The new Food Safety Modernization Act (FSMA) regulations mean you must take additional care to address the entire lifecycle of a complaint. Here’s what you need to know.

“I know a mouse when I see one, and this is a mouse in my fried chicken.” Such claims are not uncommon, and furthermore, the rapid proliferation of such claims—even those that are unfounded—through media outlets can have significant ramifications on brand reputation. In this particular case, a triage analysis completed within 48 hours of the sample being received provided indisputable scientific proof that the alleged mouse was in fact no more than a clump of fried breading. Photographs and a narrative report describing the analysis were sufficient to calm the consumer and resolve the claim.

While there have always been benefits to addressing foreign matter complaint samples in a timely, accurate and transparent manner, the new and pending Food Safety Modernization Act (FSMA) regulations will soon require it. A level of effort that was previously sufficient to mitigate internal risk is no longer necessarily enough to address all aspects of an FDA investigation, which can now request access to the records of any product with “reasonable belief” of adverse health consequences.

As a result, additional care must be taken to systematically address the
entire lifecycle of a complaint, from the initial complaint through claim resolution. For this reason, more companies are choosing to outsource such investigations to well-qualified independent laboratories that have the expertise and experience necessary to provide true forensic analytical solutions supported by rigorous scientific proof. Here are several key topics that you should consider when evaluating your company’s strategy in dealing with foreign-matter complaints from consumers.

**Consumer confidence**

Sample preservation and collection is the first critical step in establishing the facts of a case, yet many consumers (or their attorneys) hesitate to relinquish key physical evidence directly to the company they believe caused the problem. In contrast, consumers seem to be more willing to release samples to a disinterested third party laboratory with a reputation for providing unbiased analysis in both criminal and civil litigation. In addition to consumer comfort, manufacturers, stores, and restaurants often find the same peace of mind knowing that all aspects of sample handling, from retrieval through analysis, reporting and sample disposition, can be handled by a third party.

**Sample preservation**

Sample preservation must be considered from the earliest stages of contact with a client. Refrigerated samples must be maintained in a cold state, even during shipping, and all items must be physically stabilized to minimize physical degradation during transport to the laboratory. Key factual information often rests in the delicately preserved relationship between the alleged foreign matter and the product in which it was found. Improper packing, shipping, or handling of the sample can destroy this evidence, potentially hindering or even ruining the possibility of performing the best scientific analysis. The case of a mouse, which a consumer alleges was sealed in a bottle of vinegar during packaging, illustrates the importance of this concept. (See box.)

Before a sample is transferred, it is critical that a proper chain of custody be established. Thanks to popular TV shows, the term chain of custody is well known. However, implementation of the concept is a bit more delicate, and its ramifications can become critical in later litigation. While this may seem a trivial point during the early stages of a complaint investigation, an improperly preserved sample, a sample transferred under improper conditions, or one whose chain of custody is in doubt can lead to inadmissibility arguments, which can be devastating to a case where the only factual information originates from physical evidence that is now inadmissible. In our experience (in both criminal and civil cases), it is not uncommon to see significant portions of direct and cross examinations during deposition and testimony to be focused on alleged (or actual) chain-of-custody issues.

Of course, sample preservation considerations don’t end with the laboratory analysis. Statute of limitations requirements as well as pending FSMA regulations may dictate sample preservation timelines of several years. Despite the potential ramifications of such requirements, sample disposition is another topic that is often out of sight and out of mind—until a problem arises and a sample from several years ago is needed in pending litigation. In general, most companies that deal with complaint samples (be it one or two per year or hundreds per year) are not equipped to systematically catalog, preserve, and archive these samples in a manner that ensures both preservation and ease of retrieval. In contrast, independent consumer complaint analysis laboratories can typically provide secure and reliable archival storage, combined with easy sample retrieval as part of their service package.

**Ensuring an Appropriate Analysis**

Although consumer affairs professionals are well trained to perform their regular duties, the handling and scientific examination of complaint samples (particularly those involving litigation) is often beyond the expertise and range of their formal training. Similarly, quality and research laboratories within an organization may have a high level of expertise in the properties of
the products they make; however, they are not typically experts in, nor is their primary focus on, identifying and interpreting foreign matter incidents.

Since foreign matter may take many forms, a wide variety of claims, ranging from the obvious (e.g., a metal screw) to the ephemeral (e.g., an off flavor), the analyst’s expertise must extend over a wide range of materials and analytical methods (many of which are outside the scope of their typical activities). In the past month alone, our laboratory has dealt with metals, plastics, glass, illicit drugs, printing inks and pigments, off odors, off-spec ingredients, chars, animal hair, human hair, pollen, sand and cyanide, among others. Each of these materials has specific properties (as well as threat levels), and a specific analytical approach is necessary to prove the identity of any of them. Specialization becomes critical when trying to not only identify a material, but also determine when or where it was introduced into the product.

Quickly Establishing Facts

Time and certainty are often major factors in determining how to resolve a claim. For example, most of the samples submitted to our food forensics laboratory are triaged within 48 hours, which provides the client with photo-documentation of the sample as well as basic characterization of the complaint matter. This permits consumer affairs professionals to quickly assess the validity of a claim and, when necessary, take steps to mitigate the claim in an efficient manner.

As in the case of the consumer who was certain in his identification of a fried mouse, untrained personnel within a company are also subject to similar biases based on brief visual examinations of returned complaint samples. Without an analysis documented by scientific analysis, such preconceived notions by either the consumer or manufacturer can propagate through the claims process unchecked.

In one instance, an alleged glass fragment at the center of a multiyear litigation effort had been “identified” based on only a visual examination. As the

Case Study

A sample arrived in our laboratory on a Friday afternoon, which contained a mouse in a large bottle of vinegar. At that time the mouse was buoyant and had all of its hair intact. By Sunday, the mouse had sunk to the bottom and had lost more than half of its hair. By Monday, all of the hair had epilated and lay on the bottom of the bottle with the mouse. Microscopic examination of the rodent’s tear ducts showed that they were irritated, which could only have occurred while it was still alive. This proved that the mouse was alive when it dropped into the vinegar.

However, had the mouse fallen into the vinegar when the bottle was full of vinegar but before the top was applied and sealed, it would have lost its hair and sunk to the bottle bottom long ago, since it was packaged and sealed several months before the incident was alleged to have occurred. Based on these findings, we reported that the mouse had only recently been introduced to the bottle—after it had been opened. Had the sample not been documented the day it was received, such information would have been lost, and it may not have been possible to scientifically resolve the issue in such a definitive manner.
case approached its trial date, our laboratory was contacted to analyze the sample. To our surprise, our first attempts to clean the particle in water showed that it started to dissolve. Since glass isn’t soluble in water, this particle could not be glass. Subsequent analysis showed that it was a fragment of glassy sugar, a form of sugar that fractures in a manner similar to glass. This simple fact, which could have been obtained several years earlier, was sufficient to bring a multiyear legal dispute to an abrupt end. More importantly, it shows how a single fact can impact an entire claim.

**Litigation Support**

In cases that do go to deposition or trial, it is critical that the facts of the case are supported against rebuttal by documented proof. The groundwork for this must be laid in the scientific report, which must provide results that are well-documented, based on scientifically valid approaches, and transparent. The National Academy of Sciences report, “Strengthening Forensic Science in the United States: A Path Forward” (2009), critiquing the scientific basis of many disciplines of forensic science has received much public attention. Just as the forensic scientist is under greater expectations to provide scientifically supportable results, analyses in civil matters are being challenged on similar grounds.

In reviewing opposing expert reports, we find time and again that results are often based on speculation rather than actual science or that conclusions mix facts and interpretation in a manner that obscures the truth. However, experience in giving expert testimony shows that only the strongest reports based on rigorous scientific analysis can hold up to the intense scrutiny of a court proceeding.

Just as important as being able to support conclusions during testimony is the role of an independent laboratory in putting results into context for their client. Discussion and candid differentiation of indisputable facts from those that are based on challengeable suppositions and theories should be discussed at an early stage. Such discussions can provide great assistance to claims managers and their superiors who ultimately must understand the facts in a case to determine an appropriate course of action.

**Cost Savings**

The expertise required for proper sample preservation and the specialized expertise that are necessary to perform high quality complaint samples analyses makes the decision to outsource complaint samples (retrieval, analysis, archiving and testimony) a technical necessity for some companies. For others, the relatively low cost of a triage analysis coupled with the liabilities that could arise from an improper analysis make common sense. In other cases, the fast analysis turn-around time (typically less than 48 hours) is appealing. In most cases the benefits of a third party handling all aspects of the incident is appealing both to the manufacturer, seller or restaurant just as much as it is to the consumer who submits the complaint. Ultimately, the decision to outsource the handling of consumer complaint samples frees up consumer affairs professionals and quality control staff to perform the tasks that they were trained to do, while ensuring that complaint samples analyses are conducted at level of competence and professionalism that are on par with other company expectations.

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