

The Changing Face of FOOD SAFETY



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FOOD INDUSTRY EXECUTIVES ARE FEELING THE FOOD SAFETY HEAT. While liability for defective food products has always been with us, recent lawsuits over products from pet food to spinach illustrate the increasing complexity of protecting against food product liability exposure in a time of rapid globalization and widespread use of commodity crops whose origins are far-flung. *What can you do to protect your company and your stakeholders from the potentially severe legal consequences of producing and distributing food in today's world?*

The authors' practice focuses on complex, multi-case litigation and crisis management primarily in the food, agricultural and biotech/pharmaceutical areas. They served as national counsel for the major producer of StarLink genetically modified corn in multidistrict federal litigation, and as lead counsel for one of the two major defense groups in the fen-phen diet drug state and federal multidistrict litigation.



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DURING 2007, MORE THAN 50 CLASS ACTION LAWSUITS WERE INITIATED against a pet food manufacturer after contaminated wheat gluten from China was found in its domestically produced products.

In 2006, hundreds of consumers fell ill after eating spinach contaminated with the E. coli bacteria. In the litigation that followed, attorneys filed suits against producers and packagers on behalf of allegedly injured plaintiffs seeking, in some instances, millions of dollars in damages.

Just recently, the Wall Street Journal again reported the discovery of a prohibited substance in food, this time in ginger imported from China. At a minimum, the companies involved can expect to suffer substantial economic and commercial losses. In each case, pinpointing how the contamination came into the food supply has proven elusive making it difficult to limit the liability exposure to any one culpable party in the food chain.

Though liability for defective food products has always been with us, these examples illustrate the increasing complexity of protecting against food product liability exposure in a time of rapid globalization and widespread use of commodity crops whose origins are far flung. Frequently, the protection of each participant in the food supply chain from substantial liability in a case of food contamination may only be as good as the solvency of its suppliers, the strength of its insurance coverage and the sophistication of its contracts.

The far-reaching impact of a single contaminated ingredient such as the wheat gluten or ginger underscores both the urgency of protecting the food supply and the need for food producers to protect themselves from litigation exposure.

REGULATORS, LEGISLATORS AND THE FOOD INDUSTRY HAVE ALL PUT FORWARD INITIATIVES designed to ensure the safety and security of the food supply (*see box*). In combination, these proposals address multiple locations in the supply chain, and involve the development of "best practices" in the industry, increased authority for the FDA,

and systems for pushing responsibility for certifying the use of best practices upstream to food importers.

It is beyond the scope of this article to evaluate the likely effectiveness, cost, or trade implications of these proposals.

Rather, in light of these new proposals, this article addresses the potential for liability exposure of those in the food industry when the next incident of food contamination occurs, as it invariably will. In addition, this article offers steps that the food industry can take to reduce or limit that exposure.

■ *Background: Food Safety Litigation*

IN THE UNITED STATES LEGAL SYSTEM, IT IS A VIRTUAL CERTAINTY THAT LITIGATION WILL FOLLOW any injury that is traceable to an adulterated food product. Regardless of outcome or ultimate exposure, litigation is costly, time consuming, and carries costs to the reputation of a company or a brand. Moreover, liability can attach to a food producer, even in the absence of any demonstrable fault, and even if the company has employed the most up to date preventive measures, under principles of strict product liability.

The foregoing examples illustrate the range of situations that can result in potentially crippling litigation when an unsafe product enters the food supply. Litigation has also ensued in the absence of either personal injury or any credible threat of harm resulting from a food product. In the first case involving genetically modified ("GM") corn (*Starlink*), as well as the accidental release of an unapproved strain of genetically modified rice (*Liberty Link Rice*) last year, plaintiffs' attorneys brought claims arising from alleged economic harm associated with the presence of unapproved GM materials in the food supply, as well as claims for customer rebates even though neither of these products presented a safety hazard.

Despite valid legal defenses to the merits of many of these claims, these non-injurious products resulted in

■ *Summary of Recent* FOOD SAFETY PROPOSALS

Regulators, legislators and the food industry have all put forward new initiatives designed to ensure the safety and security of the food supply ...

■ **The GMA has published 'A Commitment to Consumers to Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnership.'** As described in the *Four Pillars* plan, the first two pillars "raise the bar" by incorporating certain quality assurance features of supplier agreements into industry "best practices."

The remaining two pillars address supporting increased capacity for FDA enforcement, and calling for increased international collaboration for food safety.

■ **Representative John Dingell (D-MI) has proposed legislation to increase the FDA's inspection authority and capabilities,** require food to be imported into ports of entry in close proximity to FDA testing laboratories, impose country of origin labeling requirements for food, and mandate the creation of safety assurance guidelines with which importers would have to agree to comply.

The proposed legislation, H.R. 3610, would also allow expedited inspections for importers who voluntarily agree to comply with food safety and security guidelines.

■ **The Food and Drug Administration ("FDA") has prepared a 'Food Protection Plan,'** proposing several regulatory changes, requesting additional legislative authority to implement initiatives directed at domestic and imported food safety and proposing some mandatory and some voluntary security measures to be implemented by members of the food industry.

In addition, the Interagency Working Group on Import Safety has presented a report to the President, referencing the FDA's plan, and echoing the call for the use of both mandatory and voluntary certification programs for importers of food and food products.

■ Finally, though not enacted specifically in response to the more recent food safety incidences, **the Bioterrorism Act of 2002 may be relevant to the overall food safety picture,** because its requirements for identifying and retaining records of the source of food products and ingredients may make it easier both to trace the origin of a defective food product once it is discovered, or to assess the risks associated with an ingredient or product before it is placed into a final consumer product. ■

claims for hundreds of millions of dollars of economic loss, as well as substantial litigation costs. Litigation of this type presents, at worst, serious liability exposure and at best an expensive and time consuming distraction for the producer or seller of the food product.

■ *Do New Proposals Affect Liability Exposure?*

THE SINGLE MOST IMPORTANT FACTOR in whether the new food safety proposals will reduce the liability exposure of food manufacturers and sellers is *whether they are likely to be effective.* Any system that could completely prevent contaminated or unsafe food from entering the system would unquestionably reduce or eliminate liability exposure.

In this instance, the regulatory and legislative proposals expressly call for, and to some extent rely upon, active and vigilant participation by the food industry. Beyond the incentives for participation outlined in the FDA's food protection plan and Rep. Dingell's legislation, reducing or eliminating liability exposure gives industry a substantial stake in their effectiveness.

However, eliminating the sources of potential liability often requires action by suppliers and producers outside of the reach of US law and regulations and raises almost impossible hurdles of identifying the distant source of the products or ingredients that may cause harm.

Assuming that proposed preventive measures, like most human endeavors, are imperfect, it is less clear that the full implementation of all of these measures by themselves will provide meaningful protection from liability for members of the food industry.

First, people injured by a defective or adulterated food product can recover in the absence of any fault on the part of the manufacturer or distributor, under strict product liability laws. This means that even 100-percent compliance with all applicable safety precautions will not necessarily forestall litigation.

Second, to the extent that the *Four Pillars* proposal, and the safety measures called for by the FDA, in fact "raise the bar" for industry, they do establish the standard against which companies will be judged under a fault-based theory of liability, such as negligence.

This means that the consequences of not fully com-

plying with the recommended practices could translate into additional liability exposure by giving plaintiffs very concrete evidence of a failure to meet an acknowledged standard of care. Well-intentioned adoption of rigorous company policies designed to embrace best practices can increase liability exposure in the absence of consistent compliance, as failed internal policies can become the measuring stick of fault.

Unless a company has a high degree of confidence that it can fully comply with best practice policies, it should not blindly enact aspirational goals as company policy, and best practices should be developed with an eye to what is realistic in terms of compliance.

THE FDA PROPOSAL MAY PROVIDE SOME LIMITED PROTECTION against liability. In its discussion of proposed required measures to protect the food supply against intentional tampering, the FDA asks for legislative authority to provide companies who comply with the listed requirements a defense against lawsuits arising from intentional tampering.

Importantly, however, this protection is not proposed in the context of unintentional contamination of the food supply, and all of the recent food scares have involved unintentional incidents. It would be far more useful to the industry, and make the incentives for compliance more meaningful, if the final legislative enactment contained a similar defense for strict product liability or negligence actions based on unintentional adulteration, if a company can demonstrate full compliance with food safety measures.

Given the emphasis in all proposals on the need for an effective public-private partnership in protecting the food supply, such protection would arguably be a logical and appropriate incentive to consider.

■ *Do New Proposals Facilitate Identification Of the Source of Contaminated Food?*

IN CASES INVOLVING HARM FROM FOOD PRODUCTS, IT IS OFTEN DIFFICULT TO IDENTIFY THE PARTY ULTIMATELY RESPONSIBLE, particularly if the suspect ingredient is a commodity crop or other type of ingredient subject to commingling at virtually every stop on the distribution chain.

In the case of the contaminated ginger, it will likely be impossible to identify the original source of the contam-

ination, because ginger is grown in multiple locations and commingled before export. As a practical matter, moreover, it is highly unlikely that a ginger farmer in China, even if identified, would have the resources to compensate an injured party or to provide indemnification to those down the distribution chain.

Implementation of the Bioterrorism Act, in concert with the country of origin labeling requirements in Representative Dingell's proposed legislation, may help to some extent by requiring the participants along the distribution chain to keep records of origin and to provide information about the origin of the ingredients or assembled products.

There are, however, important shortcomings. As with the Chinese ginger, knowing the country of origin would not necessarily help identify the specific producer of an overseas ingredient.

Similarly, in the case of commodity crops, domestic or imported, that are commingled shortly after harvest, it may never be possible to effectively identify the origin of the ingredients at issue.

A further obstacle to placing liability on the shoulders of the party truly responsible lies in the fact that the originating company may not be subject to the jurisdiction of the US courts, and may have no assets in the US from which to recover even in the event of a judgment. Further, in certain countries, it may be very difficult for a US food producer to recover from a local company in local courts. Even if a foreign forum is available, full indemnification may not be available to a downstream purchaser under local law.

The current proposals do seek some authority for the FDA to conduct on-site inspections of foreign facilities, as part of the consideration for certain import approvals. They do not, however, alter the landscape in terms of private remedy against a foreign entity.

■ *What Should You Do To Manage and Minimize Exposure*

POTENTIAL LIABILITY EXPOSURE FOR HARM CAUSED BY PRODUCTS IS A FACT OF COMMERCIAL LIFE in the US, a fact largely unchanged by the current food safety proposals. There are, however, certain steps that can be taken to prevent or minimize that exposure.



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■ **Implement a crisis management strategy.** The decisions made in the immediate aftermath of a food crisis (*i.e.*, a product recall) affect not only the course of subsequent litigation, but the reputation of the company and its brands.

Often, the best policy is to contain and minimize the problem through immediate, proactive and carefully articulated action publicly announced at the discovery of a problem. “*Rope-a-dope*” may be a good defense in boxing, but not in a major product liability exposure. Having a proactive strategy in place before the crisis hits that is informed by the ongoing needs of the business and by litigation management will help position the company to take immediate strategic steps that serve both interests.

The strategy should include assessment of both the likely impact on the reputation of the company’s products and on litigation exposure, and should include an immediate plan of mitigation and public relations measures.

The plan should include clear lines of authority and communications as well as timelines for implementing crisis response steps, and should be reviewed by counsel as well as relevant business leaders, and rehearsed.

■ **Audit current practices.** As discussed above, companies should be aware that any failure to implement the best practices described in the *Four Pillars* could increase the possibility of fault-based liability.

In addition, even in the absence of the *Four Pillars*, continued dealings with suppliers who are known or suspected to have poor quality control practices could unnecessarily increase the risk of a problematic product (thus increasing both exposure and the likelihood of litigation) and/or increase the risk that the company might be found at fault in the event of an unsafe food product.

To this end, companies would be well advised to conduct an audit of their procurement policies, practices and contracts to ensure compliance with industry best practices, and identify any vendors or suppliers that may be of concern.

■ **Review contracts with suppliers and customers.** In addition to ensuring that supplier contracts contain the quality assurance components described in the *Four Pillars*, to the extent possible all such contracts should be reviewed for appropriately worded indemnification language, and revised or renegotiated, to the extent possible, if they do not contain satisfactory language.

In addition, though contractual limitations on liability would not protect a company from a products liability claim based upon personal injury, it may be possible to limit liability for certain economic damages asserted by a company’s customers, particularly in a recall situation where retailers might look to their immediate supplier for recovery of recall costs as well as consequential damages.

Where appropriate, customer contracts should therefore also be reviewed to ensure that any permissible liability limiting language is included or excluded consistent with negotiated allocations of risk between the parties.

■ **Review insurance coverage terms and limitations.** Liability policies should be reviewed to make sure that existing terms cover the types of liability envisioned, and do not contain any relevant exclusions.

In addition, companies should consider requiring suppliers to maintain appropriate coverage, and potentially to list the company as an additional named insured on the relevant policy.

■ **Review of contracts with importers.** For companies that purchase directly from overseas importers, these contracts would optimally include, in addition to all applicable points raised with respect to domestic suppliers, a clear dispute resolution process, such as enforceable arbitration provision in an appropriate forum governed by the law of a predetermined jurisdiction.

■ Conclusion

THE BEST DEFENSE AGAINST WIDESPREAD EXPOSURE for improvement in the wake of another food safety crisis is, self-evidently, ensuring that the crisis does not occur. For this simple reason, adoption of and rigorous adherence to industry “best practices” could well reduce litigation and liability exposure.

To the extent litigation cannot be avoided, however, its consequences can be managed proactively, by developing a protocol for crisis management ahead of time, taking a careful look at the company’s practices and those of its suppliers, ensuring adequate insurance coverage, and structuring commercial relationships and contracts in the way that gives the broadest possible protection. ■