

Product Recalls and Food Safety

A 1996 Texas Department of Health (TDH) survey of public opinion on health department activities showed that 73% of the sample agreed with the statement, "public health means clean water and safe food."¹ The survey also indicated that people do not know exactly what health departments do. This article describes how federal agencies and TDH handle food recalls and why it is important for health professionals in private and public health practice to promptly report foodborne illness to the proper public health authorities.

Recently, federal agencies have initiated numerous recalls of lunch meat and hot dogs contaminated with *Listeria monocytogenes*. In 1998 there were many nationwide recalls of ground beef contaminated with *Esherichia coli* O157:H7. Federal and state agency recall requests are often based on noncompliance with processing, labeling, packaging, and storage regulations. Recalls also result when illness outbreaks are associated with chemical or microbiological contamination of certain food products.

Regulatory Authority

Federal food safety regulation is under the jurisdiction of the United States Food and Drug Administration (FDA) and the US Department of Agriculture, Food Safety and Inspection Service (FSIS). It is guided by the "Good Manufacturing Practices" outlined in the Code of Federal Regulations.² Texas laws governing food safety are found in the Texas Food, Drug, and Cosmetic Act.³ The Texas Department of Health has jurisdiction over product safety in the state.

There is no specific legal authority designated in either the federal or state codes that mandate recalls. However, in spite of the fact that neither FDA, FSIS, nor TDH have authority to *require* companies to recall products, it is extremely rare for a company to refuse to recall a product when presented with documentation of the public health danger associated with that product.

Federal and state laws do give health agencies the authority to shut down food manufacturing and distribution operations and to embargo food storage warehouses until all facilities and operations involved are

compliant with the food safety regulations. Recalls may involve legal proceedings against companies, though not in the majority of situations. If a federal agency or TDH determines that major violations of Good Manufacturing Practices or other legal requirements involve food adulteration or contamination, the agency may pursue an injunction, administrative action, or criminal penalties against the firm.

Identification of Products for Recall

Each year hundreds of food manufacturers voluntarily recall contaminated, adulterated, and misbranded foods and report these recalls to FDA and FSIS. FSIS-regulated product recalls are fewer than FDA recalls (50 to 60 nationwide compared with over 400) but can require more extensive efforts since almost all are for microbiological contamination. Although many FDA recalls are for relatively minor problems (eg, some product labeling errors), some are for problems that can cause illness, injury, or death.

The most regrettable source of identification is through an outbreak of illness linked to a manufactured food product. Investigation and control of foodborne illness outbreaks in Texas usually involve collaborative efforts among TDH Bureau of Food and Drug Safety (BFDS), Infectious Disease Epidemiology and Surveillance Division (IDEAS), and Bureau of Laboratories; the TDH Public Health Regions;

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and local health officials. On occasion local health officials can identify the cause of a foodborne illness outbreak in the community and remove the affected foods without assistance from regional or state staff. Tracebacks often must be conducted to determine the original source of the contaminated food. As a result, additional products that could cause illness are removed from the market.

In Texas, products that should be recalled are also identified during the routine inspections BFDS conducts of over 9,000 food manufacturers statewide. In 1998 BFDS requested that Texas food manufacturers recall a total of 19 products.

Classification of Recalls

Both FDA and FSIS have expert panels that meet routinely to classify each recall. **Class I** recalls are for those foods that pose a significant risk of illness or death. Examples are products contaminated with *Clostridium botulinum*, *E. coli* O157:H7, *Listeria monocytogenes*, *Vibrio parahaemolyticus*, and other significant microbiological hazards. **Class II** recalls may involve the presence of undeclared sulfites, tree nuts, or certain food colors such as Yellow No. 5, which can cause allergic reactions in certain individuals. **Class III** recalls are for lesser hazards, including decomposition, less significant misbranding, or off odor or taste. Although several of the 19 recalls in Texas last year were Class I, for contaminated ground beef, most were Class II, for undeclared colors, tree nuts, or sulfites. In some cases the product sources were out of state.

The Recall Process in Texas

Every time a product is recalled in Texas, BFDS works closely with the FDA's Dallas District recall coordinator, who in turn relays the information to the national FDA headquarters for classification and inclusion on its weekly Enforcement Report. For recalls involving federally inspected products, BFDS works closely with the FSIS office

in Dallas. BFDS personnel then monitor the firm's recall of these products to ensure that all products are removed from distribution and that all customers who received the product are notified. For Class I recalls and many Class II recalls, a press release is issued to notify the public. BFDS works closely with FDA and with the food manufacturer on the wording of press releases and recall notices to ensure that accurate and complete information is disseminated.

For Class I and some Class II recalls, BFDS then advises other TDH offices, including the Public Health Regions, who ensure the information reaches the local health departments. This procedure is also followed for significant FSIS recalls. Class III recalls, which have little affect on public health, are usually handled directly by the manufacturer or wholesaler. At TDH, recall information comes directly to the state epidemiologist, the Bureau of Communicable Disease Control, IDEAS, and the Bureau of Food and Drug Safety by fax and/or e-mail. The more significant recalls are posted on the TDH website and distributed by e-mail on the Foodborne Illness List ("FBIList"), an e-mail distribution system for health departments, physicians, and researchers with an interest in food safety issues.

Many companies notify FDA of their recalls, which are then classified by FDA and placed on the weekly Enforcement Report. Via fax and e-mail, FDA alerts all states possibly affected by a recall, especially if some of the product may still be on the retail shelves or in consumer's hands. In many instances the product has already been removed from the marketplace or in some cases has never reached the consumer.

Both FDA and FSIS have field staff who conduct "recall effectiveness checks" to ensure that recalled products that make their way to the marketplace are properly removed and either returned to the recalling firm or destroyed. BFDS and

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its federal counterparts often work together to ensure that a food manufacturer achieves compliance. Recently FSIS notified BFDS staff of a food warehouse with a severe rodent problem. Because the infestation was so extensive, TDH placed the entire warehouse under detention to eliminate the risk that contaminated foods would be distributed.

The lag time between the announcement of a recall and subsequent identification of exactly *who* received the products throughout the distribution chain can take a week or longer, depending upon how many links there are in the chain. Products leaving a manufacturer may be shipped to a central distribution center, then to wholesalers, then to regional/independent distributors, then to a grocery chain's warehouse facilities --all before they get to the stores. Therefore, tracing product distribution from the source to the consumer requires contacting all distribution sites and reviewing all records.

To expeditiously remove adulterated and misbranded products, health authorities must have access to accurate and complete manufacturing and distribution records. TDH is authorized to review and copy many of these records, but industry commitment to adequate record-keeping and cooperation in the sharing of these records with health authorities is essential to the recall process and the subsequent effectiveness checks.

Gaps in the System

Because the number of FDA and FSIS field staff is limited, these agencies typically do effectiveness checks on only 10% or less of product recalls. BFDS policy is that a 10% rate of effectiveness checks on all Class I and some Class II recalls is unacceptable. Consequently, BFDS staff and even local health personnel assist with the effectiveness checks on these types of recalls. For example, BFDS and local health officials helped FSIS conduct effectiveness checks during the 1998 Hudson Meats recall of 25 million pounds of ground beef

contaminated with *E. coli* O157:H7. As a result, health officials visited over 400 retail establishments in Texas to ensure removal of the recalled product.

Inadequate communication of information among agencies is a major problem in the recall process. Some communication problems stem from conflicting opinions on whether the release of specific food manufacturing/distribution information is legally required or prohibited. The Freedom of Information Act describes what types of information must be released to anyone upon request. Proprietary information is exempt. Individuals and companies who are legally required to give information to the government are also protected by state and federal laws that designate some of this information as proprietary. Concerns federal agencies have over releasing proprietary information occasionally result in state and local agencies being denied distribution information they feel is essential to effective removal of all recalled products from distribution.

Even when public health agencies try to provide recall notification to others, they often contact the wrong person at an agency, or even the wrong agency itself. State agencies cannot rely on the FDA Enforcement Report for timely information because some recalls are not included in this weekly report until months have passed. For example, an April 1998 recall of underprocessed picante sauce was not announced in the Enforcement Report until July 1998. This delay initially caused BFDS concern since the manufacturing plant was in Texas. Fortunately, the problem was detected before the product was shipped to retailers.

These mistakes can cause considerable anguish for state and local health agencies, especially when the appropriate health officials learn of recalls after the media do. Fortunately, numerous TDH personnel are on the notification lists for both FDA and FSIS. Therefore, although

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Texas health officials sometimes have difficulty obtaining complete distribution information quickly, they are less likely to have this problem than are officials in some other states.

Bridging the Gaps

The Association of Food and Drug Officials (AFDO)—a 102-year-old organization of federal, state, and local food and drug safety regulatory officials—has a long history of involvement in efforts to improve the recall system. AFDO recently developed a blueprint describing what the proposed functions of the various food and drug safety agencies should be and how the agencies should interact. Many BFDS personnel are members and officers of AFDO.

The President's Food Safety Initiative, begun in early 1998, includes efforts to rectify gaps or overlaps in the regulatory system and lapses in interagency communication. FDA, USDA, CDC, and the Environmental Protection Agency have begun efforts to bring federal, state, and local officials together to build a better system. With the AFDO blueprint as a guideline, six national workgroups have been working since December 1998 on the following goals:

- identify the gaps and overlaps in the current food safety system
- determine what each agency's roles and responsibilities should be
- develop a national communications system that will consolidate data on all foodborne illness outbreaks, laboratory sample results, and inspections
- develop minimum standards for federal, state and local agencies—including minimum requirements for inspectors, laboratorians, and epidemiologists.

Three individuals from BFDS are involved with these workgroups. Also, AFDO members will soon meet with FDA and FSIS officials to evaluate current recall procedures to determine what revisions, if any, can be made to ensure expedient removal of contaminated foods from the marketplace.

Conclusion

The public expects to be adequately protected from foods capable of causing illness or death. The recall system in the United States is a good one, but improvements can and should be made to ensure more expedient recalls and faster public notification of how to identify the recalled products and their sources. Protecting the public from foodborne illness is a cooperative effort among all involved. The sooner a food product is identified as a source of illness, the quicker the recall can take place. Therefore, it is essential that physicians and other medical professionals know how to recognize foodborne illnesses and that they promptly report them to the appropriate public health authorities.



Prepared by Dan Sowards, Director, Manufactured Foods Division, TDH Bureau of Food and Drug Safety.

References

1. Texas Department of Health. Perceptions of Public Health and the Texas Department of Health. Austin: TDH, December 1996.
2. 21 CFR Part 110.
3. Vernon's Tex Code Ann, Tex Health & Safety Code § 431.001.

To obtain information on recalls involving products under the jurisdiction of USDA's Food Safety and Inspection Service (most meat and poultry products), call (800) 535-4555. For information on recalls of FDA-regulated products, call (800) 332-4010. Contact the TDH Manufactured Foods Division by calling (512) 719-0243. Information is also available at the following websites:

<http://www.fsis.usda.gov>

<http://www.fda.gov/>

<http://www.findlaw.com/11stategov/tx/txst.html>

<http://www.tdh.state.tx.us/ideas/hottopic/hottop.htm>

***Disease Prevention News* Introduces Editorial Board**

The mission of *Disease Prevention News (DPN)* is to protect and promote the health of the people of this state by providing public and private health professionals with current, accurate, and practical information about adverse public health conditions in Texas. To further *DPN's* continuing efforts to be the best state public health newsletter in the country, the Associateship for Disease Control and Prevention established the first *Disease Prevention News* Editorial Board December 3, 1998. Their terms began January 25, 1999.

The *DPN* Editorial Board reviews all articles containing technical public

health or medical information to assure that they reflect accurate, high quality research and reporting methods.

The following health professionals at the Texas Department of Health were chosen to serve as board members not only because they have remarkable accomplishments in their specific fields of scientific expertise, but also because they have extensive experience writing, reviewing, and editing articles for professional scientific journals. Several of the *DPN* Editorial Board members also serve on the editorial boards of scientific journals and in various professional health associations.

Disease Prevention News Editorial Board

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Diseases in Nature Conference

The Texas Department of Health (TDH) Zoonosis Control Division and the University of Texas Health Center at Tyler will host the 49th Annual Southwest Conference on Diseases in Nature Transmissible to Man. The conference will be held at the Sheraton Tyler Hotel May 25 & 26, 1999.

Scheduled topics include rabies, plague, brucellosis, tuberculosis, spargosis, cryptosporidiosis, vibriosis, cestodes, *E. coli*, and tick-borne diseases. The speaker for the JV Irons Luncheon is LTC Ted Cieslak, MD, from the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. Dr. Cieslak's presentation is titled, "A Primer on Biological Terrorism."

Continuing education credits are available for physicians, veterinarians, veterinary technicians, and animal control officers. Type I Continuing Nursing Education credits have been requested. *To obtain further information and request registration materials, contact Angela Hopkins in the TDH Region 4 Zoonosis Control Division: (903) 533-5243, angela.hopkins@tdh.state.tx.us*

Bunnies can be hazardous to your health...

Around this time of year, parents and day care centers often buy bunnies, chicks, and ducklings for children. The Centers for Disease Control and Prevention discourages this practice because of the risk of exposure to salmonella infection. Health professionals who

treat patients for salmonellosis, particularly during the post-Easter season, should determine whether they contracted the disease from an animal or reptile and provide them with the following information on prevention.

Play it safe!



- Avoid contact with feces from bunnies, chicks, ducklings, hedgehogs, and reptiles (turtles, lizards, and snakes). Do not allow these animals to roam freely in the home or day care center.
- Carefully wash your hands with soap and water after handling any of these animals and after touching anything that had contact with them. (Wash children's hands if they can't.)
- Keep all animals away from food preparation areas.

...and so can the family dog.

A recent newspaper article described a horrifying fatal attack by a family's pet dog. The grandmother of an 11-month-old child saw their dog maul the boy in an attack so sudden and violent she could not prevent it. As is common, family members never imagined their dog would hurt the boy. Unfortunately, attacks like this occur much more often than people realize.

The main victims of fatal dog bites are the very young and the very old—people least able to protect themselves. Most of the time, the victims know the dog. It is often the family pet. The case-fatality rate for infants bitten by dogs is over 300 times the rate for adults 35 to 45 years of age. In many cases, the infant was killed while in a crib.

*Bite Prevention
Week Begins
May 16*

Dogs of all sizes and breeds attack children, often for no obvious reason. In a small West Texas town, a 6-week-old puppy mauled a 3-week-old baby while the father was asleep in the home.

Dogs bites are a major public health problem, especially for children. Public health professionals can help prevent this problem by sharing these guidelines with parents:

Fido is not "baby's best friend"!



- **Never, under any circumstances, leave any dog** unsupervised around a baby, young child, or elderly person—no matter how well known, friendly, trustworthy, or small that dog may be. A parent sleeping in the same room with a child, even one in a crib, does not constitute supervision.
- Lavish extra attention on the dog when a new baby is brought home. Include the dog in family activities, rather than isolating it in the back yard.
- Help the dog feel good about the baby by petting it while holding the baby.

For more information on dog bites, including free educational brochures and posters, contact the Texas Department of Health Zoonosis Control Division at (512) 458-7255.

Bimonthly Statistical Summary of Selected Reportable Diseases

Jan/Feb 1999

Selected Diseases/Conditions	HHSC Region											Selected Texas Counties								This Period		Cumulative[1]	
	1	2	3	4	5	6	7	8	9	10	11	Bexar	Dallas	El Paso	Harris	Hidalgo	Nueces	Tarrant	Travis	1998	1999	1998	1999
Sexually Transmitted Diseases[2]																							
Syphilis, primary and secondary	0	0	27	1	9	14	8	7	0	3	1	6	24	3	11	0	1	3	2	50	70	50	70
Congenital Syphilis	0	0	1	0	0	11	0	0	0	1	0	0	0	1	11	0	0	1	0	19	13	19	13
Resistant Neisseria gonorrhoeae	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Enteric Diseases																							
Salmonellosis	14	7	23	8	5	1	16	7	3	2	20	2	19	2	0	5	3	1	9	200	108	200	108
Shigellosis	24	15	35	3	4	2	12	13	2	2	23	4	27	2	0	4	7	2	7	423	138	423	138
Hepatitis A	17	13	37	2	5	3	18	16	3	0	39	7	24	0	1	6	1	2	13	669	153	669	153
Campylobacteriosis	2	2	8	2	3	6	10	11	1	1	10	0	5	1	2	0	4	1	5	127	62	127	62
Bacterial Infections																							
H. influenzae type b, invasive	0	0	1	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	2	2	2	2
Meningococcal, invasive	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	52	2	52	2
Lyme disease	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	0
Vibrio species	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	15
Other Conditions																							
AIDS[4]	2	7	77	17	11	101	25	20	7	14	32	17	45	14	88	8	6	21	8	793	349	4232	349
Hepatitis B	0	0	6	0	0	0	0	0	0	0	2	0	3	0	0	1	0	2	0	265	8	265	8
Adult elevated blood lead levels	0	0	42	0	0	5	0	1	0	9	0	0	2	1	0	0	0	0	0	229	57	229	57
Animal rabies - total	0	2	5	3	0	2	15	6	11	0	4	0	0	0	0	0	0	0	1	29	48	29	48
Animal rabies - dogs and cats	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	2	0	2
Tuberculosis Disease[2]																							
Children (0-14 years)	1	0	1	0	0	5	0	0	0	0	0	0	0	0	5	0	0	0	0	19	7	19	7
Adults (>14 years)	1	2	18	7	2	66	6	1	3	3	10	0	12	3	60	4	3	2	3	188	119	188	119
Injuries[2]																							
Spinal Cord Injuries (5)	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1

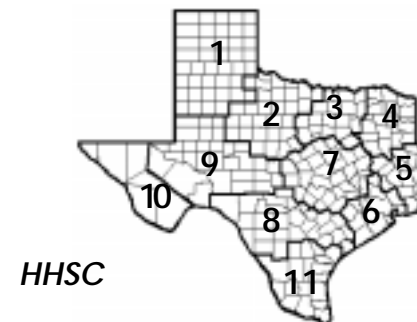
1. Cumulative to this month. 2. Data for the STD's, Tuberculosis, and spinal cord injuries are provided by date of report, rather than date of onset. 3. Voluntary reporting. 4. AIDS totals include reported cases from Texas Department of Corrections, which are not included in the regional and county totals. 5. 6 reports were missing PHR identification *Data incomplete.

Call 1-800-705-8868 to report

1997 POPULATION ESTIMATES

HHSC REGIONS							
1	764,497	4	5,104,222	7	4,404,421	10	743,763
2	533,392	5	687,951	8	2,017,179	11	1,607,762
3	5,104,222	6	4,404,421	9	555,363		
STATEWIDE TOTAL					19,307,387		

SELECTED COUNTIES			
Bexar	1,324,190	Hidalgo	492,619
Dallas	2,099,876	Nueces	311,154
El Paso	715,807	Tarrant	1,427,664
Harris	3,163,342	Travis	632,922





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The electronic versions of *Disease Prevention News* are available at the following locations:
<http://www.tdh.state.tx.us/phpep/dpnhome.htm>
 TDH Healthy Texans BBS: (800) 858-5833

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Vaccine-Preventable Disease Update Reported Cases with Onset From 1/1/99-2/28/99

Condition	County	Number of Cases	Date of Onset	Condition	County	Date of Cases	Date of Onset
H Flu Infect	Bexar	1	2/16	Mumps	Gillespie	1	1/28
	Collin	1	1/2			1	1/30
Hep B	Cameron	1	1/6			1	2/1
	Dallas	2	1/5	Pertussis	Travis	1	1/28
		1	1/15		El Paso	1	1/2
	Hidalgo	1	1/3		Jefferson	2	1/7
	Palo Pinto	1	1/6		Lubbock	1	1/4
Tarrant	1	1/7			2	1/12	
			1/13			1	1/13
Measles	Travis	2	1/8		Tarrant	1	1/3
Mumps	Bell	1	1/20			1	1/8
	Dallas	1	1/8			1	1/13
		1	1/21		Wharton	1	1/10
	Gillespie	1	1/8				
YTD	H Flu	Hep B	Measles	Mumps	Pertussis		
	2	8	2	8	10		