

FOOD SAFETY NEWSLETTER

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Editorial by Jeff Gilles

The pending legislation is just the beginning of a journey leading to higher food costs, higher taxes, fewer family farms, adverse environmental consequences and more litigation. Now, not all laws are bad. And, there are a couple on the last page of this newsletter that are about research rather than blame and unwarranted penalties – for example, AB1024. I applaud Anna Caballero, who understands that increasing consumer protection is about preventing the next outbreak of E.coli by seeking the tools to understand where the pathogen came from, how it travels, grows, and where in the process from farm to fork it can be killed. Building a fence, or creating a wider buffer and creating penalties for violating those standards may feel right, but they are pointing us down the

wrong path. As a result, we have processors insisting that they will not buy from certain counties, and they want to distinguish themselves to their customers by insisting that their farmer not only build fences, but they build them higher and create larger buffers.

So what do we do? The course we are on is fraught with unintended adverse consequences.

We live in a dynamic environment. We can't fence out the birds, all rodents, a determined wild pig or the wind. We don't even know if the cow, pig, bird or wind is the problem. However, we can together create a strategic plan to identify the problem and its nature and figure out how to kill it. Unfortunately, we haven't been doing this “together”. The concept of working transparently,

collaboratively and in a bi-partisan fashion with legislators, government agencies, environmental advocates, and our respective industry competitors is a challenge. However, we need to jointly develop a funding source to create and implement a plan to not only protect the consumer from this pathogen, but also to protect the symbiotic relationship between the farmer and the environment.

Leadership is required to place us squarely on the right path. The desire to work collaboratively is out there waiting for us.

For more information on our contribution, logon to www.lomgil.com.

“Voluntary” Recalls and Third Party Insurance Claims by Paul Rovella

Shortly after the recent E. coli outbreak attributed to bagged spinach, the federal Food and Drug Agency released a statement that the tainted spinach was grown in either Santa Clara, San Benito or Monterey Counties. Experts and government inspectors descended on the Salinas Valley in order to track down the source of the outbreak. Fuelled in part by this new attention, several growers were pressured into making the difficult and costly decision to “voluntarily” recall their products from the marketplace or to “voluntarily” plow under their spinach fields.

These precautionary measures, although necessary, forced those who made them to face economic hardship. As spinach has been allowed back on the shelves of grocery stores, and as the industry begins to implement safety measures to prevent future outbreaks, the growers who took these “voluntary” safety measures may begin to search for ways to recover from the losses suffered from destroying their product. However, the affected suppliers may not be able to look to the source of the outbreak or its insurer for repayment.

I. Claims Against the Source

A third party grower, forced to suffer economic damages because of the public response to an outbreak caused by an unrelated party, probably wouldn't be successful in attempting to recover from the grower deemed responsible for the outbreak. Assuming there was no oral or written contract between growers requiring that they provide untainted spinach to consumers and suppliers, there could be no breach of contract claim. Assuming also that the third party grower did not purchase any of the tainted spinach, there is no applicable

breach of warranty claims. In addition, a third party grower seeking to recover lost profits probably could not succeed in a products liability claim because there has been no physical injury sustained by the claimant. A third party grower-claimant would have the highest likelihood of recovering damages under a claim of negligence; however such a claim would be unlikely. California courts have established that in order to succeed on a claim for negligence, a grower would have to show that the source of the outbreak owed its market competitors a duty of care and that it breached that duty when it provided tainted spinach to consumers and/or suppliers. Further, the third party claimant would have to prove that as a result of this action, it incurred damages for which it could be compensated. Duty and causation would be the biggest hurdles to a third party claimant seeking to recover based on a negligence claim.

a. Duty

California courts have held that people should be held responsible not only for the result of their voluntary acts, but also for injuries to others which are caused due to a lack of ordinary care or skill in undertaking such acts. California courts have established legal duties in cases of a particular type where liability should be imposed for the harms caused to others. In these instances, actors have a duty not to act so negligently as to disregard the threat their actions pose to others.

No California court has ever held that market competitors owe each other a duty to conduct business in a way that protects each other's expected profits. A court would be hard pressed to find that the source grower owed a duty to

another spinach grower to conduct its business in a way that would ensure that the other spinach grower would continue to earn the same level of profit from the sale of its products.

Further, public policy dictates that such a duty would be impossible to fulfill. Courts are willing to establish exceptions where duties are owed when it would be against public policy to enforce such duties. Public policy exceptions are established based on a variety of factors such as the foreseeability of harm to the plaintiff, the certainty of claimant's injury, the relation between the source's conduct and claimant's injury, the moral blame attached to the defendant's conduct, the desire to prevent future harm, the potential burden on the source, and the availability and cost of insurance for the risk involved.

Imposing a duty upon market competitors to protect the each others' expected profits could potentially result in massive numbers of lawsuits for any level of reduction in industry-wide revenues as a result of any negligible action, no matter how inconsequential, by an industry member. Any act, defensible or not, which could have lead to a downturn in the industry, would inevitably give rise to one or more lawsuits. The California court system could not handle such an increase in the number of lawsuits it hears.

b. Breach

In the unlikely event that a court finds the source of the outbreak did have a duty to protect its competitors' profits, the judge or jury must then decide whether the defendant's protective measures were reasonable under the circumstances--that is, whether there was a breach of the duty of care. If a

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fact finder determines there was a breach, there still remains the question whether that breach was the cause of the plaintiff's injuries.

A third party spinach grower may argue that the grower breached its duty by failing to adhere to the Good Agricultural Practices (“GAPs”), established by the industry and in effect at the time of the outbreak. However, the development and implementation of the GAPs were not established for the protection of other industry members' profits. They were implemented in response to bacteria outbreaks caused by consumption of certain food product for the protection of consumers from such microbial contamination. Even if the source did breach a duty, the duty breached was owed to consumers, not to its fellow spinach growers.

II. Claims Against the Insurer's Source

a. Common Law Fraud

Assuming that the third party spinach grower/claimant is not a named or additional insured on source's insurance policy, there would be no privity of contract, and thus no contract-based claims against the insurer. For the third party grower/claimant to

succeed on a claim of fraud against the source's insurer, it would have to prove: (a) false representation; (b) knowledge of falsity; (c) intent to defraud; (d) justifiable reliance; and (e) damage.

Although courts do tend to err on the side of insurance coverage, under the common law claim of fraud, the claimant must still meet the elements explained above. A claim must first be filed, and the insurer must make false representations in the analysis of those claims. Provided this does not occur, the third party claimant would not have a cause of action for fraud. However, until this exchange takes place, we would not know whether or not a third party claimant could succeed.

b. Bad Faith Settlement of an Insurance Claim

Cal. Ins. Code § 790.03 states that “[t]he following are hereby defined as unfair methods of competition and unfair and deceptive acts or practices in the business of insurance. . . . (h) Knowingly committing or performing with such frequency as to indicate a general business practice any of the following unfair claims settlement practices: . . . (5) Not attempting in good faith to effectuate prompt, fair,

and equitable settlements of claims in which liability has become reasonably clear.” The California Supreme Court has concluded that CAL. INS. CODE § 790.03(h) does not establish a private claim. In other words, private citizens cannot sue for violations of Cal. Ins. Code § 790.03(h). Therefore, A private third party grower/claimant is unable to file a bad faith settlement claim against the insurer.

However, the California Insurance Commissioner may file suit against source's insurer under § 790.03 if it is determined that the insurer did not make a good faith attempt to reach a settlement on third party claims. An insurer is not required to settle such claims; it need only make a good faith attempt to settle. So long as the insurer can produce evidence of a good faith attempt to settle the claim, then there would be little likelihood of success.

In the event a source of an outbreak like the recent E. coli outbreak is ever determined, it would still be unlikely that a competitor who has suffered economic damages due to recalling their products would be able to recover from the source.

A Statutory Look at Recalls by Tim Ibbeson

The E. coli contamination of spinach this past September brought food-safety recalls back into our living rooms and kitchens. As Paul mentioned in his article, many farmers were forced by the FDA to “voluntarily” recall their product. What does it mean to “voluntarily” recall your product? Is there such a thing as an “involuntary” recall?

Statutes in the Code of Federal Regulations define recalls and what occurs when a company fails to issue a recall on its own.

Title 21, Part 7, Subpart C, Section 7.46(a) looks at a “voluntary” recall. It states, “A firm may decide of its own volition to remove or correct a distributed product.” A firm that

does so because it believes its product to be in violation of the Food, Drug and Cosmetic Act is required to immediately notify the appropriate Food and Drug Administrative office listed in Sec. 5.115 of this chapter.

The Food and Drug Administration may also “request” a recall. Section 7.45(a) states, “The Commissioner of

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Food and Drug or his designee may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception; (2) That the firm has not initiated a recall of the product; and, (3) That an agency action is necessary to protect the public health and welfare.”

The book, *Food Safety Law*, by Schumann, Schneid, Schumann and Fagel, 1997, p. 17, states that the FDA can initiate formal judicial proceedings, but the mere threat of action on their part (the FDA) almost always results in voluntary recalls. “Under the voluntary recall process, the FDA informs the organization that other enforcement actions may be taken if the recall is not commenced as soon as practicable.”

Enforcement mechanisms can include: (1) seizure of all available

product; (2) and/or an injunction of the firm in question; and (3) criminal proceedings. Title 21 of the United States Code, Chapter 9, Subchapter III, Sections 332-335 deal with the process of enforcing an FDA requested recall when a company fails to comply.

Enforcement, however, is a rarely used tool within the FDA. While it has the authority, through the Food, Drug and Cosmetic Act, to initiate judiciary proceedings if a firm doesn’t initiate its own recall or it doesn’t comply with an FDA “requested” recall, many firms do comply. The food industry is very competitive and a company’s brand name and reputation are at stake.

It is for these reasons that you seldom hear of “involuntary” recalls. Additionally, “voluntary” recalls are the fastest and most effective way to protect the consumer. Title 21, Part 7, Subpart C, Section 7.40(c) of the

Code of Federal Regulations reads, “Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, or discovers that the violation is continuing.”

To summarize, most companies “voluntarily” initiate their own recalls and the FD&C Act does not statutorily give the FDA the authority to “order” a recall. Yet, the FDA may “request” a product recall. And if the firm is not willing to initiate removal of the product from the marketplace without an FDA written request, it (the FDA) has the legal authority to remove the product from the marketplace.

Insurance Policy Considerations by Ken Gorman

As a result of the E. coli incidents here recently, a number of our clients have asked us to review their insurance policies for applicability to claims stemming from contaminated food. We have analyzed policies from several different insurance carriers in this regard.

There are two common things that we wanted to bring to your attention in obtaining, renewing or negotiating your next policies.

First, many carriers offer what they call “recall” insurance, which generally gives about \$100,000 in coverage for labor and proven lost profits in the event of a recall. The problem with the coverage is that it, as it reads, is

not triggered unless there is a mandatory government recall, neither the FDA, CDHS or any other government entity has the authority to issue a mandatory recall. While insurance policies are subject to interpretation by the court, a plain reading of these policies shows they are essentially never going to be applicable. We do not believe the policies are worth purchasing unless the language is changed.

A related type of policy we have seen is “contaminated produce” insurance. At first glance that policy seems more attractive because it does not require a recall by the government to be applicable, it applies if you voluntar-

ily recall or withdraw your product from the market. The problem with some of these policies is that they do not apply unless your product is actually contaminated. First, as we have seen in food-borne illness cases, it is very difficult if not impossible to prove that product was contaminated on a particular farm. Secondly, to get the benefit of the policy you would have to prove that your food was contaminated. The obvious downside to this is that it could expose you to millions of dollars worth of damages; not a sound economic trade off. Other policies apply if you recall your product because contamination is suspected. The policies generally have limits of \$100,000.

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Thus, we urge you to review the language of any “recall” or “contaminated produce” coverage with your broker before purchasing it.

The other item that we feel is important is the “self-insured retention” (SIR). This has become increasingly common in commercial policies in the past decade.

A SIR is similar to a deductible. It requires the insured to pay for the first part of any claim before the insurance company’s obligations to defend (provide attorneys) or indemnify (pay for damages) apply. Generally, the higher the self-insured retention, the lower your premium. The availability of self-insured retention varies greatly from carrier to carrier.

You will have to explore that with your brokers to see how much the benefits of a lower premium are offset by the cost of the SIR. Generally, attorney’s fees, consultant/expert costs and testing costs that you incur all count against your SIR. Thus, in a case of a food-borne illness case, small SIR’s (\$10,000-\$15,000) are consumed very quickly. Given the magnitude of food-borne illness cases, it would not be unusual to reach a \$50,000 or \$100,000 SIR even before a suit is filed.

Another advantage to a large SIR is that it gives you control over the case up to the exhaustion of the SIR: you get to pick your own lawyers and consultants; you are not stuck with

the ones your insurance company chooses. Virtually every commercial general liability policy gives the insurance company, not the client, the right to appoint the attorneys to defend the case. Our clients and our firm have found great reluctance from some of the insurance carriers to having ourselves or other firms with experience in agribusiness food-borne illness law defend them; the carriers tend to stick with law firms they know and have used in the past, regardless of their experience. With a large SIR and a firm familiar with the case, as well as your business, you might have more success getting the law firm of your choice to be appointed by your insurer.

In a Crisis...It’s Always “Think” First by Greg Larsen

In the heat of a crisis, it is natural to want to react immediately to either correct misstatements or to simply make your case.

After all... “HOW could they say THAT about US?”

But, in virtually all cases – when in a crisis – the best course of action is to resist that immediate temptation.

Take a breath. Determine a clear course of action. Build an effective strategy.

Communications in a crisis are often complicated by the need (real or imagined) to move quickly, heated emotions and the lack of complete information or adequate research. This cannot always be helped. But, more times than not, these issues can be overcome and the risks and costs of miscommunication mitigated.

While all cases and circumstances are different, there are a few basic steps

you can take to help you take control of the communications environment in a crisis:

Do not respond to media or speak publicly until you are as prepared as possible.

Gather all of the facts – good and bad – so your thoughts are clear and you can anticipate what others might say or know.

Use the resources of your team to weigh ‘all’ of the implications (legal and otherwise) of what you might say and how other audiences might interpret your comments.

Set up a clear process for reviewing information or requests for comment.

Identify and focus on the audience with whom you need to communicate.

Designate and train an individual or individuals to speak on your behalf.

Know exactly what you ‘want’ to say and stick with it. Stay ‘on’ your message.

In working through a crisis, an outside set of eyes and ears can be invaluable. This should be someone you can trust, with whom you can work and who offers the perspective of someone who is not immersed in the details of your business or crisis. Remember, most of the people with whom you will likely need to communicate will not have the background or information you do. How you communicate with them will greatly influence the outcome.

The rules of clear communications apply more than ever in a crisis. If you do not present your case publicly in words and terms your audiences will understand, you cannot achieve your goals.

Safe Produce: Applying Good Agricultural Practices to the Production and Handling of Fresh Fruits and Vegetables

by Dr. James W. Rushing, Clemson University, Coastal Research and Education Center

Historically, illness was not associated with eating fresh fruits or vegetables. Very little attention was given to the idea of preventing microbiological contamination of produce. Of particular importance was the indiscriminate use of animal manure as fertilizer. The industry has changed dramatically in the past decade. The family farm has all but disappeared in the United States. Corporate production is the norm. To maintain a consistent year-round supply of the commodities we want, we source our food from most continents on the globe. The National Geographic Society today recognizes 191 independent nations and USDA statistics indicate that we import food from approximately two-thirds of those countries. In some parts of the world, fresh fruits and vegetables are still produced and handled in a primitive fashion. Food safety is not just a local concern. It is a worldwide affair that impacts every consumer.

Approximately 20 years ago, fresh produce began to be more widely implicated as a potential carrier of human pathogens. Growers and handlers were reluctant to accept the idea that consumption of their products could potentially cause illness. Outbreaks of illness were sporadic, isolated, usually small, and seldom linked to consumption of fresh produce. Industry was slow to adopt safer handling practices. Only the companies that were directly impacted by an outbreak were inclined to take proactive steps to implement food safety programs.

In 1998, the US-FDA released formal guidance for reducing microbial risks on fresh produce. Good Agricultural Practices (GAP) and Good Manufac-

turing Practices (GMP) were specifically defined as a means of reducing the risk of illness (US-FDA, 1998). This marked the beginning of the modern era in fresh produce safety. Today that guidance document is our primary point of reference. Seven broad areas were identified for the implementation of food safety principles: water for production and processing; use of animal manures and municipal bio-solids; worker health and hygiene; sanitary facilities for workers; field sanitation; packing facility sanitation, and; transportation. Development and implementation of specific safety practices relative to each of these broad areas are processes that are ongoing.

An overriding factor for industry in the adoption of any new practice is cost. The cost was reasonable for the implementation of a food safety program in the early 1990s following two outbreaks of salmonellosis associated with consumption of fresh-market tomatoes, considering that no additional outbreaks have been associated with that specific company (Rushing, 2001). In contrast, the cost of an apparent failure of a program for green onions has been enormous due to outbreaks of hepatitis in 2003 (Calvin, et al., 2004). In both of these cases, evidence that fresh produce was the source of illness was circumstantial, although epidemiological reports are convincing. The costs of repeated outbreaks, such as those associated with imported cantaloupes resulting in a detention order on Mexican suppliers, are enormous and disastrous for the associated industries (US-CDC, 2002; US-FDA, 2002).

made sincere, focused efforts to implement GAP-GMP in all steps of their operations. Others continue to show the lack of interest and poor understanding of food safety practices. Of special concern is the attention, or lack of attention, to training programs for workers to ensure that the awareness of the importance of safe practices permeates every level of activity within a company. Social issues play a critical role in effective communication between management and the work force. The degree of sensitivity to the cultural background of workers can determine the success or failure of any training program.

Processing water quality management is absolutely critical to food safety. In rare cases, employees have an in-depth understanding of the scientific principles involved in maintaining the quality of processing water. But more commonly workers have had little or no formal training and there is a tendency to “cookbook” the adjustment and regulation of sanitizers in water. The importance of water chemistry, particularly pH, on the efficacy of some sanitizers is seldom understood and frequently is ignored. Industry managers often do not understand the benefits or the limitations of technology that is available for managing water quality. Proper management at this step can reduce decay as well as help ensure food safety.

Keeping records of GAP-GMP practices is perhaps the greatest challenge within any company. Failure to keep adequate records suggests a lack of due diligence and good faith on the part of management and may result in liability issues if people become ill.

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Those companies that do it well often do it to excess. Others regard it as a nuisance and may take only a casual approach to record-keeping if in fact it is done at all.

Reliance upon third-party auditors may give companies a false sense of security about the effectiveness of their food safety programs. While auditors have a valuable role in the industry, managers must recognize that an audit is only a snapshot of the activity in the company on the day of the audit. Food safety is a constant process, not simply a preparation for an inspection. In a case study of a wholesale restaurant supplier (Rushing, unpublished) end users each

demanded their own audits of the wholesaler's facilities at the wholesaler's expense, imposing a tremendous cost to the wholesaler and demonstrating the excess that can occur in auditing requirements.

Public agencies, both state and federal, have made invaluable contributions to the advancement of safe production and handling practices in the fresh fruit and vegetable industries. Numerous training programs have been developed and the educational materials made available to all interested parties (JIFSAN, 2002; Osborne, et al., 2003; Rangarajan, et al., 2003). The private sector has responded, in general, in a positive

manner but deficiencies remain. We in government and academia can do much to help develop effective policy and regulations, but it is business that drives change. The industry responds most quickly when it realizes that practices that help ensure food safety usually help ensure better quality of fresh produce and thus enhance profitability. Teachers and trainers should attempt to integrate the concepts of safe handling practices with routine business activities to minimize the likelihood that contamination of food will occur, ensuring that the U.S. will continue to have the safest and most abundant food supply in the world.

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CURRENT STATE AND FEDERAL FARM BILLS

LEGISLATOR	BILL	SUMMARY	STATUS
Florez	SB200	Adopt recall and sanitary regulations, license growers, create inspection program, establish civil penalties for violating laws.	Passed 3-2. Sent to Health Committee. To be heard 4.11.07.
Florez	SB201	Prohibit diverting water for irrigation, prohibit use of raw manure, toilet facilities for field works, prohibit using water that exceeds contamination levels, prohibit putting into production or distribution leafy greens that do not meet contamination standards, establish HACCP & GAP standards for growers.	Passed 3-2. Sent to Health Committee. To be heard 4.11.07.
Florez	SB202	Establish coded lot numbering system (Julian dating) to trace produce back to the field of origin, identify recall coordination teams.	Passed 4-1. Sent to Health Committee. To be heard 4.11.07.
Maldonado	SB358	Legislative intent to establish BMPs for production and processing.	Referred to Committee on Health. To be heard 4.25.07
Maldonado	SB486	Non-substantive changes to § 78581 of Food & Ag Code.	Referred to Committee on Agriculture. To be heard 4.17.07.
Maldonado	SB517	Additional funding successful candidates using state conservation programs on agricultural land.	Referred to Committee on Agriculture. To be heard 4.17.07.
Caballero	AB1024	Appropriate unspecified funds for WIFSS for research that increases knowledge and scientific understanding about causes and detection of food-borne illnesses.	Referred to Committee on Health. To be heard 4.24.07.
Caballero	AB1026	Legislative intent to enact legislation to present to voters a bond measure to fund tertiary treatment of water sources used to wash leafy greens.	May be heard 3.25.07.
Caballero	AB1604	Non-substantive changes to § 11501 of Food & Ag Code.	First hearing date set. Cancelled 4.11.07 at request of author.
Caballero	AJR13	Request additional funding from federal government to conduct research to prevent E. coli O157:H7 contamination of leafy greens. Funds to WIFSS.	Referred to Committee on Health. To be heard 5.01.07.
Farr	HR912	Provide \$26M for food safety research, emergency funds for growers who suffered losses during spinach outbreak.	Referred to House Committee on Agriculture 2.08.07.
Durbin	S654	Establish Food Safety Administration, performance standards for contaminants in food, inspection of food establishments and production/processing facilities, conduct monitoring of animal and environmental effects on farming, establish requirements for traceback.	Referred to Senate Committees on Ag, Nutrition and Forestry 2.15.07.
Strickland	AB698	Sets penalties for making false food-borne illness reports.	Referred to Committee on Judiciary. No hearing date scheduled.