



## **Good Food Safety Practices: Managing Risks to Reduce or Avoid Legal Liability**

Elizabeth Haws Connally, Esq.<sup>1</sup>  
Alston Hunt Floyd & Ing, Honolulu, Hawai'i

Consumers today demand that the food they eat be safe and free from harmful contaminants that cause illness. They require growers, shippers, wholesalers, retailers, and restaurants to take appropriate actions to ensure a safe food supply. Consumers have also demonstrated that they will hold all these “food suppliers”—indeed, all segments of the food supply chain—accountable for foodborne illnesses. Aside from their potentially devastating public health effects, these illnesses are costly to the consumer and the food industry. For the food industry, the impact may last beyond the resolution of the food illness outbreak. Once consumer confidence is lost, it may take a long time before consumers return to buying the product.

This publication reviews the potential liabilities that the food industry (“from farm to table”) faces from the increasing spread of foodborne illnesses. In addition, it addresses ways to manage these risks through using the Good Food Safety Practices and purchasing insurance.

### **Foodborne illness: origins and impacts**

The most harmful of potential contaminants that can cause foodborne illness are disease-causing microbes (pathogens) of human or animal origin (these pathogens are commonly called “germs”). Food suppliers and handlers must do all they can to reduce the chance of contaminating food products with pathogens.

One pathogen, *Escherichia coli*, commonly referred to as *E. coli*, is currently the leading cause of foodborne illness in the United States. The U.S. Department of Agriculture

(USDA) Economic Research Service estimates that more than 73,000 cases of illness caused by *E. coli* strain O157 occur annually, resulting in health-related costs of more than \$450 million.<sup>2</sup> *E. coli* is just one of several pathogens that have contaminated food and caused illnesses.<sup>3</sup>

Recent food scares such as the one involving spinach contaminated with *E. coli* O157:H7<sup>4</sup> have heightened interest in food safety and awareness of food industry vulnerabilities. In September 2006, the Centers for Disease Control and Prevention informed the U.S. Food and Drug Administration (FDA) that it linked the outbreak of *E. coli* O157:H7 to contaminated prepackaged, fresh-cut spinach packed for Dole Foods by Natural Selection Foods LLC, a California specialty lettuce processing company.<sup>5</sup> This *E. coli* outbreak spread to 26 states and resulted in 204 confirmed illnesses and three deaths.<sup>6</sup> This one incident caused economic losses in California estimated at \$37–74 million.<sup>7</sup> In addition, everyone in the spinach supply chain was exposed to and/or embroiled in litigation for more than two years. The total amounts paid out in legal settlements are not known.

Lawsuits in the food industry are on the rise, as attorneys are becoming more successful in proving foodborne illness causation, thanks to better science. In February

2008, one law firm in Seattle, Washington claimed to be handling more than 1,000 active foodborne illness cases, originating in all 50 states.<sup>8</sup> Many lawsuits settle before trial, but not without significant expense.

In 2003, more than 650 people were sickened and four died from hepatitis A, contracted from Mexican green onions served at the Chi-

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Chi's Mexican restaurant near Pittsburg, Pennsylvania.<sup>9</sup> FDA attributed the outbreak to poor sanitation. This was the largest single-source epidemic of hepatitis A in U.S. history.<sup>10</sup> The total compensation paid by Chi-Chi's was \$50 million.<sup>11</sup>

### **Foodborne illness litigation**

A person affected by a foodborne illness may attempt to obtain financial compensation for his or her illness by pursuing legal action against the firms that produce, process, distribute, cook, or sell the food product that allegedly caused the illness.<sup>12</sup>

In order to prevail in foodborne illness litigation, people filing the lawsuit, (plaintiffs) must prove by a preponderance of the evidence that the food supplier (defendants) committed wrongful acts that caused harm to the plaintiffs.

### **Potential causes of legal action**

A plaintiff in these lawsuits will identify specific claims ("causes of action") and must cite facts that support these claims and a demand for damages. There are three common causes of action in foodborne illness lawsuits: product liability, breach of express or implied warranty, and negligence. These, however, are not the only causes of actions that a plaintiff may allege. All food suppliers are subject to these legal claims.

#### ***Product liability***

Product liability law is invoked in most foodborne illness lawsuits. In a product liability case, the plaintiff must prove that the product was defective and unreasonably dangerous when it left the food supplier's control and that the defect was the "proximate cause" of the plaintiff's injury.<sup>13</sup> Proximate cause is the legal term for linking the illness or injury to the product. Companies in the chain of production, transfer, and handling may be exposed to the claim to the extent that they participate in the "production" or alteration of the food item. The core of product liability cases is the determination that the food item and its production or alteration was the proximate cause of the illness.

#### ***Breach of warranty***

A plaintiff may claim breach of warranty in a foodborne illness case by claiming that the food product does not conform to an express or implied warranty. The plaintiff may recover damages if the food product did not conform

to the warranty and the non-conformance caused the plaintiff's injury.<sup>14</sup>

#### ***Negligence***

Persons who sell or supply food products for human consumption must exercise due care and diligence regarding the "fitness" of the product. Food suppliers may be held liable because of any negligence on their part that contaminated the food and caused persons who purchased the food to become ill. Negligence can be alleged in foodborne illness cases when the defendant fails to exercise "reasonable care" in the food production process and a person becomes ill.

To show that a defendant was negligent, a plaintiff must prove three elements: (1) the defendant had a legal duty to exercise "reasonable care" in producing, growing, handling, storing, or transporting the food product, and/or to warn all users of the foreseeable dangers; (2) the defendant failed to perform this duty; and (3) the defendant's failure to perform the duty caused the plaintiff's injury. The food supplier has a duty to use reasonable care and inspect the food they sell to prevent it from becoming contaminated or harmful to the consumer.

A seller of the food product may also be liable when a person consumes a food product that contains items the consumer did not expect in the product and he or she becomes ill or injured by that item. A food supplier may be held liable for negligence if they fail to warn the consumer about potential dangers in the food product. For example, food labelers may fulfill a duty to warn of known causes of severe allergies by noting on the packaging, "this product may contain peanuts" (or shellfish, etc.).

A plaintiff may pursue a "negligence *per se*" cause of action if the defendant violates a statute or regulation designed to prevent the type of illness or injury suffered by the plaintiff. For example, if the plaintiff can demonstrate that a defendant linked to a foodborne illness violated the law or deviated from proper food safety and health standards, the defendant could be automatically liable.

Good Food Safety Practices, which follow food safety and health standards, are discussed below. These are tools for the food industry to manage its legal liability risks.

### **Management of risks**

#### ***Good Food Safety Practices***

Following are four sources of food safety and health standards, policies, procedures, and guidelines that col-

lectively will be referred to in this publication as “Good Food Safety Practices”:

- *Guidance for Industry; Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (“The Guide”)<sup>15</sup>
- good agricultural practices (GAPs) and good handling practices<sup>16</sup>
- good manufacturing practices (GMPs)<sup>17</sup>
- hazard analysis and critical control points (“HACCP”).<sup>18</sup>

Underlying these Good Food Safety Practices are federal guidelines and policies established to provide guidance to prevent foodborne illness. These documents apply to all segments of the food industry that grow, harvest, process, manufacturer, and distribute food. If a food supplier is compliant with these policies, as confirmed by a third-party audit, it will have an established food safety and sanitation program and documentation to support implementation.

If the Good Food Safety Practices apply to the food product, a food supplier is at risk of a legal claim, especially if the food supplier (1) does not have a safe food handling plan and/or (2) does not follow or implement the plan or document procedures.

### **The Guide**

In 1998, FDA, in cooperation with USDA, issued The Guide. The basic principles of The Guide are to prevent microbial contamination of fresh produce through use of good quality water, proper health and hygiene, and sanitation practices. The Guide urges food suppliers to take a proactive role in minimizing food safety hazards. In February 2008, FDA issued an additional guide to provide more specific food safety practices for handling fresh produce.<sup>19</sup>

### **Good agricultural practices (GAPs)**

The USDA and FDA also established GAPs in 1998. The GAPs program is broken down into three major sections: (1) good agricultural practices that examine farm practices; (2) good handling practices that concentrate on packing facilities, storage facilities, and wholesale

distribution centers; and (3) food defense, which provides protocols for food handling used throughout the food chain.<sup>20</sup>

### **Good manufacturing practices (GMPs)**

The current GMPs are published in the Code of Federal Regulations.<sup>21</sup> GMPs describe the methods, equipment, facilities, and controls for producing processed food. The GMPs establish the minimum sanitary and processing requirements for producing safe and wholesome food. They are an important part of regulatory control over the safety of the nation’s food supply.<sup>22</sup>

### **Hazard analysis critical control points (HACCP)**

The FDA established the HACCP (pronounced “hassip”) rules for the food processing industry to address a variety of food safety concerns. HACCP involves the following seven principles:

- **Analyze hazards.** Analyze potential hazards that may enter the food: microbial, chemical, or physical, such as glass, or metal fragments.
- **Identify critical control points.** These are points in the food production process when the potential hazard can be controlled or eliminated during the cooking, cooling, packaging, and metal detection processes.
- **Establish preventative measures with critical limits for each control point.** For example, in cooking, minimum cooking time and temperatures can be established.
- **Establish procedures to monitor the critical control points.** These might include determining how the cooking time and temperature should be monitored.
- **Establish corrective actions to be taken when monitoring shows that a critical limit has not been met.** For example, if the minimum temperature is not

met, food may be disposed of or reprocessed in accordance with best practices.

- **Establish procedures to verify that the system is working properly.** For example, time and temperature can be tested to verify that a cooking unit is working properly.

- **Establish effective record-keeping to document the HACCP system.** This includes records of hazard control meth-

#### **For more information on the Good Food Handling Practices—**

**The Guide:** <http://www.foodsafety.gov/~dms/prodguid.html>

**GAPs:** <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5050869>

**GMPs:** <http://www.cfsan.fda.gov/~dms/cgmps.html>

**HACCP:** <http://www.cfsan.fda.gov/~comm/haccpov.html>

ods and the monitoring of safety requirements.<sup>23</sup>

Use of the above-listed Good Food Safety Practices by the entire food supply chain minimizes the chance of a foodborne illness outbreak and provides legal defenses. To manage the risk of foodborne illness, all segments of the food chain must focus on (1) good health and hygiene practices and (2) ways to maintain the viability of the business. The various members of Hawai'i's food industry can work together to adopt these practices and should seek further guidance and assistance from the University of Hawai'i College of Tropical Agriculture and Human Resources.<sup>24</sup>

### ***The Good Food Safety Practices are a defense***

The best defense to any future lawsuit is prevention, through compliance with the Good Food Safety Practices. Even if the defendant is found liable, punitive damages can be avoided and the damages may be reduced if the defendant can show that (1) it took "reasonable care" when producing, handling, and selling the food product; (2) it used state-of-the art technology in producing the food product; and (3) it complied with laws, regulations, and guidelines designed to prevent the harm suffered by a plaintiff.<sup>25</sup> A defendant who follows the safe food handling requirements and has documentation to prove it is more likely to be found to have exercised reasonable care and control to prevent contamination. Thus, the defendant taking these preventative measures has better defenses than a defendant with no safe food handling procedures in place.

### ***Use contracts with vendors***

A buyer of food products may require by contract that its food supplier adopt and implement safe food handling practices to ensure safe handling of the food throughout the entire food supply chain. By requiring the food supplier use safe food handling practices, the food buyer lowers the risk that contamination will occur. If it does occur, the buyer may contractually require that the food supplier defend and indemnify the buyer against any liability caused by the food supplier's failure to use safe handling practices.

In addition, the buyer may require the food supplier to purchase sufficient insurance coverage, to cover the risks faced by the food buyer. The food buyer may also insist on being named as an additional insured on its food supplier's insurance policies.

### ***Insurance***

To manage the cost of lawsuit risks, more food processors, packagers, and distributors are requiring the food supplier to carry insurance. Owning an insurance policy, however, does not guarantee total financial protection if a lawsuit is brought against the food supplier. It is important to

- recognize that there are different types of insurance
- determine if claims from foodborne illness are covered by your insurance policy
- determine if the insurance coverage levels are sufficient to meet your potential risks, and know what the "deductible" amount is on each policy.

An insurance carrier usually has a duty to defend and indemnify the insured if the claim is within the scope of the policy. For the food supplier with insurance, the policy may require the food supplier to follow the Good Food Safety Practices and do what is possible to minimize the incident of foodborne illness. Insurance companies may also encourage safe food handling practices through the terms of the insurance policy or by reducing insurance premiums based on the level of food safety precautions taken.

### ***Types of insurance***

Insurance product coverage is diverse. The following are some standard types of business insurance:

1. commercial general liability
2. business interruption
3. product recall
4. product liability.

The following is only a brief description of these types of policies and is not intended as legal advice or to promote or recommend specific types of insurance policies.<sup>26</sup> An insurance professional can assess a food supplier's needs and provide further guidance on these various types of insurance.

- **General liability coverage.** General liability insurance protects the assets of the business when the business is sued for something it or its agents did or did not do that caused injury or property damage. The amount of coverage a business needs depends on the amount of risk associated with the business.
- **Business interruption coverage.** Business interruption insurance covers losses due to the shutdown of a product line or the entire company, but it often only

applies where there is physical damage to the facility.

- **Product recall coverage.** Product recall coverage insures a company for its own financial losses suffered because of a recall, such as the cost of physically removing the product from retailers' shelves, storing or disposing of the product, and, in some cases, the cost of rebuilding the company's reputation following a recall.
- **Product liability coverage.** Product liability insurance provides coverage to the business for claims relating to an injury from the food product. This type of coverage is important for the food supplier, as it should provide some protection if a person becomes ill or injured from the food product.

#### **Carefully review insurance policy coverage— Does it cover your risks?**

A food supplier must carefully review the terms of the policies prior to purchase, paying close attention to the items excluded from coverage, the deductible amounts, and the obligations of the policyholder. The food supplier should confirm that the final version of the policy accurately reflects the intended coverage. As mentioned above, the policy may require the food supplier to follow the Good Food Safety Practices for the coverage to apply.

Recently, the U.S. District Court for the Southern District of New York denied plaintiff Tradin Organics USA, Inc. ("Tradin"), an organic food distributor, recovery on a product liability claim filed with its insurer, defendant Maryland Casualty Company, under a policy that provided commercial general liability coverage.<sup>27</sup> The court held that a "your product" policy exclusion precluded coverage for losses caused by contaminated or defective products sold by Tradin. The court concluded that companies manufacturing or selling food products should have a separate product liability policy.

#### **Buy enough coverage**

An inexpensive insurance policy with minimal levels of coverage might cost less now, but it may prove to be very costly in the future, if the business is not adequately insured. A food supplier needs to evaluate its risks and ensure it purchases proper coverage for the risks, at levels adequate to protect the business.

#### **Due diligence is needed**

In summary, to avoid outbreaks of foodborne illness, all segments of the food supply chain must diligently use the Good Food Safety Practices to provide the safest food possible to the consumer. Unsanitary practices put consumers' health and the viability of your business at risk. To protect the financial stability of the business, the food supplier must also take steps to acquire the proper type of insurance with adequate coverages to address the risks. *Don't risk it*—use the Good Food Safety Practices.

#### **Notes**

1. Elizabeth Haws Connally is an associate with the law firm of Alston Hunt Floyd & Ing, Honolulu, Hawai'i. Her e-mail address is EHaws@AHFI.com. This article was written for UH-CTAHR with funding support from the Hawaii Farm Bureau Federation.
2. U.S. Department of Agriculture Economic Research Service, Foodborne Illness Cost Calculator, <http://www.ers.usda.gov/data/foodborneillness/>.
3. U.S. Department of Agriculture's Economic Research Service also reports the following pathogens as causing foodborne illness: *Campylobacter*, *Salmonella*, and *Listeria*.
4. *E. coli O157:H7 and the Spinach Scare*, <http://www.ctahr.hawaii.edu/oc/freepubs/pdf/FST-19.pdf>.
5. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01593.html>.
6. *Food Safety & the CEO; Keys to Bottom Line Success*, William Marler, <http://www.marlerclark.com/pdfs/FSMCEOBottomLine.PDF>.
7. *Spinach Contamination Demonstrates Need for Recall and Business Interruption Coverages*, Insurance Journal, November 6, 2006, <http://www.insurancejournal.com/magazines/south-east/2006/11/06/features/74360.htm>.
8. Article about William Marler, *E. Coli Lawyer Is Busier Than Ever*, Associate Press, February 4, 2008, <http://www.marlerblog.com/2008/02/articles/lawyer-oped/e-coli-lawyer-is-busier-than-ever/>.
9. *Chi-Chi's Files Lawsuit Against Wholesalers*, Pittsburg Tribune-Review, August 3, 2004, [http://www.pittsburghlive.com/x/pittsburghtrib/s\\_206267.html](http://www.pittsburghlive.com/x/pittsburghtrib/s_206267.html).
10. The Centers for Disease Control and Prevention – *Hepatitis A Outbreak Associated with Green Onions at a Restaurant – Monaca, Pennsylvania*. MMWR Nov. 21, 2003, 52 Dispatch 1-3.
11. See note 6, above.
12. Litigation may also involve food suppliers who are sued by consumers but to seek to pass on liability to other food suppliers who are "higher" in the supply chain.
13. Harl, N.E. *Agriculture Law* Through release # 50. New York, Mathew Bender, 1997.
14. The Uniform Commercial Code ("UCC") provides a warranty of merchantability that applies to food sold, if the seller is a merchant with respect to goods of that type. Under this section of the UCC, serving food or drink for value that is consumed on the premises or elsewhere is a sale. To be "merchantable," goods must be at least fit for ordinary purposes for which the goods are used. Uniform Commercial Code §2-314. Courts have applied an implied warranty of fitness for human consumption to food. *Ex*

- parte Morrison's Cafeteria of Montgomery, Inc.* 431 So. 2d 975, (Ala. 1983). Another court wrote, "There is simply no room for dispute with regard to the applicability of the UCC. The service of food in a restaurant is a sale. And a restaurant which sells the food to its customers warrants that the food will not be foul. The sale of food in a restaurant therefore fits perfectly within the UCC definition of the implied warranty of merchantability." *Koster v. Scotch Associates* 273 N.J. Super.102, 640 A. 2d 1225 (1993).
15. <http://www.foodsafety.gov/~dms/prodguid.html>.
  16. Additional information concerning the Good Agricultural Practices and Good Handling Practices Audits and the audit verification checklist can be found at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5050869>.
  17. FDA's current GMPs can be viewed at <http://www.cfsan.fda.gov/~dms/cgmps.html>.
  18. More information regarding HACCP can be found at <http://www.cfsan.fda.gov/~comm/haccpov.html>.
  19. In February 2008, FDA issued *The Guide to Minimize Microbial Food Safety Hazard of Fresh-cut Fruits and Vegetables*. <http://www.cfsan.fda.gov/~dms/prodgui4.html>.
  20. <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=Good%20Agricultural/GoodHandlingPracticesAuditVerificationProgram&rightNav1=Good%20Agricultural/GoodHandlingPracticesAuditVerificationProgram&topNav=&leftNav=&page=GAPGHPAuditVerificationProgram&resultType=&acct=freshgrdcert>.
  21. 21 CFR 110.
  22. <http://www.cfsan.fda.gov/~dms/gmp-1.html>.
  23. <http://www.cfsan.fda.gov/~lrd/bghaccp.html>.
  24. The Agricultural Development in the American Pacific project at the University of Hawai'i at Mānoa's College of Tropical Agriculture and Human Resources provides workshops and guidance for compliance with good food safety practices. Contact ADAP by phone, (808) 956-9539, or e-mail to James Hollyer, [hollyer@hawaii.edu](mailto:hollyer@hawaii.edu).
  25. Weddig, L.J. May, 1994. *Economics of HACCP for the Seafood Industry*. Food and Drug Journal 49: 493–498.
  26. <http://www.iii.org/media/glossary/alfa.A/>. For additional information on product recall insurance, see *Insuring Against Product Liability*, Lemov and Hewitt, ABA Section of Business Law at <http://www.abanet.org/buslaw/blt/9-1recall.html>.
  27. *Tradin Organics, Inc. v Maryland Cas. Co.*, 2008 WL 241081 (S.D.N.Y. 2008).

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## **User Notes**