Food safety: Records help identify target defendants and trigger insurance coverage

How records from food manufacturers and the FDA can be used in cases involving foodborne illness

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Food manufacturers and the FDA prepare and maintain records to document efforts to prevent foodborne illness. These documents can also help identify target defendants, support causation, and trigger insurance coverage.

Foodborne illness is a serious problem

Foodborne illness is a serious problem. One in six Americans suffers a foodborne illness annually. (http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html.) About 128,000 people are hospitalized, and 3,000 die annually from them. (*Ibid*.) Each year, food poisoning costs the U.S. $15.6 billion (primarily medical expenses and wage loss). (http://www.foodpoisonjournal.com/food-poisoning-information/food-poisoning-costs-u-s-156000000000-yearly/#.VZ2IxXtdQ84.)

Food safety records help identify bad actors and bad conduct

• FSMA will require food companies to prepare and keep food safety records

Presently, food companies prepare and maintain a number of records to document their food safety efforts. Soon, the FDA Food Safety Modernization Act ("FSMA," P.L. 111-353) will require food companies to identify even more risks and document their efforts to manage them. (FSMA § 103.) The availability of these records will help identify target defendants and potential causes of foodborne illness relatively quickly. (FSMA §§ 101, 103; *n.b.*, the current deadlines for the FDA to promulgate final rules to implement FSMA range from August 30, 2015 to May 31, 2016; see http://www.centerforfoodsafety.org/files/2014-2-20-dkt-82-1-joint-consent-decree_26503.pdf.)

• A trail of bread crumbs: more documentation = more proof for your case

Documentary evidence is critical to proving a food injury claim. (http://www.marlerclark.com/food-poisoning-litigation.pdf.) Specifically, what (if any) records can a food company produce to document that it properly trained its personnel? (See *ibid*.) For prior food injury incidents, what steps did the company take to prevent recurrence? (See *ibid*.)

FSMA's record-keeping requirements will provide at least three advantages for proving a plaintiff's food injury case. First, the records may help identify the source(s) of an outbreak and identify additional target defendants. (Target defendants that fail to meet FSMA record preparation and maintenance requirements may be negligent per se and subject to adverse inference jury instructions like CACI 203-205.) Second, they provide evidence of causation. Finally, they should help develop facts to trigger insurance coverage and minimize policy exclusions.

FSMA documents will help identify additional target defendants

FSMA will require most food companies to prepare and maintain a panoply of records to help the FDA detect and respond to food safety problems. (FSMA §§ 201-211.) The FDA will have authority to inspect most food company records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of adulterated food if there is a reasonable probability that that food will cause death or serious injury. (FSMA §§ 101, 103.) FSMA will also require food companies to track and trace products throughout the supply web and maintain these records for at least two years. (FSMA § 103; see http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC204.)

Traceback records can also help identify target defendants at every step of food production and distribution. (FSMA § 204; *see* http://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2014/traceback-investigations-mapping-the-maze/.) For larger outbreaks in multiple locations, FDA investigators can review shipping invoices that may identify a common source of food that caused injury. (*Id*.; see http://www.cdc.gov/salmonella/paratyphi-b-05-15/.)

FSMA documents will help identify evidence of causation

The records the FDA may request to identify target defendants can also be used to identify facts that support an injured plaintiff's potential claims. (See FSMA § 101.) Because food injury cases are so fact-specific, the FDA determines the scope of records to request on a case-by-case basis (see *ibid.)*, which means the agency will likely request as many records as needed to contain an outbreak. Injured plaintiffs can request copies of these records from

the defendants (e.g., any and all records provided to government agencies charged with investigating an outbreak) and through FOIA (Freedom of Information Act) record requests.

Below are three examples of records that FSMA will make available to support food injury claims (some are currently available):

• **HACCP Plans and Safety Protocols**

Some food industries (e.g., juice and seafood) already prepare written Hazard Analysis and Critical Control Point (HACCP) plans to identify, control, and correct potential hazards, and FSMA will expand this requirement for more foods. (http://www.fda.gov/Food/GuidanceRegulation/HACCP/; FSMA § 103; see FSMA § 202.) The FDA has also produced guidance documents and checklists to help companies comply with FSMA in many areas, including for preparing HACCP plans and tracing products. (http://www.fda.gov/Food/GuidanceRegulation/default.htm.) Even if the FDA's final rules for implementing FSMA are still pending, food companies should have product safety plans and be developing compliance strategies for the new requirements.

• **Transportation: Clean and cold**

FSMA will also require sanitary transportation of food, which includes controlling temperature to minimize the risk of pathogen growth. (FSMA § 111; http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm.) This should help to quickly identify evidence supporting causation against defendants that maintain real-time temperature traceability records. (See http://intelleflex.com/ Solutions.FoodIndustry.Growers.and.Producers.asp.) Other types of temperature control records should still be available from other companies to demonstrate non-compliance with sanitary transportation requirements. (See, e.g., http:// www.sanitarycoldchain.com/assessment/areyouincompliance.html.) However, companies that fail to prepare or maintain temperature control records may be unable to explain or to deny why they did not. (See CACI 203-205.)

• **Protection from intentional adulteration**

FSMA will require food companies to protect their products from intentional adulteration. (FSMA § 106.) Although the FDA's final rule will not be issued until May 31, 2016, companies that take no action in anticipation of the rule will be hard-pressed to argue that they did not foresee the risk and resulting injuries. (See generally CACI 432, cmt. [citing *Akins v. County of Sonoma* (1967) 67 Cal.2d 185, 199].)

• **Multiple causes for food injuries = higher policy limits**

Food production records may help identify multiple causes for food injuries, triggering higher aggregate policy limits (instead of lower single occurrence limits).

In 2012, about 425 people suffered salmonella food poisoning after allegedly consuming raw "tuna scrape" (ground tuna) imported (and later recalled) by Moon Marine. (http://www.cdc.gov/salmonella/bareilly-04-12/.) The FDA inspected the fishery in India that produced the tuna and identified numerous *potential* causes for contamination. (http://www.accessdata.fda.gov/cms_ia/importalert_841.html.) These included microbial water contamination; ice machines with "apparent bird feces"; "filth" found "in and on" equipment; and raw fish residue remaining on knives even after cleaning. (*Golden Eagle Insurance Corp. v. Moon Marine (U.S.A.) Corp.* (N.D. Cal. Nov. 15, 2013) 3-12-CV-05438-WHA [slip op.] p. 3.) However, the FDA did not identify "the cause" of the outbreak, and no one determined how the fish became contaminated. (*Ibid*.)

Moon Marine tendered the injury claims to its carrier, Golden Eagle Insurance Corporation. (*Id*. at p. 4.) The carrier filed a declaratory relief action contending that the outbreak was a single "occurrence" to which a policy limit of only $1 million applied instead of the aggregate limit of $2 million. (*Ibid*.) Golden Eagle defined that "occurrence" as Moon Marine's *importation* of contaminated fish from its sole supplier. (*Id*. at p. 6.)

The court denied Golden Eagle's motion for summary judgment. (*Id*. at p. 4.) Under California law, the number of occurrences is defined by the number of proximate causes. (*Id*. at p. 5.) Summary judgment was properly denied, because these occurred before importation:

> …to decide what the occurrence is in this action, we need to trace the accused products back to the original source to determine the nature of the specific defect, recognizing that according to the FDA multiple strains of salmonella might have been at work.

(*Id*. at p. 8.)

The Moon Marine recall demonstrates three ways in which food safety records may help successfully litigate food injury cases. First, the relatively low cost of developing liability evidence: the FDA investigated the processing plant in India, and public agencies paid for a number of laboratory tests. Second, the identified records likely support application of higher policy limits: the FDA identified many potential causes of illness from the fishery's documentary evidence, investigator observations, and tests that identified multiple salmonella strains. Finally, the fishery's *lack* of sanitation records likely increases the difficulty of Moon Marine rebutting causation of the underlying injury claims and of the carrier in proving that the single occurrence policy limit applies. As FSMA will require food companies to prepare and maintain even more records, future outbreaks will likely produce even more evidence of multiple causes.

Insurance coverage and CGL Coverage for third-party claims

Generally, food poisoning and allergen claims that involve bodily injury, sickness, or disease do not result in coverage disputes regarding third party liability. (See *Aim Ins. Co. v. Culcasi* (1991) 229 Cal.App.3d 209, 226.)

However, it is important not only to trigger coverage but also to address policy limits and exclusions that prevent

plaintiffs from being adequately compensated.

• Consider assignment of defendant's first party property damage claim

If the defendant's policy limits are not sufficient compensation for plaintiff's (or plaintiffs') damages, the defendants may be willing to assign their rights to first party property damage claims. These claims can arise when a manufacturer's product is contaminated by an ingredient sourced from an upstream supplier (e.g., wood splinters that cannot be removed from diced almonds that are used to make nut clusters). (See, e.g., *Shade Foods, Inc. v. Innovative Products Sales & Marketing, Inc.* (2000) 78 Cal.App.4th 847, 866.) The measure of damages for this first party claim is often based on the product's sale price, not just the manufacturer's out-of-pocket loss. (39 Tort & Ins. L.J. 844 (2004).) This first party claim will likely be easier, faster, and cheaper to prove than an indemnity claim against the upstream supplier (although settlement may also include an assignment of that claim). (See generally *Shade Foods, Inc. v. Innovative Products Sales & Marketing, Inc.*, *supra*, 78 Cal.App.4th at p. 866.)

• Consider assignment of defendant's bad-faith claim against CGL carrier

If a defendant's CGL policy fails to provide (adequate) coverage for plaintiff's injuries, consider an assignment of the defendant's bad-faith claim against its carrier. There are at least two ways that CGL insurance policies may not meet food companies' reasonable expectations of coverage. First, a carrier may unreasonably determine that a single event is the only "occurrence" that triggers coverage, so a lower limit applies instead of the higher aggregate policy limits. (Some CGL policies for food injuries also define an "occurrence" as all damages that arise out of one lot or batch of products. [See http://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2013/maximizing-insurance-coverage-for-food-contamination-claims/].)

An overly-limiting definition of "occurrence" may not meet the insured's "reasonable expectations" of coverage. (See generally CACI 2330, cmt. [citing *Century Surety Co. v. Polisso* (2006) 139 Cal.App.4th 922, 949].) California determines the number of occurrences based on the number of causes for injury. (*Golden Eagle Insurance Corp. v. Moon Marine* (*U.S.A.*) *Corp.* (N.D. Cal. Nov. 15, 2013) 3-12-CV-05438-WHA [slip op.] pp. 5-6 [citing *Safeco Ins. Co. of Am. v. Fireman's Fund Ins. Co.* (2007) 148 Cal.App.4th 620, 633; *Caldo Oil Co. v. State Water Resources Control Bd.* (1996) 44 Cal.App.4th 1821, 1828].)

However, as the Moon Marine recall demonstrates, determining the number of causes for foodborne illness can be fact-intensive and case-specific. Some courts have determined that the single occurrence of *preparing* a common source of food is the cause of a large outbreak of foodborne illness. (http://www.foodrecallmonitor.com/2012/08/10/e-coli-outbreak-constitutes-a-single-occurrence/ [discussing *Republic Underwriters Ins. Co. v. Moore*, No. 11-5075, 2012 WL 2948177 (10th Cir. July 20, 2012)].) Others have reasoned that *serving* contaminated food is an "occurrence" for each person who suffers injury. (See *State Farm v. Elizabeth N.* (1992) 9 Cal.App.4th 1232, 1237 [discussing *Mason v. Home Ins. Co. of Illinois* (1988) 177 Ill.App.3d 454, 460].)

Second, some CGL policies incorporate exclusions that may result in illusory coverage. Yogurt and cheese manufacturers may receive no benefit of coverage if their policies contain a mold and bacteria exclusion. (See http://www.foodsafetymagazine.com/magazine-archive1/april-may-2013/maximizing-insurance-coverage-for-food-contamination-claims/.) So if a food company's carrier asserts a coverage position that fails to meet the insured's reasonable expectations, consider pursuing an assignment of the manufacturer's first party bad-faith claim.

Conclusion

Food safety records can help identify target defendants, evidence of causation, and facts that trigger coverage. After FSMA is fully implemented, plaintiffs' counsel will have even more power to leverage food companies' own records against them and their insurance carriers.


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