Appendix

Product Liability Law As It Applies to Foodborne Illness

The Legal Process

A person affected by foodborne illness who believes he or she can identify the injurer (i.e., the party responsible for the foodborne illness) can attempt to obtain compensation for his or her costs of the illness by directly contacting the injurer, contacting the injurer's insurer, consulting an attorney about pursuing litigation, or some combination of these actions (Hensler et al., 1991). A claim is any effort, including the filing of a lawsuit, by an individual or group to obtain compensation, directly or through an attorney, for injuries or illnesses suffered. This appendix provides some background on U.S. product liability law as it relates to foodborne illness, a type of personal injury.

Most people pursuing foodborne illness litigation (plaintiffs) hire attorneys as the first step, but the formal litigation process begins once a document called a complaint is filed in a court, describing the illness, citing laws that may have been violated, and identifying one or more parties or defendants allegedly responsible for the illness.

- Plaintiffs are generally individuals seeking compensation for their foodborne illness but may also include parents on behalf of dependent children, guardians on behalf of legally incompetent individuals, and estates seeking monetary damages in cases of wrongful death. Plaintiffs may also include food companies who sue suppliers or others in the food distribution chain for loss of reputation and goodwill, loss of profits, and other damages.
- *Defendants* are usually firms that produce, process, distribute, or sell food products although they may occasionally include individual proprietors, employees such as food servers, or even hosts of informal meals or other events where food was served.¹ Almost all firms in the food industry have some form of insurance protection against a foodborne illness claim (Clark, 2000). When one of these firms is sued, the insurance company provides a legal defense at the insurer's cost

and pays any resultant settlement or judgment (Clark, 2000).² (For simplicity here, we use the term "firms" to include both defendants and their insurers.)

Comprehensive data on the proportion of foodborne illness claims that become lawsuits or the proportion of foodborne illness lawsuits that reach different stages of the litigation process are unavailable. However, what is clear is that most of the 76 million foodborne illnesses in the United States each year never result in a foodborne illness claim. Among the claims that are pursued, the vast majority is resolved without a trial through settlements and other types of negotiations. Among the claims that become lawsuits, relatively few reach the courtroom to be resolved in jury trials. Only a very small portion of jury verdicts is later overturned through post-trial motions or following appeals from dissatisfied plaintiffs or defendants.

Some legal experts believe that unlike some other areas of law such as auto accident claims where there is a higher proportion of fraudulent claims, most foodborne illness claims are bona fide (Clark, 2000), which means without deceit or fraud (Black's Law Dictionary, 1975). And because most foodborne illness claims are bona fide, they are resolved without a trial (Clark, 2000). Settlements occur when firms pay compensation to plaintiffs prior to trial.³ Legal analysts believe that clear cases of product liability settle relatively quickly while more complex cases go to trial

² Litigation may be very costly for firms, even when they have insurance coverage (e.g., business disruption, negative publicity, reduced product demand).

³ Most cases are settled out of court through informal negotiations between the lawyers for each side. Other cases are settled through alternate dispute resolution (ADR) procedures such as mediation and arbitration. *Mediation* involves both parties agreeing to the selection of an independent third party (mediator) who will help the parties resolve the issues between them, reach a settlement, and draft a mediation agreement. This agreement is binding upon the parties and is enforceable by the courts. *Arbitration* ocurs when the parties, either by prior contact, or by court order, submit their dispute to an impartial person or group of people for resolution. In this report, the term "settlements" is used to cover all types of formal and informal negotiations through which a lawsuit is resolved.

¹ Employees will rarely be named individually in a lawsuit, and then only for tactical reasons (Clark, 2000). They will face no individual liability (Clark, 2000).

(Eisenberg, 1991). Foodborne illness claims that become lawsuits are typically those where there is a serious causation question or where the amount of damages is disputed (Clark, 2000). In the case of medical malpractice lawsuits, Vidmar (1997) found that there is a selection process whereby the cases with ambiguous evidence tend to be decided by juries. This pattern suggests that court cases are not representative of all claims (Priest and Klein, 1984).

Firms have incentives to settle and keep the terms confidential in order to limit legal costs, avoid the uncertain outcome of a public trial and delays to resolution, avert the potentially adverse impact of a public trial on the reputation of the firm or its products, and avoid encouraging copycat claims and lawsuits. National or well-known food firms may be particularly likely to settle cases quickly (Rosenbaum, 1998). Because defendants' insurers are risk averse, settlements will always predominate in bona fide claims (Clark, 2000).

An extensive 1989 survey of accidental personal injuries by RAND found that liability claims were filed in 3 percent of accidents such as product-related injuries, slips, and falls, excluding work-related and motor vehicle accidents (Hensler et al., 1991). The claim rate may be even lower for foodborne illness than for other types of personal injuries because the cause of injury is not immediately apparent and identification of the source of contamination is often difficult or impossible. Although these data are for accidents, foodborne illness and accidents are similar in that the greater the injury, the greater the incentive to sue.

Earlier data from the 1977 Insurance Services Office Product Liability Closed Claims Survey of 23 insurance companies (n=10,784 claims) indicate that 19 percent of claims against insurers were dropped by the plaintiffs. An estimated 95 percent of other claims were settled out of court, and only 5 percent ultimately reached a court verdict by a jury or a judge (Viscusi 1991).

The significant number of confidential settlements that keep the monetary value and other information on a case out of publicly available court records, legal summaries, and the media suggests that the available data on foodborne illness settlements underestimates the relative number of plaintiffs compensated through settlements. The average compensation may also be underestimated if cases with the potentially highest damages are more likely to be settled out of court and kept confidential. On the other hand, the average compensation may be overestimated if plaintiffs' lawyers

tend to publicize the largest settlements. Either way, the direct feedback and information to other firms about the costs of producing safer foods is distorted and limited. However, when insurers pay for a large foodborne illness claim, they may raise the premium rates of similar firms, in effect providing indirect feedback to firms about the costs of not producing safer food. Insurers may also drop firms that cause repeated insurance losses. And big settlements always generate whisper information (i.e., private discussions) among firms, and repeat offenders face pressure from insurers or risk losing market share to safer competitors (Clark, 2000).

U.S. Product Liability Law Is State Law

Product liability law governs most legal actions arising from foodborne illness. This branch of tort law describes the circumstances under which one can recover damages for a defective food item. The laws of individual States govern the nature and extent of compensation that may be awarded for injuries or deaths due to contaminated food products (Clark, 2000). There is no uniform and comprehensive Federal law governing product liability in the United States. State trial courts (e.g., District or Superior court) have jurisdiction over foodborne illness cases. However, some foodborne illness cases are litigated in Federal courts (Clark, 2000). These cases are typically removed from State court to Federal court when the defendant firm invokes diversity jurisdiction (Clark, 2000), such as when the parties are from different States, or when one party requests a trial in Federal court as a means to minimize perceived biases which would negatively impact the party if the case were tried locally. Most plaintiff lawyers, however, prefer to represent their clients in State courts (Clark, 2000).

The annual number of product liability cases is unknown. Michael Saks, a University of Iowa law professor, estimates that there may be up to 90,000 product liability cases (all kinds, not just foodborne illness) filed in State courts each year (Mergenhagen, 1995). In 1993, there were 18,959 product liability cases filed in Federal courts, up from 2,393 cases in 1975 and 8,026 cases in 1983 (Mergenhagen, 1995).

Causes of Action

The complaint a plaintiff files in court must identify or specifically state one or more legally recognized causes of action, facts supporting the elements of a cause of action, and a demand for damages or some other form of judicial relief. Buzby and Frenzen (1999) outline the three main causes of action raised in foodborne illness lawsuits: strict product liability, negligence, and breach of express or implied warranty (table 11, fig. 2). Additionally, plaintiffs may also raise other issues such as misrepresentation (Quesada, 1995); however, these would not be separate claims.

Strict Product Liability

To recover monetary compensation from the defendant under a strict product liability cause of action, the plaintiff must prove that the product was defective and unreasonably dangerous when it left the manufacturer's control and that this defect proximately caused the injury (see Harl 1997, p. 7-17). Proximate cause is the legal term for the link connecting the illness or injury with the product defect. The defendant's liability is limited to only "foreseeable damages" suffered by "foreseeable plaintiffs."

In other words, the central issue in most strict product liability foodborne illness cases is causation, i.e., it is the plaintiff's burden to prove by a preponderance of the evidence (more than a 50 percent likelihood) that his illness resulted from the food item at issue (Clark, 2000). If strict liability is proven, the defendant is liable for damages. For example, the defendant's care in manufacturing or handling the product is irrelevant under strict liability and is not considered a defense (Clark, 2000). The focus is not on whether the defendant food firm did anything wrong, but simply whether the illness in question can be traced to its product. Strict liability is usually unsuccessful in foodborne illness litigation.

One consideration by the courts is the recognition that most foods cannot be made risk-free. For example, *Campylobacter* is a naturally occurring bacteria found in poultry that may contaminate poultry products despite intensive efforts to prevent, reduce, or eliminate contamination. Therefore, the defendant may not be held liable for the contamination.

Consumers do not have legal recourse if they are fully aware of the product's health risks but voluntarily proceed to use or consume the product and are injured by the product.⁵ One example is if a person with liver disease knows the risks of eating raw oysters yet still continues to eat them and then becomes ill. Another consideration in determining liability is whether or not consumers can and did take precautionary measures while handling and cooking food. The tapeworm, *Trichinae*, in raw pork does not make the pork defective and "unreasonably dangerous" to consumers because consumers are generally aware of the risks of eating undercooked pork and know that they can eliminate this risk by cooking pork thoroughly.⁶

Liability for microbial contamination of restaurant food does not fall on the consumer because the consumer had little if any control over how the food was prepared. As an aside, liability for other hazards associated with restaurant foods is less clear cut. For example, a consumer in a restaurant situation is still expected to examine the food for obvious physical hazards, such as bones in a whole intact chicken leg. However, the situation is less clear when a physical hazard, such as bone fragments are present in shredded chicken, hamburger patties, or other foods. In these situations, liability will fall with the party who was in the best position to examine the food and remove the hazard.

Negligence

Negligence in foodborne illness cases occurs when the defendant fails to exercise "reasonable care" in producing, marketing, or selling the implicated food, and because of this failure, someone became ill. The three elements that the plaintiff must prove in order to recover compensation under this cause of action are: (1) the defendant had a legal duty to exercise "reasonable care" in manufacturing the product and to warn all

⁴ Foresesable damages are consequences or damages that an ordinary person would reasonable expect to occur, and foreseeable plaintiffs are plaintiffs than an ordinary person might expect to be potential plaintiffs.

⁵ American Law of Products Liability, 1987, p. 9, § 81:3. ⁶ Restatement of Torts (2d § 402A); American Law of

Products Liability, 1987, p. 9, § 81:3. Also, see *Trabaudo v. Kenton Ruritan Club, Inc.* (517 *Atlantic Reporter*, 2d Series, 706). Changes are underway in common law--the 1997 Restatement of Torts (3d) tries to eliminate the negligence and strict liability distinction and tries to have a unified approach for product liability. However, the more traditional approach from Restatement of Torts (2d) is described in this report because it is appropriate for the 1988-97 data presented in chapter 4.

⁷ The Restatement (Third) uses an example of a 1-inch chicken bone in a chicken enchilada, raising the question of whether this is a manufacturing defect or an inherent aspect of the product (see Steenson, 1998).

foreseeable users of all foreseeable dangers, (2) the defendant failed to perform this duty, and (3) the defendant's failure to perform this duty caused the plaintiff's injury (Harl, 1997).

In more recent case law, liability through negligence has been extended beyond manufacturers to middlemen such as distributors or warehouses, although relatively few cases have been brought against them because of the difficulty of establishing proximate cause (Harl, 1997). In most instances, retailers are not liable under negligence theory for latent defects unless they represent themselves as the manufacturer, assemble the package prior to its sale (Harl, 1997), or were in a situation where they could have tested the product for safety. Food sellers are expected to use reasonable care to inspect the food that they sell and may be found negligent if there is a feasible procedure for inspecting the food but they failed to use it (American

Law of Products Liability, 1987, p. 6). Sellers are not expected to open sealed containers and inspect the food although some courts have stated the contrary (*American Law of Products Liability*, 1987, p. 6).

Failure to warn consumers of a product's hazards or of a potentially dangerous condition can result in negligence claims, particularly when the law requires warnings or labels yet they were not used. In certain products, manufacturers are legally obligated to provide warning labels to alert consumers about potential dangers. Common warnings are for foreign objects in foods (e.g., "the product may contain" bones, shell, pits, etc.). More recently, there are mandated label requirements for safe handling and cooking instructions on raw meat as well as for refrigeration instruction on smoked seafood packaged using modified-atmosphere techniques (e.g., keep refrigerated at 38° F or less). Manufacturers or product sellers may also be

Appendix table 1—Three causes of action for product liability cases

Cause of action	Focus T	ype of law ¹	Description
Strict product liability	Product defect	Tort	To prove a strict product liability action in most jurisdictions, the plaintiff must prove that the product was both defective and "unreasonably dangerous" but need not prove negligence.
Negligence	Manufacturer's	Tort	Either through neglect or carelessness, or seller's conduct, the defendant failed to exercise reasonable care to prevent the product from becoming defective and harming the user.
			Negligence per se Defendants violate a Federal, State, or local statute or regulation that was specifically designed to prevent the type of injuries that the plaintiff suffered.
Breach of warranty	Whether produ conforms to warranty	ct Commercial	According to the Uniform Commercial Code (UCC), just by selling a product, seller incurs obligations under both implied and express warranties. The plaintiff can recover damages if the product did not conform to one of these types of warranties and was not "reasonably safe."
			Breach of express warranty The representations or promises relating to the material facts (e.g., safety and wholesomeness) about the products, as described in salespersons' statements, in pictures or writing on food containers, and in advertisements induced the consumer to buy the food. A breach occurs when these representations are not true.
			Breach of implied warranty Implied warranty of merchantability "The product sold is reasonably fit for the general purpose for which it is manufactured and sold" (Harl, 1997, p. 7-18).
			Implied warranty of fitness The seller knows the buyer's intended purpose or use of the product and the buyer relies upon the seller's judgment or skill in selecting a suitable product for the purpose.

¹Torts are private or civil wrongs resulting in property damage or personal injury. Source: Adapted from Buzby and Frenzen (1999) with permission from Elsevier Press.

required by law to provide health warnings for raw milk and unpasteurized juices and for restaurant and retail sale of raw shellfish.

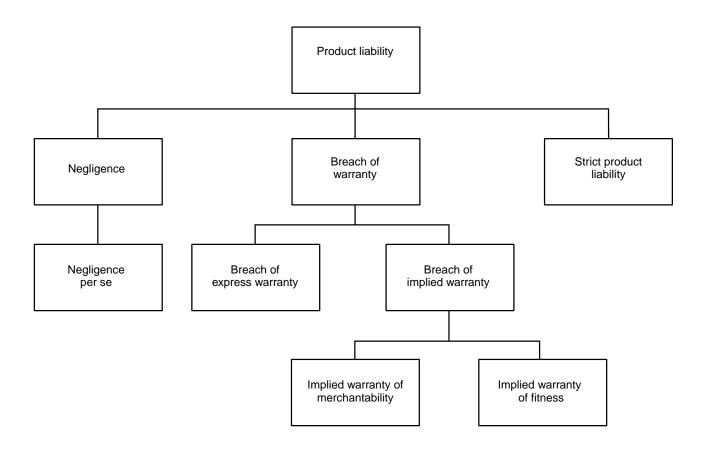
A related cause of action is "negligence per se" which occurs when defendants violate a statute or regulation that was specifically designed to prevent the type of injury the plaintiff suffered. Negligence per se is particularly relevant to the food industry because there are Hazard Analysis and Critical Control Points (HACCP) regulations and/or guidance documents that specify or suggest prevention techniques to follow. These regulations and guidance documents currently cover a broad range of areas including meat and poultry, food service establishments, unpasteurized fruit juices, and fish and fishery products. HACCP regulations require formalized food safety and sanitation programs to be implemented with supporting documentation that they are being followed.

A food firm is at risk of a negligence per se claim if its food products or food service activities are covered by a HACCP regulation but the firm has no HACCP plan in place or does not follow its own written rules, standards, or procedures (Rosenbaum, 1998). For example, in the 1993 outbreak associated with E. coli O157:H7 contaminated hamburgers, microbial standards and control procedures were established but not effectively implemented (Rosenbaum, 1998). In particular, the outbreak occurred because some of the fastfood restaurants failed to follow State-required cooking procedures (Tansey, 1993). Unfortunately, compliance with food safety laws and regulations does not guarantee that the food will be free of contamination.

Breach of Express or Implied Warranty

Under the Uniform Commercial Code (UCC), sellers incur obligations called warranties when they sell a product. Breach of warranty is a cause of action that may be claimed in a foodborne illness lawsuit and applies when the food does not conform to either an express warranty or an implied warranty. In essence, plaintiffs can recover compensation if the food did not conform to a warranty and that non-conforming feature of the product caused the plaintiff's injury.

Appendix figure1 Schematic of the main causes of action for product liability for food safety issues



An *express warranty* is an affirmation of fact or promise about the food, as made in sales respresentatives' statements or in pictures or writing on food containers, menus, or advertisements, that induces the consumer to buy the food. The warranty is breached if these representations prove to be false. For example, a company that advertises its eggs as *Salmonella*-free when they are not has breached an express warranty. For food products, express warranties that are commonly breached involve foreign objects in the food (bones for example).

An *implied warranty* requires food to be both merchantable and fit for consumption.

- A product is merchantable if it meets certain prescribed safety standards and is fit for the "ordinary purpose" for which it was sold. For example, raw pork is merchantable because its ordinary purpose is human consumption after thorough cooking to kill foodborne parasites such as *Trichinae*.
- A product must also meet an implied warranty of fitness for a particular purpose in certain representations made about it. In essence, a seller makes an implied warranty of fitness when he knows the buyer's intended purpose or use of the product, and the buyer relies on the seller's judgment or skill in selecting a suitable product. For example, if a seller told a buyer that a particular type of raw fish could be used to make sushi and the buyer became ill from consuming the sushi because it was contaminated with Anisakid parasites, this warranty would be breached.

The plaintiff is not required to show that the food seller was negligent or at fault to recover damages under the implied warranty theory. Instead, the plaintiff must only prove that the seller sold the non-conforming food and that this non-conforming feature of the food caused the plaintiff's illness. This seemingly simple proof is complicated by the issues described below.

Two main tests are used to determine if a food is fit for human consumption and whether there has been a breach of "implied warranty of merchantability." The most commonly adopted test is the reasonable expectation test. This is based upon what an ordinary consumer might reasonably expect" to be present in the food (Rubin and Lamb, 1993). For example, would ordinary consumers be aware of the risks from *Salmonella* (*Salmonella* serotype Enteritidis in particular) when they ate lightly poached eggs? Under this test, the socioeconomic, cultural, and demographic characteristics of the individual plaintiff are used to

determine what the plaintiff should have reasonably expected to be in the food.

The second test is the *foreign-natural* test based on the characteristics of the foreign material that caused the injury. Under this test, consumers can recover from injuries caused by an unexpected foreign substance in the food (glass in chicken soup) but not if the same injury was caused by a "natural" material in the food (bone in chicken soup).

Common Defenses in a Product Liability Lawsuit

Issues in product liability lawsuits are usually decided in two stages: determination of liability, and assessment of damages if liability is found. The key issue in determining liability is whether or not plaintiffs can prove causation, that is, link their foodborne illness to the implicated food, to a negligent act or omission by the defendant, or to a defect or non-conforming feature of the implicated food.

Defendants may try to weaken the alleged causal link between the food and the plaintiff's illness by providing evidence that the illness-causing pathogen can be associated with multiple foods or could have been spread via other routes, such as person-to-person contact. The further removed a defendant is from the plaintiff in the chain of food production, processing, and distribution, the more difficult it may be for the plaintiff to establish a causal link. A causal link may be easier to establish between divisions of a vertically integrated company and harder to establish if consumers or intervening parties such as middlemen could also have made food-handling errors. For example, in very rare instances, defendants may claim that the foodborne illness due to home-cooked food was due to the consumers' faulty food-handling and preparation practices. They may also claim that no one else became ill while eating the same food, the food is not a commonly recognized vehicle for the pathogen, or that the timing of the illness is inconsistent with the pathogen's incubation period.

Defendants may try to prove that the plaintiff was fully aware of the health risks but nevertheless voluntarily proceeded to use or consume the food and then became ill. Defendants may also use a plaintiff's preexisting medical condition to try to show that a plaintiff was negligent or reckless. The effect of such counterclaims on case outcomes is unclear.

In general, if the defendant is found liable, damages may be decreased if the defendant: (1) showed that "reasonable care" was taken when producing, handling, and selling the implicated food, (2) used state-of-the-art technology in producing the food, and (3) followed laws and regulations designed to prevent the harm suffered by the plaintiff. A defendant that uses its HACCP records to show that it had exercised all reasonable preventive controls following regulatory guidelines will have a better defense than a firm that cannot (Weddig, 1994).

Legal Compensation for Foodborne Illness

If a defendant in a foodborne illness jury trial is found liable and compensation is awarded to the plaintiff, the award may be based upon components such as medical costs (past, present, and projected, after insurance), lost productivity (e.g., actual salary losses and projected lost future earnings), other dollar losses (e.g., burial expenses, travel costs to obtain medical care), and general losses that are difficult to monetize (e.g., pain and suffering, loss of consortium (i.e., a spouse's help and affection), disability, psychological and emotional distress).

If there are multiple defendants, *joint and several liability* might be used to allocate the burden of compensating the plaintiff. Historically, if more than one defendant was found joint and severally liable for a single indivisible injury but only one was capable of paying the monetary damages, that defendant might have to pay all of the damages. However, monetary damages are commonly based upon the percent of liability attributed to each defendant. The legal theory of *contributory negligence* apportions liability to the plaintiffs. In some jurisdictions, if the plaintiff is found to be over 50 percent liable for his or her injury, the defendant will not have to pay any damages (Sims, 1995).

Defendant Costs

In addition to any compensation paid to plaintiffs, monetary losses to a corporate defendant from an incident resulting in a lawsuit may include any or all of the following costs: direct and indirect costs of a product recall (including lost product and replacement of product), lost profits, lost sales (i.e., affected products and other product in the same product line or similar product category), loss of customers, reduced market share, loss of business reputation, and legal expenses.

Defendants found liable in foodborne illness cases may also be assessed punitive damages if the defendant was found grossly negligent with food production, handling, processing, and sanitation practices and/or willfully contaminated the food. Punitive damages are assessed to punish defendants for their conduct and are based upon the defendant's ability to pay, not upon the damages suffered by the plaintiff. However, courts seldom award punitive damages (Cooter, 1991). Punitive damage claims do, however, have real legal tactical use in the gathering of information during a lawsuit (discovery process) against firms and in leveraging settlements (Clark, 2000). Also, individuals who have intentionally violated a Federal or State law could be subject to criminal prosecution which may lead to additional financial and personal costs such as fines and/or imprisonment (Cooter, 1991).

Discussion

Historically, many attorneys were reluctant to take foodborne illness cases because they did not know how to proceed with them because there is so little precedent (Rosenbaum, 1998). More recently, there has been a system-wide increase in the level of expertise in trying these cases, and more attorneys are willing to accept them (Rosenbaum, 1998). In general, attorneys with less experience with these cases are less likely to be successful (Rosenbaum, 1998).

Meanwhile the medical community is becoming more educated about foodborne disease (Rosenbaum, 1998), and there is increased government surveillance to identify foodborne illness cases, hospitalizations, and deaths. Additionally, new technologies are being developed that can detect foodborne illnesses and pathogens in food (e.g., Pulsed-Field Gel Electrophoresis for examining DNA fingerprints of specific pathogens). Greater information about foodborne illness and greater documentation of sporadic and outbreak cases will assist attorneys in foodborne illness lawsuits.

Class Action Suits

A *class action* suit is "a lawsuit brought by representative member(s) of a large group of persons on behalf of all of the members of the group" (Gifis, 1975). Class action suits began to proliferate in the 1970's (Mergenhagen, 1995). Courts may agree to accept class action lawsuits in cases involving a large number of plaintiffs with similar damages when it is more efficient to treat the plaintiffs as a group than as individu-

als. However, Federal and State courts are generally unreceptive to requests to certify personal injury claims as class actions because the injuries are rarely similar enough to justify group treatment (Clark, 2000). Some well-known examples of consumer products that have been involved in class action suits include Dalkon shield contraceptive devices, silicone breast implants, and tobacco products.

Class action lawsuits involving foodborne illness have been rare. Severe foodborne illnesses are likely to involve a variety of different symptoms and damages, particularly when chronic sequelae occur. Therefore, injuries of this kind are unlikely to meet the general standard for a class action lawsuit, even in the case of large outbreaks where liability is not contested (Clark, 2000). Class action lawsuits involving foodborne illness are probably most likely to be certified when a foodborne illness outbreak resulted in many mild illnesses with relatively uncomplicated claims for monetary damages.

A large foodborne illness outbreak due to Salmonellacontaminated milk linked to Jewel Food Stores in the Chicago area during the late 1980's was apparently the first class action lawsuit involving foodborne illness. Several other foodborne illness outbreaks since then have also resulted in class action lawsuits. The increase in class actions may reflect the widespread media coverage of the successful class action lawsuit involving the 1993 outbreak due to E. coli O157:H7contaminated hamburgers linked to the Jack-In-The-Box restaurant chain. Class action lawsuits involving foodborne illness might become even more common in the future as methods for detecting outbreaks continue to improve, and as lawyers and consumers become more aware of the class action option for recovering damages due to mild illnesses associated with mass outbreaks of foodborne illness.