

The FDA Top Ten: The Riskiest Foods Regulated by the U.S. Food and Drug Administration

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Introduction

In recent years, U.S. consumers have faced outbreak after outbreak of contaminated food. A complex, globalized food system, archaic food-safety laws, and the rise of large-scale production and processing have combined to create a perfect storm of unsafe food. Unfortunately, the hazards now come from all areas of the food supply: not only high-risk products, like meat and dairy, but also the must-eat components of a healthy diet, like fruits and vegetables.

This report identifies the Top Ten riskiest foods regulated by the Food and Drug Administration (FDA) (the “FDA Top Ten”), the agency responsible for all produce, seafood, egg, and dairy products. Together, these ten foods alone account for nearly 40 percent of all foodborne outbreaks linked to FDA-regulated foods since 1990, as tracked by the Center for Science in the Public Interest (CSPI) using data from the Centers for Disease Control and Prevention (CDC). Over 1500 separate, definable outbreaks were linked to the FDA Top Ten, with almost 50,000 illnesses reported, ranging from temporary gastrointestinal distress to long-term disability and death.

While this data represents the best data available from the CDC, the hurdles to accurate outbreak tracking are many: people rarely see a doctor to treat foodborne illness; those who do are often treated without the lab testing needed to document the cause of the illness (the pathogen involved); illnesses need to be investigated by state health officials in order to be identified as part of an outbreak; states often lack the resources to conduct thorough investigations to identify the food involved; and finally outbreaks that are investigated must be reported to CDC.

Thus, the outbreaks included here represent only the tip of the iceberg of foodborne illness. In fact, in 1999 the CDC estimated that for each case of salmonellosis that is clinically diagnosed and reported to health officials, another 38 cases were unreported.¹ All told, unsafe food causes tens of millions of illnesses, hundreds of thousands of hospitalizations, and thousands of deaths every year in the United States.

¹ Mead P, Slutsker L, Dietz V. Food-Related Illness and Death in the United States. Centers for Disease Control and Prevention, *Emerging Infectious Diseases*, Vol. 5, No. 5, 1999.

Findings

Many of the FDA Top Ten are, unfortunately, some of the healthiest and most popular foods consumed in the U.S. And while some are already considered “high risk” foods, others are surprising. The FDA Top Ten riskiest foods regulated by FDA are:

1. **Leafy Greens: 363 outbreaks involving 13,568 reported cases of illness**
2. **Eggs: 352 outbreaks involving 11,163 reported cases of illness**
3. **Tuna: 268 outbreaks involving 2,341 reported cases of illness**
4. **Oysters: 132 outbreaks involving 3,409 reported cases of illness**
5. **Potatoes: 108 outbreaks involving 3,659 reported cases of illness**
6. **Cheese: 83 outbreaks involving 2,761 reported cases of illness**
7. **Ice Cream: 74 outbreaks involving 2,594 reported cases of illness**
8. **Tomatoes: 31 outbreaks involving 3,292 reported cases of illness**
9. **Sprouts: 31 outbreaks involving 2,022 reported cases of illness**
10. **Berries: 25 outbreaks involving 3,397 reported cases of illness**

Illnesses caused by these ten foods may be as minor as stomach cramps and diarrhea for a day or two, or as serious as kidney failure or death. Notably, pathogens most commonly associated with meat and poultry—such as *Salmonella*² and *E. coli* O157:H7³—also have been repeatedly linked to these food items. In fact, *Salmonella* was identified as the cause in 33 percent of the outbreaks from the FDA Top Ten. Other pathogens causing the outbreaks associated with these foods include *Campylobacter*, Scombrototoxin, Norovirus, and *Vibrio*.⁴

The FDA Top Ten in detail

LEAFY GREENS. Can salad really be bad for you? While nutritionists shudder at the thought, it is sadly the case that nutritious greens can also be highly contaminated with pathogens. Overall, CSPI identified 363 separate outbreaks linked to leafy greens, making them the number one entry in the FDA Top Ten. Salads and other food items containing leafy greens -- iceberg lettuce, romaine lettuce, leaf lettuce,

² *Salmonella* bacteria are found worldwide in warm- and cold-blooded animals, in humans, and in nonliving habitats. They cause illnesses, such as typhoid fever, paratyphoid fever, and the foodborne illness salmonellosis, in humans and are associated with disease in some animal species. *Salmonella* Typhimurium and *Salmonella* Enteritidis are the most common in the United States.

³ *Escherichia coli* (abbreviated as *E. coli*) are a large and diverse group of bacteria. *E. coli* O157:H7 is found in the guts of ruminant animals, including cattle, goats, sheep, deer, and elk. Infection with *E. coli* O157:H7 can cause severe stomach cramps, diarrhea, and vomiting. Around 5–10% of those who are diagnosed with STEC infection develop a life-threatening complication known as hemolytic uremic syndrome (HUS).

⁴ *Vibrio* bacteria—which occur naturally in warm salt water—belong to the same family of illnesses as Cholera. The two most common *Vibrio* strains in the United States are *Vibrio vulnificus* and *Vibrio Parahaemolyticus*.

butter lettuce, baby leaf lettuce (immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula or chard⁵ — account for 24 percent of all of the outbreaks linked to the FDA Top Ten. Those outbreaks sickened over 13,568 people who were reported to have become ill — almost 30 percent of all the reported illnesses caused by the FDA Top Ten.

In 2006, leafy greens hit the national radar screen as a high-risk food when bagged spinach contaminated with *E. coli* O157:H7 caused several deaths and hundreds of illnesses. That same year, deadly *E. coli* O157:H7 appeared in two other outbreaks linked to leafy greens. Though produce companies have voluntarily increased their vigilance, *E. coli* O157:H7 is still cropping up in these products, and accounts for 10 percent of all outbreaks in leafy greens. Another pathogen appearing frequently in leafy greens is Norovirus, which is commonly spread by the unwashed hands of an ill handler or consumer. This pathogen was linked to 64 percent of the outbreaks in leafy greens. *Salmonella* was responsible for nearly 10 percent of the outbreaks.

Outbreaks from leafy greens occur anywhere these popular food items are consumed. Contamination may be present from production and processing, or may occur through improper handling and preparation, such as inadequate handwashing and cross-contamination of cutting boards and other equipment. In restaurants, any of these problems in only a single food item can affect multiple patrons. For example, an outbreak of *E. coli* O157:H7 in 2006 began at Taco John's, a popular Iowa eatery. Over 80 people were sickened—including two who developed potentially deadly hemolytic uremic syndrome—from contaminated iceberg lettuce from California's Central Valley. Overall, restaurant outbreaks accounted for almost 240 outbreaks from leafy greens. Private homes accounted for another 24 outbreaks. Notably, outbreaks in school settings — from elementary to college — tended to be quite large -- averaging 89 reported illnesses per outbreak — though luckily not very frequent.

Leafy greens can become initially contaminated on the farm through contact with wild animals, manure, contaminated water, or poor handling practices during harvest. Once they are contaminated, leafy greens can support, grow, and spread pathogens until consumed. Chlorine washes and other post-harvest treatments can help reduce cross contamination between lots, but they don't make contaminated products truly safe to eat. In fact, bacteria can inhabit the washing systems used in making pre-washed bagged lettuce, transferring dangerous bacteria from one contaminated lot to the next, with the potential of effecting a full day's production.

EGGS. Often described as a perfect breakfast food, eggs are unfortunately among the worst of the FDA Top Ten regulated by FDA. Overall, CSPI found 352 outbreaks linked to eggs and egg products. The overwhelming majority of illnesses from eggs

⁵ Leafy greens do not include herbs such as cilantro and parsley.

are associated with *Salmonella*, which sickened over 11,000 people whose illnesses were reported from 1990 to 2006.

Most types of *Salmonella* live in the intestinal tracts of animals and birds and are transmitted to humans when animal feces contaminate a food item of animal origin (such as eggs). Regulations for cleaning and inspecting eggs were implemented in the 1970s and have reduced salmonellosis caused by external fecal contamination of egg shells. However, *Salmonella enteritidis*, the most prevalent type of *Salmonella* in eggs today, infects the ovaries of otherwise healthy hens and contaminates the eggs before the shells are formed. Notably, final regulations that require the adoption of controls aimed at minimizing *Salmonella enteritidis* in egg production were issued in July 2009 (and will become effective in 2010 or 2012, depending on producer size),⁶ after over a decade of inaction by the federal government.

Half of all egg outbreaks occurred from restaurants and other food establishments. While proper egg handling and cooking should destroy most pathogens, serving eggs raw or “runny,” or leaving egg dishes at improper holding temperatures (such as on a breakfast buffet) can allow the bacteria to multiply.

Notably, the largest egg outbreaks occurred in prisons, with an average of 143 people reported sick in each outbreak. Catered events also had large outbreaks, averaging almost 60 people reported to have been sickened.

TUNA.⁷ While a step down from leafy greens and eggs, tuna was linked to 268 outbreaks in the FDA Top Ten. Some consumers may be familiar with warnings about tuna and methylmercury, but the pathogens that show up in the outbreak data are rarely discussed when it comes to this fish.

Scombroid, the illness caused by scombrototoxin, was by far the most common cause of illness related to tuna dishes, affecting over 2300 people who were reported to have been sickened to authorities, according to CSPI’s Outbreak Alert! database. Fresh fish decay quickly after being caught and, if stored above 60° F, begin to release natural toxins that are dangerous for humans. Adequate refrigeration and handling can slow this spoilage, but the toxin cannot be destroyed by cooking, freezing, smoking, curing, or canning. Symptoms of scombroid poisoning can include skin flushing, headaches, abdominal cramps, nausea, diarrhea, palpitations, and loss of vision.

Notably, scombroid illnesses frequently involve fresh product. These products are subject to HACCP (Hazard Analysis Critical Control Points), a safety system in which hazards are identified and steps taken to control them. As a naturally-occurring toxin, scombrototoxin is foreseeable and should be properly addressed by HACCP.

⁶ See 74 FR 33030 (July 9, 2009).

⁷ CDC does not distinguish between foodborne-illness outbreaks from fresh tuna versus canned tuna products.

Tuna's appearance in the FDA Top Ten suggests that FDA's seafood program needs to more effectively address this hazard.

In addition to Scombrototoxin, Norovirus and *Salmonella* caused illnesses related to tuna consumption, affecting nearly 1000 people. Over 65 percent of outbreaks linked to tuna occurred in restaurants.

OYSTERS. Often considered an expensive delicacy, contaminated oysters can ruin more than just a gourmet dinner. The fourth entry in the FDA Top Ten is responsible for almost 2000 people who were reported to have become ill from tainted oysters. Not surprisingly, the majority of outbreaks from oysters occurred in restaurants.

Illnesses from oysters occur primarily from two sources: Norovirus and *Vibrio*. Although Norovirus in other foods is usually associated with improper handling during harvest or preparation, oysters can actually be harvested from *waters* contaminated with Norovirus. When served raw or undercooked, those oysters can cause gastroenteritis, an inflammation of the stomach and small or large intestines.

Surprisingly, those consumers infected with Norovirus may have avoided the more dangerous of the two pathogens found in oysters -- *Vibrio*. This hazard is a type of bacterium in the same family as cholera. The most common strains in the U.S. are *Vulnificus* and *Parahaemolyticus*, both of which can cause severe disease. In immuno-compromised persons, particularly those with chronic liver disease, *V. vulnificus* can infect the bloodstream, causing a severe and life-threatening illness characterized by fever and chills, decreased blood pressure (septic shock), and blistering skin lesions. *V. vulnificus* bloodstream infections, called septicemia, are fatal about 50 percent of the time.

POTATOES. One of America's most popular and versatile food items appears in the middle of the FDA Top Ten list. Potatoes, often in the form of potato salad, were linked to 108 outbreaks, with more than 3600 consumers reported to have been sickened by spuds since 1990.

Potatoes are grown in the soil, but they are always cooked before consuming. Outbreaks are linked to dishes, like potato salad, that can contain many ingredients and also a broad range of pathogens. *Salmonella* is most common, associated with almost 30 percent of potato outbreaks. *E. coli* also appears in the potato category, accounting for 6 potato outbreaks. Normally found in animal feces, the presence of *Salmonella* and *E. coli* in potato dishes could indicate cross contamination from the raw to the cooked ingredients or possibly from raw meat or poultry during handling and preparation.

Shigella and *Listeria* also appear in outbreaks associated with potatoes. *Shigella* is easily transmitted from an infected person to a food product, and thus may indicate

improper handling during food preparation. *Listeria* is stubborn bacteria that can live on deli counters and in other kitchen areas, and is often associated with cold deli salads.

More than forty percent of potato outbreaks were linked to foods prepared in restaurants and food establishments (including grocery stores and delis).

CHEESE.⁸ A perennial favorite among consumers for its variety and versatility—hard, soft, mild, sharp, melted and sliced—cheese products were linked to 83 outbreaks that sickened thousands of consumers since 1990, making it one of the FDA Top Ten. *Salmonella* was the most common hazard among cheese products.

Cheese can become contaminated with pathogens during the initial phases of production (curdling, molding, and salting), or later during processing. Most cheeses are now made with pasteurized milk, lowering the risk of contamination with milk-borne pathogens. However, as recently as August 2009, California officials warned consumers about eating Latin American-style cheeses (such as *queso fresco*, *queso Oaxaca*, and others), which may be made by unlicensed manufacturers using unpasteurized milk that could contain harmful bacteria.

Pregnant women should be particularly cautious about consumption of soft cheeses (such as feta, Brie, Camembert, blue-veined, and Mexican-style cheese), which can carry *Listeria*. Listeriosis infection can cause miscarriage, often without the mother experiencing any symptoms. Linked to at least four outbreaks from cheese since 1990, listeriosis is vastly underreported, since overt symptoms of infection can be mild in those who are not particularly at risk. Those most at risk include people who are immunocompromised by pregnancy, another underlying health condition, or treatments like chemotherapy. For the elderly, however, *Listeria* can cause severe illnesses, with high rates of hospitalization and death. For high-risk consumers, foods likely to carry *Listeria*, like soft cheeses and deli salads, should be avoided or heated before consuming.

Outbreaks from cheese products occur most frequently in private homes.

ICE CREAM. Can your favorite cold treat really make you sick? Unfortunately, numerous outbreaks documented in the Outbreak Alert! database show that these scoops can occasionally carry a load of dangerous bacteria. Whether served with sprinkles or jimmies, in a cone or a cup, frozen treats have caused nearly 75 outbreaks from hazards like *Salmonella* and *Staphylococcus* since 1990.

The largest ice-cream outbreak in history occurred in 1994, when a popular ice cream manufacturer used the same truck to haul raw, unpasteurized eggs and pasteurized ice cream premix. Contaminated with *Salmonella* en route to the plant,

⁸ CDC does not distinguish between types of cheeses (e.g. cheeses made with raw milk and those that are aged or fresh).

the premix was not pasteurized again before being incorporated into ice cream products. The result: thousands of people sickened in 41 states.

Soft ice cream can be a particular hazard to pregnant women and others who are more susceptible to listeriosis. A particularly hardy bacteria, *Listeria* can survive on metal surfaces—such as the interior of soft ice cream machines—and may contaminate batch after batch of products.

Almost half of all ice-cream outbreaks contained in CSPI's database occurred in private homes. This is most likely due to the use of undercooked eggs in homemade ice cream.

TOMATOES. Reds, rounds, Romas, and grapes: a favorite addition to salads, tomatoes have unfortunately been repeatedly linked to foodborne illness. In 2005 and 2006, for example, tomatoes were implicated in four large multistate outbreaks of *Salmonella*, sickening hundreds of people across the country. Although tomatoes may have been wrongly implicated in a sweeping 2008 outbreak (later linked to fresh jalapeno and Serrano peppers), tomatoes have caused at least 31 identified outbreaks since 1990.

The most common hazard associated with tomatoes is *Salmonella*, which accounted for over half of the reported outbreaks. *Salmonella* can enter tomato plants through roots or flowers and can enter the tomato fruit through small cracks in the skin, the stem scar, or the plant itself. Once inside, destruction of *Salmonella* without cooking the tomato is very difficult. Norovirus was the second most common hazard.

Restaurants were responsible for 70 percent of all illnesses associated with tomatoes.

SPROUTS. The germinating form of seeds and beans, sprouts have become a common food item in grocery stores, salad bars, and Asian dishes. As the popularity of sprouts increases, however, so does the potential for sprout-related illnesses.

Raw and lightly cooked sprouts have been recognized as a source of foodborne illness in the U.S. since the 1990s. Since 1999, CDC and FDA have recommended that persons at high risk for complications of infection with *Salmonella* and *E. coli* O157:H7, such as the elderly, young children, and those with compromised immune systems, not eat raw sprouts. Although FDA has provided guidance to sprout producers to enhance the safety of sprout products, these commodities are still causing problems. Number nine of the FDA Top Ten, sprouts have been linked to at least 31 outbreaks since 1990.

The most likely source of sprout contamination is the seeds that are used to grow the sprouts. Seeds may become contaminated in the field or during storage, and the warm and humid conditions required to grow sprouts are ideal for the rapid growth

of bacteria. Improper handling and poor hygiene in sprout production have also caused some sprout-related outbreaks of foodborne illness in the past.

Many different serotypes (strains) of *Salmonella* have been implicated in sprout outbreaks, as well as *E. coli*. Twenty-five of the reported outbreaks since 1990 have been linked to *Salmonella*, and six others to *E. coli*.

Notably, FDA has been encouraged to mandate consumer warning labels for sprouts. These labels would warn high-risk consumers about the dangers of raw sprout consumption. While similar warnings exist for other high-risk foods (such as unpasteurized juice and raw oysters), FDA has not moved forward to mandate sprout warnings.

BERRIES. The last entry on the FDA Top Ten list may also be the sweetest. Strawberries, raspberries, blackberries, and other berry products have caused 25 outbreaks with more than 3300 illnesses since 1990.

In 1997, over 2.6 million pounds of contaminated strawberries were recalled after thousands of students across several states reported illnesses from eating frozen strawberries in their school lunches. Hepatitis A was the culprit, and contamination may have occurred through an infected worker at a farm in Baja California, Mexico. That same year, raspberries imported from Guatemala and Chile were implicated in an outbreak of *Cyclospora* across five states.

Most of these illnesses, affecting 2,700 consumers, were *Cyclospora* in berries. The resulting infection is a parasitic illness of the intestines, which can cause severe diarrhea, dehydration, and stomach cramps. Importantly, the illness doesn't resolve without antibiotics, thus requiring a trip to the doctor.

Conclusion

Reported outbreaks from the Top Ten riskiest foods in this report represent the tip of the iceberg. Millions of consumers are being made ill, hundreds of thousands hospitalized and thousands are dying each year from preventable foodborne illnesses. Unfortunately, FDA is saddled with outdated laws, and lacks the authority, tools and resources to fight unsafe food. Congress is working on legislation that makes much-needed changes to bring our food safety system into the 21st century.

Legislation currently being considered in Congress would create a modern food safety program at FDA. It would ensure food processors design and implement food safety plans, provide specific safety standards food growers would have to meet, and require FDA to visit high-risk plants every 12 months or less, and most other facilities every 3-4 years. The bills also put new safeguards in place for imported

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foods, making importers ensure that foreign food meets the same high safety standards as domestically grown and processed food.

These bills strive to give consumers farm-to-fork protection. But Congress needs to take action. The House of Representatives passed H.R. 2749, the Food Safety Enhancement Act, on July 30, 2009. The Senate now needs to pass S. 510, the FDA Food Safety Modernization Act. And Congress should complete its critical work on food safety legislation before the end of this year. Two years ago, Congress expressed its commitment to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission in the Food and Drug Administration Amendments Act of 2007. It is time to move forward with strong public health oriented legislation to reduce foodborne illnesses and outbreaks by focusing on prevention, not reaction.

DRAFT

Methodology

CSPI maintains a database of foodborne illness outbreaks, compiled largely from the Center for Disease Control and Prevention's (CDC) annual outbreak line listings. Additional outbreaks are obtained from scientific articles, federal government publications, state health department postings, and newspaper reports verified by public health officials; data from these additional sources constitute about 5 percent of the database.

Outbreaks are only included in the CSPI database if they meet the CDC's definition of an outbreak: when two or more people have consumed the same contaminated food and come down with the same illness. Also, each outbreak must have an identified food vehicle and pathogen and must have occurred in the U.S. or its territories. *Excluded* from the CSPI database are sporadic cases of foodborne illness (individual illnesses not linked to an outbreak, such as an illness in a private home from a consumer failing to wash off a cutting board used for raw poultry), outbreaks with no identifiable etiology (i.e. no known bacterial or other cause of disease), those not known to have been triggered by a specific food, and waterborne outbreaks. The majority of outbreaks reported to CDC do not have both an identified food *and* an identified pathogen. In the years analyzed for this report, 56 percent to 73 percent of all outbreaks reported to CDC have no known etiology or food vehicle, and are therefore not included in CSPI's database.

For this report, CSPI analyzed only those foodborne illness outbreaks that have been definitively linked to FDA-regulated products between 1990 and 2006.