Aerosol anatomy:
Aerosol product litigation—Part 2

This two-part series focuses on strategies that can be used to provide accurate verification that an aerosol product is developed, manufactured and tested to specific principles that meet "adequate standards of care."

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This series, Aerosol Anatomy, focuses on dissecting and examining various technical topics in aerosol technology, including, but not limited to: product development, new technology, components of the aerosol system, quality control of aerosol products and other related topics that may be of interest to formulators and manufacturers of aerosol products. This month's topic falls into the "related topics" category, and is a continuation of the Aerosol Product Litigation discussion that appeared in the July issue of *ST&M*.

Part One of this discussion set the stage by introducing some of the basic legal techniques used by the plaintiff's attorneys in the pursuit of a product liability lawsuit. We examined how these tools can reach deeply into your company to extract information used to build a case for the plaintiff. Then, in response, we looked at strategies for building robust, well documented R&D procedures.

This two-part discussion concludes by extending the analysis to the "plant side" of the operation: discussing

manufacturing operations and quality assurance systems. In addition, we will look at how customer complaints can lead to corrective actions that may mitigate the potential of future legal issues. In fact, for purposes of our discussion, this process can serve as one of your company's "early warning systems" with regard to product quality, product design issues and potential product liability.

Production and Quality Assurance Documentation

In the previous article we focused on strategies, methods and procedures used to provide accurate and thorough verification that your aerosol products were developed in accordance to what the legal profession calls "adequate standards of care." These same standards apply to the aerosol manufacturing and plant quality assurance operations as well. All of the legal investigative tools that the plaintiff's counsel has at their disposal (subpoenas, depositions, interrogatories, etc.), as discussed extensively in Part One, are available to probe deep within the company's manufacturing and quality departments. This includes access to current and past personnel, as well as all written and electronic records.

Documentation in the production environment is vital. Developing the proper data intake forms, and installing rigorous procedure for capturing and storing data, is essential to a manufacturing company. The more robust these systems are, the more "defensible" your position in a legal battle will be. The ability to prove that an aerosol product was manufactured and quality tested properly goes a long way in defending against lawsuits.

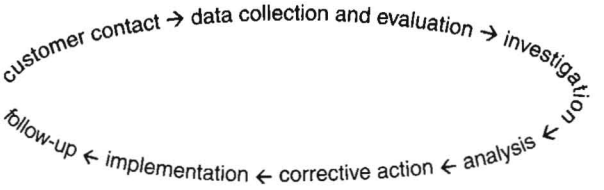
This process starts with the inspection and verification of raw materials used to manufacture the aerosol product. Both chemical and packaging components are evaluated upon delivery for conformance to pre-established specifications before being released for transfer to the production line. These records are stored with the run documentation and provide two advantages. First, it substantiates that the correct components were used to make a given product, and secondly, it provides accurate traceability of a component if a problem is discovered later in the process.

The data acquisition and documentation process extends into production. Production line setup is documented; this may entail initial quality checks of the setting of crimp specifications, fill control, propellant charging, vacuum, etc. Typically the Quality Department, responsible for finished product quality, interfaces with production at line startup.

I have often seen a "line" between the responsibilities of the Production Department and the Quality Department. Unfortunately, this line often widens into a gap, and into this gap can fall several things, including seamless continuity of production and maintenance of top level consistent quality throughout the run. Most companies wrestle with the issue of how to make product quickly with minimal scrap and downtime while maintaining top level quality. There are many alternatives and that is another topic for another article. Suffice it to say that a company, whose Production and Quality Departments learn not only to co-exist, but to blend seamlessly together, benefits in numerous ways. Germaine to our topic is the avoidance of sub-standard, and potentially unsafe (read: lawsuit-waiting-to-happen) aerosol products.

Customer Complaints: The "Early Warning System"

While consumer complaints are sometimes thought of as nuisances that marketers must deal with, they can, in fact, serve as a very valuable warning system for potentially larger quality and product safety problems. Let's look more closely at internal systems used by manufacturers to address, evaluate and correct aerosol complaints. While the application of this process varies widely from company to company, the generic flow path typically looks like something this:



The initial contact is made when the customer reports a problem, usually to a customer service representative, who creates and saves a permanent document of the exchange.

The next, deeper level of this process consists of evaluating accumulated complaints to look for commonalities, and a higher-than-baseline frequency of a specific complaint. If a particular complaint type is flagged as substantial and/or recurring, then the complaint type is identified for further consideration. Examples of aerosol product complaints might include "can does not spray" or "can does not shut off." While the format varies from company to company, typically a team of department representatives meet at scheduled intervals to review complaints. The group looks for patterns and decides which complaints are selected for further investigation. This screening process serves to identify complaints that merit further consideration and potential corrective actions.

High profile complaints are investigated. Information from customers' complaint submissions is reviewed and a determination is made as how to best substantiate the complaint and gather information to determine if, how and when corrective action(s) should be taken. Assignments are given to the representatives of departments where more information is needed, a timeframe for completion is set and a "point person" for the specific complaint is identified.

After a pre-established time, the group reconvenes to analyze the results of the investigation, and if necessary, suggest a corrective action plan to eliminate or minimize the problem. Upon management approval, the plan is put into place and changes are made. A critical part of the plan is follow-up to determine whether the corrective action(s) is/are working satisfactorily and if additional changes are needed based on the initial implementation of the plan.

While most complaints do not rise to the level of "potential litigation," the benefits to the company of installing a robust corrective action process are numerous. Surprisingly, the problem is often not where you might expect to find it. Let me illustrate with an example I found interesting from a technical perspective. Several years ago, I worked on a project with a major marketer of aerosol deodorant and antiperspirant products. The subject product had been in production for many years and the current formula, can and valve had not seen changes for the previous three years. There was a large spike in consumer complaints—consumers reported either poor spray or no spray even though the can was more than half full. We looked at everything—the basic formula raw materials, the propellant and, of course, the valve system itself. All the sub-components of the aerosol valve were molded and assembled properly and the stem gasket and orifices were all correct. Yet the complaints mounted and the pressure was on (excuse the pun, the aerosol chemist in me couldn't resist).

As it turned out, the problem was traced to a specific supplier's plastic polymer that was used to mold the "body" of the aerosol valve system. In the molding process, plastic resin is heated and, under high pressure, is forced into a metal mold. After the molding cycle is complete a fully formed valve body is produced and ready to be assembled into a valve system. While this specific supplier's polymer material tested "in-spec" for all QC attributes, there was a high percentage of un-reacted monomers. We discovered that these monomers were, over time, susceptible to extraction by the high level of alcohol in the formulation. These semi-solid monomers accumulated on the surfaces of the valve body. When the customer actuated the valve, product flowed through the valve and "washed" the monomers into the stem where they proceeded to block the stem orifice, resulting in valve clogging, and a few hundred thousand unhappy customers.

The corrective action system used by this manufacturer provided for a thorough investigation by including not only internal departments, but supplier representatives as well.

To summarize, all of the guidelines for system enhancements and thorough documentation discussed in Part One of this series pertain to production and quality assurance as well. In addition, companies who make the most of their "early warning system" can react proactively by implementing modifications to their internal processes, procedures and control systems, which may mitigate the potential of future legal actions. SPRAY

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