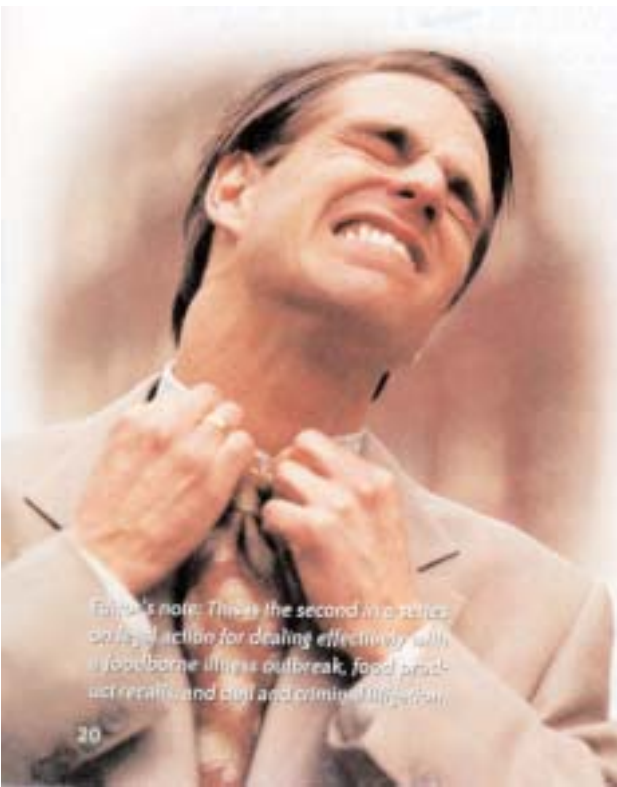
The importance of using science to exonerate a company of charges of causing foodborne illness is obvious. But equally vital is that when an investigation convinces a food manufacturer that one of its products is contaminated, scientific inquiry can enable the manufacturer to act responsibly as a corporate citizen, while at the same time weeding out frivolous or nuisance lawsuits that seek to piggyback on the company's misfortune.

The US Players Involved In Investigating Foodborne Illness

Numerous federal regulatory agencies have complementary, interdependent, and occasionally conflicting food safety missions. The agency directly involved in a food recall or other government investigation of contamination or foodborne illness varies according to the nature of the product involved, and the nature of the contamination.

Within the Department of Agriculture (USDA), the Food Safety Inspection Service (FSIS) bears responsibility for ensuring the safety and wholesomeness of meat, poultry, and egg products. Its website (www.fsis.usda.gov) contains useful links to news and information on past and present recalls, Congressional testimony on food safety matters, and current food-related regulatory actions. Other agencies within USDA that have a food safety mission include the Animal and Plant Health Inspection Service (APHIS; www.aphis.usda.gov), whose primary function is to protect against plant and animal pests and diseases.

The Food and Drug Administration (FDA; www.fda.gov), within the Department of Health and Human Services (HHS), is charged with ensuring the safety and purity of all food products other than those regulated by FSIS – which is about 75% of all foods consumed in the United States. (“Mixed” products – such as a sausage pizza or a packaged turkey sandwich – usually fall under FDA’s jurisdiction.) FDA also has regulatory responsibility over animal feed, and would be the lead agency in a recall involving animal food



Editor's note: This is the second in a series of articles on action for dealing effectively with foodborne illness outbreak, food product recalls, and civil and criminal litigation.

EXPERTS TO CONSIDER RETAINING

The nature and extent of the recall, the number of persons affected, and the identity of the pathogen involved will all affect the experts who should be retained for recall-related matters. However, the following categories of scientists have expertise which is likely to prove highly useful in connection with a food recall.

• Clinicians and/or epidemiologists:

In the early stages of a recall, an epidemiologist or infectious disease expert, particularly one with experience in outbreak investigations, may prove highly useful in communicating with government investigatory agencies, such as CDC, and may facilitate dialogue and the exchange of information between the agency and the company. In addition, if it is possible to obtain the investigating agency's raw data, and particularly if the recall is associated with a widespread outbreak of foodborne illness, an experienced epidemiologist may be needed to analyze and corroborate the agencies' methodology and results.

Depending on the number of potential patients with the foodborne illness, it may prove highly useful to retain experts and consultants in the diagnosis and treatment of infectious disease, who may assist in evaluating the medical records of claimants. An infectious disease spe-

cialist with particular expertise with the pathogen associated with the recall should be able to determine whether the symptoms the claimant displayed are consistent (or inconsistent) with manifestations of disease caused by the pathogen at issue; whether the claimant was appropriately treated; and whether the claimant suffered from any other condition which may have been an intervening cause of the illness.

• Microbiology laboratory/testing:

Acquiring the services of a laboratory to test product and examine possible sources of contamination within the processing facility, and/or any product that remains within the facility, is likely to be crucial to understanding what did – and did not – happen at the facility whose product is subject to recall. If the plant has been closed, a laboratory with the ability to do rapid testing will be able to help develop and determine the efficacy of new procedures for testing environmental samples, or samples from product contact surfaces within the plant, or suggest intensive testing protocols for starting the plant up again.

As PFGE and other forms of testing become more prevalent, the services of a microbiologist and up-to-date laboratory with sophisticated equipment are likely to prove highly useful. More non-govern-

mental laboratories, such as those associated with food science departments at large universities, now have the capacity to do their own PFGE analysis. However, if you are trying to “match” the government's testing, it is necessary to make sure that the laboratory is capable of reproducing PulseNet's methodology and testing protocols, or the results will not be useful for comparison. A microbiologist may also be able to provide advice regarding other testing that may be suggested in defending recall-related claims. This will be particularly true if the pathogen at issue has not been thoroughly studied or analyzed.

• Food science and operations: A food science expert, especially one with expertise in plant operations issues, may help the company assess the quality and efficiency of its current operations, and suggest areas of improvement or change.

Regulatory/policy experts may be helpful in communicating with the relevant regulatory agency (i.e. USDA or FDA) on several issues connected with a recall. This will be particularly true where the plant has been shut down, and the government is placing conditions on its reopening, or is demanding changes to the plant's HACCP plan. Such an expert may help the company make sure that it is in complete regulatory compliance.

products. In the case of an outbreak of foodborne illness among animals, FDA will cooperate and coordinate with FSIS, which has authority over the animals that consume the feed, as the primary investigative agencies.

Both FDA and FSIS are active participants in the investigatory and data-collection programs of the Centers for Disease Control. The agencies also frequently collaborate in other research such as risk analysis for specific pathogens. Thus, in responding to an outbreak of foodborne illness, while they will frequently defer to CDC's expertise in epidemiological investigations, either USDA or FDA will be an active partner in activities ranging from investigating the possible sources of contamination within a manufacturing plant and/or the reason for an outbreak to coordinating activities among agencies and con-

ducting laboratory analysis of both foodstuffs and environmental samples taken from the facility under investigation. If an investigation leads to a product recall or a plant closing, USDA or FDA will help supervise the recall and destruction of product, and help establish protocols for re-opening the facility.

Centers for Disease Control

If a recall is contemplated because of an outbreak of any human foodborne illness, however, regardless of the nature of the product or the contamination, the lead federal agency is usually the Centers for Disease Control (CDC), whose principal mission is protecting the health and safety of people. The group within CDC principally responsible for infectious disease surveillance, researching foodborne illness, and investigating

outbreaks of foodborne illness is the Foodborne Outbreak Response and Surveillance Unit (which itself is part of the National Center for Infectious Disease's Division of Bacterial and Mycotic Diseases (www.cdc.gov/ncidod/dbmd/)), along with the Epidemiological Program Office (www.cdc.gov/epo/) and its Epidemic Intelligence Service (EIS).

CDC maintains and monitors a formidable amount of information relating to pathogens and foodborne illness. CDC personnel communicate regularly with state and local health officials, who report their observations of certain illnesses to CDC. Because it receives and coordinates data gathered from across the country, CDC is often the first to recognize that an outbreak is taking place. Once CDC suspects an outbreak, its mission is to act quickly and aggressively to stop the outbreak and identify its source. Among other things, CDC alerts state and local authorities, collects medical records, and designs initial and follow-up questionnaires for use in tracking the source of the outbreak. CDC personnel also direct on-site investigations of patients' homes and of food processing facilities they believe may be associated with an outbreak. At the same time, CDC uses sophisticated techniques to collect, analyze, and compare samples of bacteria in order to zero in on the source of illness. Although CDC has no authority to shut down facilities or seize products – a power that lies rather with USDA and FDA – it may nonetheless take a lead role in urging a manufacturer to institute a product recall.

For food manufacturers, information provided by CDC can be extremely useful in defending claims resulting from an outbreak investigation and/or product recall. Of course, CDC's mission is protecting public health and safety, not helping a company safeguard its goodwill, or facilitating – or hindering – litigation. (Indeed, by law, CDC employees are not allowed to testify in court regarding its data and conclusions.) However, CDC officials may discuss an investigation with the targeted company if the CDC officials believe that such dialogue will help limit the outbreak or aid in implementing food safety measures that will prevent future outbreaks. And manufacturers can receive information from CDC through the Freedom of Information Act. This information – which can include raw data such as epidemiological field questionnaires or a live copy of the pathogen thought to have caused the outbreak — can be extremely useful in defending claims. In addition, apart from its outbreak investigations, CDC conducts both active and passive surveillance of foodborne illnesses, and its websites are an important source of useful information on issues related to food safety.

Three of CDC's data-gathering networks – FoodNet, NARMS, and PulseNet – offer especially helpful supplemental and background information about pathogens and the diseases they cause: FoodNet, or Foodborne Diseases Active Surveillance Network (www.cdc.gov/foodnet/), is the principal foodborne disease component of CDC's Emerging Infections Program (EIP). It is a collaborative project of the CDC, USDA, FDA and nine EIP sites (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon and Tennessee). FoodNet has expanded each year since its inception in 1995 and now covers about 10% of the U.S. population. FoodNet conducts active surveillance of seven bacterial pathogens (salmonella, shigella, campylobacter, E. coli O157:H7, Listeria monocytogenes, Yersinia enterocolitica, and Vibrio) and two parasites (Cryptosporidium and Cyclospora).

The goals of FoodNet include determining how much foodborne illness results from eating specific foods, estimating the frequency and severity of foodborne diseases in the United States each year and describing the epidemiology of new and emerging foodborne pathogens of bacterial, viral, and parasitic origin. FoodNet investigators actively contact laboratories across the country to gather information on confirmed cases of diarrheal illness (the most common symptom of foodborne disease), survey clinical laboratories to determine their practices and techniques for isolating pathogens, contact physicians to learn how and when they order clinical tests on patients with possible foodborne illness, conduct random population surveys for information about diarrheal illness, and run epidemiological studies of selected pathogens. Isolates of pathogens from the patients in these studies are sent to CDC for further analysis, including molecular subtyping.

NARMS, the National Antimicrobial Resistance Monitoring System for Enteric Bacteria, is a collaboration between CDC, FDA's Center for Veterinary Medicine, and USDA's Food Safety Inspection Service, and is conducted within the framework of FoodNet. NARMS measures the resistance of certain gastrointestinal bacteria (Campylobacter, salmonella, E.coli O157:H7, and Shigella) to antibiotics such as ampicillin and streptomycin. By revealing patterns of resistance, NARMS data may be useful in outbreak investigations. **FP**

Authors: Anton R. Valukas, Jeffrey D. Colman, William A. Von Hoene, Dean N. Panos and Edward F. Malone are partners at Jenner & Block. Julie L. Bentz, Molly J. Moran and Chaka M. Patterson are associates at the Firm. Jenner & Block attorneys have extensive experience in food recalls and food product litigation.