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Food scientists worry about food safety risks. Food lawyers worry about legal risks. While these two perspectives could superficially seem to oppose one another, sophisticated practitioners in each field study both disciplines and use their knowledge to deliver safe food with a low legal risk. Ultimately, good food lawyers recognize that food safety considerations must drive legal risk decisions, and considerations that undermine food safety cannot lower legal risk.

The scientific process has at its foundation the six steps of the scientific method:[1]

> (1) Purpose/Question—Ask a question. (2) Research—Conduct background research. Write down your sources so you can cite your references. (3) Hypothesis—Propose an educated guess about what you expect to find. (4) Experiment—Design and perform an experiment to test your hypothesis. (5) Data/Analysis—Record observations and analyze what the data means. (6) Conclusion—Conclude whether to accept or reject the hypothesis. Communicate your results.

Food scientists are scientists. The natural curiosity that led many of them to their chosen profession was supplemented by years of deductive training. They generally approach a problem by following the scientific method and figure out, for example, the root cause of the foreign material in the food or the source of the foodborne illness and then provide a testable solution for that cause.

Food lawyers' natural curiosity is informed by years of training in risk avoidance and mitigation, supplemented by years of exposure to plaintiffs' lawsuits of varying degrees of legitimacy. Food lawyers are generally charged with lowering legal risk and consequently, exposure to lawsuits.

Why are food scientists and food lawyers sometimes at odds with one another? Partially because the transparency and objectivity of the scientific method does not translate well into the subjective, plaintiff-driven aspects of legal risk—particularly within torts (such as negligence), where four ele-

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1. Anne Marie Helmenstine, *6 Steps of the Scientific Method*, ABOUT EDUCATION (Jun. 15, 2016), http://chemistry.about.com/od/chemistrylab/fl/6-Steps-of-the-Scientific-Method.htm.

ments must be demonstrated to provide remedy to a plaintiff. A negligence claim involves four elements to recover a remedy:

1. The existence of a duty.[2] The duty at issue could be, and is, often as simple as the duty not to act negligently.[3]
2. The breach of a duty.[4] The breach in food safety often involves failure to implement a food safety system reasonably designed to detect and prevent unsafe food or a negligent failure in the execution of such a system.[5]
3. The existence of harm.[6] The harm caused by a food-safety failure is generally illness (or in the most severe cases, death) due to the unwanted presence of a chemical, biological or physical element in the food.[7]
4. Causation.[8] For a plaintiff to recover for harm, it must have been caused by the defendant's negligent action or inaction.[9]

The work of the food scientist can readily be mapped onto the tort analysis necessary for the tort-plaintiff attorney's case following the scientific method laid out above. That is, the speculative work of the food scientist in positing and testing his or her root cause hypothesis (for example, the food safety system generally or the specific injury at hand) might complete the causal connection needed to press the case by the plaintiff's lawyer. Effectively then, it is feared the food scientist will have done the plaintiff's work for her. But this contrived worst-case scenario does not very well track the real-world interactions of food scientists and the lawyers who work with them to control food safety risks.

Food safety lawyers have learned that perceived reductions in legal risk, at the expense of real food safety, is a terrible exchange. Food lawyers know that interference with the work of food scientists to deliver safer food does

2. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 7(a) (AM. LAW. INST. 2011).

3. *Id.* § 6 cmt. F; RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 2, 7 (AM. LAW. INST. 1998) (stating that a harm-causing ingredient of a food product constitutes a defect if a reasonable consumer would not expect the food product to contain that ingredient and that such defect exists when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product).

4. Dunning v. Nat'l R.R. Passenger Corp., 2014 WL 4275508 *1, *2 (D. Conn. Aug. 28, 2014).

5. *Id.* at *3.

6. *Id.* at *2.

7. *Id.* at *3.

8. *Id.* at *2.

9. *Id.*

not reduce legal risk. Accordingly, food lawyers have developed best practices to ensure that the work of food scientists are not impaired by legal considerations, while mitigating the risk that the work of food scientists will generate unnecessary fodder for plaintiffs' lawyers.

Food lawyers and the companies they represent care about the health and well-being of consumers and their families. Unlike other industries, food lawyers, food scientists, and the companies they represent have to eat what they produce and sell. Understandably, food companies and their legal counsel generally understand and agree to appropriately address plaintiffs in the event of failures in the food safety process, especially when such harm is the result of fault.

But baseless lawsuits and food-safety fishing expeditions often result in less safe food. Unfounded fishing expeditions require significant resources on a company's part—resources which could otherwise be used to respond to legitimate subpoenas, interrogatories, and interview requests. Time and money spent on illegitimate claims take resources away from legitimate ones, on both sides of the bench. As the proportion of illegitimate to legitimate claims increases, companies increasingly expect illegitimacy and then tend to resolve legitimate cases less quickly. As a noted food lawyer and consumer educator, Bill Marler, has observed, the result is that ". . . pursuing false claims only increases the risk that more people will get sick."[10]

Food scientists and food lawyers share the desire to create and implement robust food safety programs to protect consumers (and their corporate clients) from the harms that can result from unsafe food. Developing a strong quality assurance program is also an excellent way to assess food safety risk and drive continuous improvement.

It is important to recognize, acknowledge, and gain alignment from company leadership that as quality assurance programs and assessments improve, become increasingly strict, and expand into new areas previously largely unregulated, more risks will be uncovered, particularly in early phases of operation. In fact, that is the goal! It is important to create a culture that recognizes that detection of risks is a good thing, and that "no findings" can be an indication of an altogether absent program, rather than a perfect, errorless program. It is imperative that leadership understands that the identification of risks is a good thing and that they appreciate the importance of addressing any concerns identified appropriately.

Here are a few best practices for a food-safety monitoring and reporting system that inspires leadership confidence and enables the food scientists to do their jobs without creating unnecessary legal risk:

1. Document solutions, not just problems. Food scientists, including quality assurance team members and auditors, should document solutions in the same manner that they document concerns identified.

10. Bill Marler, *Lawyers, Microbiologists, and Safe Food*, FOOD SAFETY NEWS (July 1, 2010), www.foodsafetynews.com/2010/07/lawyers-microbiologists-and-safe-food/#.WHpsk7Yrl_U.

Doing so is good practice to ensure that potential identified solutions are implemented. Further, this ensures that later observers, including internal auditors, regulators, and plaintiffs' attorneys, find the solution affiliated with each problem. While time may have been of the essence in implementing the solution (and the creation of a paper trail was understandably of secondary concern), to a later observer, in the absence of solution documentation, it may erroneously appear that nothing was done to address the problem.

2. Put problems in context. As problem-solvers by nature, food scientists tend to focus on the five things that could be improved, rather than the ninety-five things that were beyond reproach. This narrow focus on defects gives a misleading presentation to later reviewers, who only see a record of everything that went wrong. If an auditor or quality assurance professional only documents the five problems, a later observer might wrongly infer that 100 percent of the observations of the food safety system were concerning. Over time, hundreds or thousands of problems may be identified, so it becomes increasingly important to keep proportion in context.
3. Do not hyperbolize to inspire action. Create a reporting and action system that identifies concerns and their severity appropriately. In a well-designed system, food safety concerns are remedied promptly without the need for hyperbole. If an identified, serious food safety concern requires hyperbole ("this is the worst facility/line/product I've seen in my long career as a food safety scientist") to garner attention and action, a better, more reliable system should be designed and implemented.
4. Strike the right balance of blame and accountability. Premature or poorly placed blame may result in defensive finger-pointing, that can undermine food safety and problem-solving. Defensive emails may create more problems than they solve, particularly if tempers are high. It is often more productive to identify and address root causes without resorting to placing blame on a particular individual. Generally, a documented and audited fix will lead to a better long-term outcome that inspires cooperation and encourages problem identification and resolution. Assignment of blame, on the other hand, can lead to secrecy, burying of problems, and finger-pointing that can undermine effective resolution and systematic improvement.
5. Characterizations of findings or opportunities for improvement should be concise, objective, and matter-of-fact. When food safety concerns arise, often well after the fact, the context of the original records of audits and opportunities for improvement are almost always absent. Accordingly, it is important to take into account that even preliminary speculation as to causation, even if at the observation it is acknowledged that it is likely to be wrong in accordance with the tenants of the scientific method, may later be presented by

> plaintiffs out of context as known fact. Similarly, even summary conclusions as to whether an action or process is in compliance with regulations or is permitted by law—even if they turn out to be misunderstood—may later be presented out of context as knowing, nefarious behavior. Food scientists know, and the scientific method assumes, that such speculation is premature by its nature and often turns out to be wrong. But tort plaintiffs may not be nearly so accommodating, and the speculation as to hypothesized cause could later be misconstrued and may be almost impossible to surmount, even though it may have been based on incomplete information (at best) when offered.

Finally, the legal and food science teams should work together to develop a records management program. Complete records are necessary to ensure and demonstrate a good food safety program. However, records kept past their usefulness for a specific concern only enlarge the pond for illegitimate fishing expeditions that distract from legitimate food safety needs. Accordingly, a records management program should be developed that takes into account:

1. Regulatory (compliance) requirements—What are the retention requirements established by state and federal regulations or auditing standards?[11]
2. Business (operations) requirements—What records are necessary for operational, analytic, and improvement purposes?
3. Legal (contractual) requirements—Are there contracts in place that establish record-keeping or audit timelines?

While law and science are sometimes at odds, food safety is common ground where the two considerations operate in tandem. Accordingly, any perceived improvement in legal risk at the expense of actual food safety is a false improvement and a poor exchange. Good food lawyers and food scientists work together with this understanding to create and implement food safety and reporting systems designed to minimize the risks of unsafe food for consumers and the companies that serve them.

11. 21 C.F.R. § 1.360 (2004).