

# **LexisNexis® Mealey's™ Litigation Report**

## **Food Liability**

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### **Consumer-Driven Diacetyl Litigation: Boom or Bust**

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With asbestos litigation entering its twilight years, personal injury lawyers have been searching long and hard for a new toxin to form the foundation of lawsuits for decades to come. And while personal injury lawyers have enjoyed some success in prosecuting cases involving occupational exposure to diacetyl, the limited number of individuals exposed to the substance in the occupational setting has been a major stumbling block to crowning diacetyl as the toxin of the new millennium. Years of research into the health effects of diacetyl, together with recent medical findings and increased public scrutiny over food safety issues, however, may serve to broaden diacetyl litigation into the consumer arena and provide personal injury lawyers with the opportunity they have been so anxiously seeking.

### **What Is Diacetyl?**

Diacetyl is an artificial food flavoring agent, producing a butter-like flavor in combination with other ingredients. Although used in a host of food products ranging from pastries to candy, it is more widely recognized for its use in microwave popcorn. Diacetyl is also a natural byproduct of the fermentation process and, thus, may be found in alcoholic beverages. At low levels in beer and wine, it contributes a slippery feeling in the mouth. As levels increase, it imparts a buttery flavor.

Diacetyl, despite widespread use, remained largely unknown to the general public until 2002. Then, the *USA Today* reported on a study conducted by the Centers for Disease Control (CDC), linking artificial butter flavorings containing diacetyl to a rare but serious lung disorder, bronchiolitis obliterans, among workers at a microwave popcorn manufacturing plant in Jasper, Missouri. Bronchiolitis obliterans, or so-called popcorn workers' lung, is a progressive disease of the lung's smallest airways. Ordinarily associated with lung transplantation, the disease may also be triggered by adverse drug reactions, certain bacterial or viral infections, or inhalation of airborne toxicants.

## Occupational Exposure To Diacetyl Studies

### BASF

Potential adverse health effects of diacetyl exposure roused the interest of the food flavoring manufacturing industry years before the *USA Today* report was published. Indeed, concerns over occupational exposure to diacetyl were first documented in a 1993 BASF study, involving forced inhalation exposure of diacetyl to three groups of 10 rats over the course of four hours. The first group was forced to inhale low diacetyl levels (2.25 mg/L), while the second and third groups were forced to inhale moderate (5.2 mg/L) and high diacetyl concentrations (23.9 mg/L). The result: none of the rats exposed to low levels died during the study, versus all those exposed to moderate and high levels that died within seven days of exposure. Notably, rats exposed to moderate and high levels had a number of symptoms pointing to respiratory tract injury.

### NIOSH, Jasper, Missouri Plant

After several former workers of the Gilster-Mary Lee microwave popcorn manufacturing plant in Jasper, Missouri suffered from severe obstructive lung disease, the National Institute of Occupational Safety and Health (NIOSH) was called upon in 2000 to investigate this plant and five others. A survey at the plant in November 2000 revealed workers preparing the butter mixture containing diacetyl had reduced lung abilities, and in some cases, symptoms of bronchiolitis obliterans in amounts significantly higher than the general public.

Ultimately, the evaluation of the plant's workforce showed a relationship between exposure to butter flavoring vapors used in the popcorn production process and reduced lung ability. Obstructive lung disease was discovered in workers at other plants using or manufacturing flavorings, with five or six quality control workers - who repeatedly popped 100 bags of popcorn in microwave ovens in poorly ventilated settings - also having obstruction on spirometry. It is this aspect of the NIOSH study that may ultimately be the spring board for consumer-driven diacetyl exposure litigation.

## **Diacetyl in California**

Concern over occupational exposure to diacetyl has spread across the country. Case in point, in August 2004, the California Department of Health Services and Division of Occupational Safety and Health obtained an initial report of bronchiolitis obliterans in a food flavor manufacturing worker at a state facility. Less than two years later, another report found that a worker from a different flavor manufacturing company had bronchiolitis obliterans. While not employed in the microwave popcorn industry, both handled pure diacetyl during the manufacturing of artificial butter flavorings. Since April 2006, five additional flavor manufacturing workers have been diagnosed with severe fixed obstructive lung disease, bringing the combined total to seven workers from four different flavoring manufacturers in California.

What's more is that California is now vying to become the first state to take action against diacetyl use in the workplace. Fueled in part by the foregoing workplace injuries, the state's legislature proposed a bill that, if enacted, would ban manufacturing, packaging, mixing, or blending of diacetyl or products containing diacetyl in the workplace, on or after January 1, 2009. Under the proposed bill, naturally-occurring diacetyl in food or beverages, or processes that result in the natural production of diacetyl, would be excluded from this prohibition.

## **Occupational Lawsuits**

Alleged diacetyl-induced injuries in the occupational setting have led to hundreds of lawsuits against microwave popcorn and food flavoring manufacturers, resulting in hundreds of millions of dollars in jury awards and settlements. In fact, two new lawsuits on behalf of 44 more plaintiffs were recently filed in Jasper County, Missouri, against the makers of a butter flavoring used at a local microwave popcorn plant. The plaintiffs involve 43 current and former workers at the plant and a man who lived nearby. Until now, however, little attention has been given to the potential effects of diacetyl inhalation upon consumers of microwave popcorn.

Indeed, the Food and Drug Administration (FDA) has given diacetyl "Generally Regarded as Safe" (GRAS) status. Several advocacy groups and politicians, however, have petitioned the FDA to remove diacetyl's GRAS designation, including U.S. Congresswoman Rosa L. DeLauro, who urged FDA Commissioner, Andrew von Eschenbach, to re-examine the GRAS designation.

## Effects On Consumers

As for the effects of diacetyl exposure on consumers, no comprehensive scientific study results have been released. While a study was spearheaded by the U.S. Environmental Protection Agency (EPA) in 2003 to examine the type and amount of chemicals released from popped microwave popcorn bags, it will not address the health effects of those chemicals on consumers. "Once we know what the chemicals are and the amounts, somebody else can look at the health effects," said Jacky Rosati, an EPA scientist involved in the study. "Obviously, we are looking at diacetyl because it is a known compound that will come off this popcorn. But we're not looking at that alone." Results have not been released as of this writing.

Although the risk to consumers was previously believed to be low, various factors may provide ammunition for potential consumer-related suits. To start, two of the nation's largest microwave popcorn product makers, ConAgra Foods and Pop Weaver, announced they will remove diacetyl from their products due to worker safety and potential consumer health concerns, and will seek alternatives to achieve the butter flavor.

Moreover, in September 2007, the FDA announced it received a report from Dr. Cecile Rose, a pulmonary expert from the National Jewish Medical and Research Center in Denver, Colorado. Dr. Rose alerted federal regulators that she may have found the first non-occupational case of bronchiolitis obliterans in a man who was exposed to diacetyl vapors while preparing butter flavored microwave popcorn several times a day over a number of years.

In a written statement to the FDA, the CDC and other public health agencies, Dr. Rose argued the individual's level of diacetyl exposure was the only reasonable explanation for his illness. Levels of airborne diacetyl measured at the patient's home near the microwave area were "similar to those reported in the microwave oven exhaust area" at one microwave popcorn processing plant, where employees developed severe fixed obstructive lung disease. Furthermore, Dr. Rose stated the

patient's respiratory troubles seemed to stabilize after stopping microwave popcorn consumption.

In reaction to Dr. Rose's letter, the Flavor and Extract Manufacturers Association (FEMA) released a statement recommending its members reduce "to the extent possible" the quantity of diacetyl in butter flavorings.

"This new information suggests a possible association between inhaling the fumes from the preparation of several bags of heavily butter-flavored microwave popcorn each day when the butter flavor contains diacetyl and the development of the patient's severe respiratory illness," the FEMA statement said.

The FDA is currently evaluating the recent information associating inhalation of the food additive diacetyl with lung disease, and is reportedly considering the safety and regulatory issues it raises. "This is the first time we're being made aware of a potential consumer case. We're taking (the doctor's) report very seriously," said Bernadette Burden, a spokeswoman for the U.S. Centers for Disease Control and Prevention.

## **Consumer-Driven Diacetyl Litigation**

Until now, the primary impediment to diacetyl becoming the "next asbestos" has been the relatively limited number of individuals exposed to it in the workplace. It is without a doubt, however, that the plaintiffs' bar will seize upon recent developments, such as the announcements of Dr. Rose, ConAgra and Pop Weaver, and increase collective efforts to further establish a causal link between diacetyl exposure at the consumer level and respiratory disease. If successful, every person who suffers or has suffered from respiratory disease is a potential plaintiff.

Consumer-driven diacetyl litigation may no longer be a legal theory in search of scientific support. Indeed, much of the research conducted to date, including the NIOSH rat study, clearly provides the foundation for the contention that diacetyl vapors can cause respiratory injury to consumers of food products. Bolstered by a potentially larger pool of litigants from the consumer sector - especially if medical cases linked to the chemical flavoring agent such as that reported in Denver rise in number - and teamed with legislators like Rosa L. DeLauro, trial lawyers are likely to succeed in expanding diacetyl litigation far beyond that which we know today in the industrial occupational environment.

As promising as consumer-driven litigation may be to the plaintiffs' bar, it is not at all clear whether recent developments in this area will have a significant impact on court cases. For example, it is highly likely that the plaintiffs' bar will attempt to introduce evidence of various food manufacturers removing or planning to remove diacetyl from their products. The defense will undoubtedly oppose such an attempt by arguing that the removal of diacetyl from food products constitutes a subsequent remedial measure. Although Rule 407 of the Federal Rules of Evidence and many states' laws generally preclude admission of subsequent remedial measures at trial to prove negligence, culpable conduct, a defect in a product, a defect in the product's design, or a need for a warning or instruction, exceptions to this rule exist. For example, subsequent remedial measures may be admissible when offered for another purpose, such as proving ownership, control, feasibility of precautionary measures (if controverted) or, of course, for impeachment.

Regardless of whether such exceptions will exist in future litigation, diacetyl's removal from consumer products and the publicity surrounding its alleged dangers has the potential to adversely affect jury pools. Keep an eye out for the results of the EPA's study, as it could be exactly what is needed to crown diacetyl the "next asbestos" and the toxin of the new millennium.