

The Evolution Of Diacetyl-Related Litigation: Part 1

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For over a decade, plaintiffs attorneys have targeted the flavoring chemical diacetyl in a series of national lawsuits, which started when respiratory disease was discovered in nine workers at a Missouri microwave popcorn processing plant back in 2000. In recent years, however, plaintiffs have shifted their focus to new industries and alternative chemicals. This two-part series looks at some recent trends in flavoring litigation and offers recommendations for facilities that use the chemicals at issue.

What are Flavorings?

Flavorings are natural or man-made substances used to impart a different, stronger or more agreeable taste to food or drink. Some flavorings are simple and composed of only one chemical, while others are a mixture of several substances. The U.S. Food and Drug Administration regulates flavorings to make sure that they are safe when eaten, but does not require testing for other routes of exposure to these chemicals, such as inhalation.

History of Diacetyl (2,3-butanedione) and Related Litigation

Diacetyl is a naturally occurring chemical present at low concentrations in a variety of foods such as dairy products, beer, coffee, honey and fruits. Food and flavor manufacturers have used natural and synthetic forms of diacetyl in artificial flavorings due to its buttery taste and smell. Nearly two decades ago, workers at a microwave popcorn facility in Missouri who handled butter flavors containing diacetyl were diagnosed with bronchiolitis obliterans (BO), a nonreversible respiratory disease that scars the bronchioles (small airways).

Since that time, lawsuits have been filed by microwave popcorn processing workers, employees of flavoring companies who used diacetyl as an ingredient, and even a few consumers who have alleged respiratory disease as a result of cooking and eating microwave popcorn in their homes. Plaintiffs lawyers have traditionally targeted diacetyl manufacturers and suppliers, although flavor companies have also been sued in cases where the plaintiff was an employee of a downstream user (i.e., microwave popcorn manufacturer).

In support of their claims, plaintiffs point to toxicology studies finding that vapors from heated butter flavorings can cause damage to airways in animals.[1] Studies in both rats and mice demonstrate that the cells lining the airways can be damaged by inhaling diacetyl vapors in both acute and subchronic



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settings.[2] In mice, aspiration of diacetyl caused a pattern of injury that replicates some of the features of human BO.[3] A study from the Netherlands also found that chemical workers at a diacetyl manufacturing plant developed the same type of lung disease as microwave popcorn workers.[4]

New Chemical: Acetyl Propionyl (2,3-pentanedione)

Due to its potential to cause respiratory illness, diacetyl has been largely phased out of artificial flavoring and replaced with acetyl propionyl (AP).[5] Although AP (like diacetyl) is approved for food use, some researchers have recently raised questions about the potential toxicity of AP inhalation due to structural similarities between these two chemicals (which share the same functional α -diketone group). Similar to diacetyl, toxicology studies have found that inhalation of AP can cause damage to airways in rodents.[6] AP vapors also have been measured in workplace air.[7] According to the Centers for Disease Control and Prevention, these findings raise concerns that AP and diacetyl share the same mechanism of toxicity.[8]

In recent cases filed on behalf of flavoring workers alleging respiratory illness, plaintiffs have added AP manufacturers and suppliers to the mix. These cases now allege respiratory illness due to the effects of diacetyl, AP and a handful of other chemicals. Per the American Conference of Governmental Industrial Hygienists (ACGIH), when two or more hazardous substances have a similar toxicological effect on the same system or organ (e.g., lungs), their combined effect should be given primary consideration rather than their individual effect.[9] Thus, plaintiffs likely have been quick to add a number of potential manufacturers to each lawsuit so as to argue that an additive effect of multiple chemicals may put workers at an increased risk.

The Flavor and Extract Manufacturers Association (FEMA), a trade association for the flavorings industry, has identified a number of flavoring substances that may have the potential to pose respiratory hazards in flavoring-manufacturing workplaces. FEMA has identified 27 "high priority" flavoring substances that may pose a respiratory hazard in the workplace and "merit a higher degree of attention" including consideration of work practice controls, engineering controls and personal protective equipment (PPE).[10] Diacetyl and AP are listed by FEMA as "high priority" substances. Notably acetoin and acetaldehyde, two other flavoring chemicals targeted (albeit less frequently) by plaintiffs, are also on the "high priority" list.

New Industry: Coffee Processing Facilities

Coffee processing facilities may be one of the next targets. Studies have shown that diacetyl and AP are naturally produced and released during the coffee roasting process,[11] and subsequent grinding of roasted coffee beans releases significant concentrations of these chemicals.[12]

This issue caught the attention of the CDC in 2012, after five workers at a coffee roasting plant in Texas were diagnosed with BO.[13] NIOSH investigators found high concentrations of diacetyl and AP at the plant, particularly in the grinding/packaging room and flavoring room.[14] They also found workers in those areas had an increased risk for dyspnea and pulmonary obstruction.[15]

A 2015 study by scientists at Cardno ChemRisk measured naturally occurring diacetyl and AP at a coffee roasting/grinding facility that uses no flavoring agents.[16] The authors found that airborne concentrations of naturally occurring diacetyl and AP associated with unflavored coffee processing are similar to concentrations measured in certain flavoring facilities, and are likely to exceed some recommended short-term occupational exposure limits.[17]

The authors found, however, that the concentrations were far below those expected to cause even a minimal response in humans, based on dose-response relationships published in animal studies.[18] The study ultimately concluded that coffee processing workers are not at any heightened risk of developing BO as a result of exposure to naturally occurring diacetyl.[19]

During the last year, the potential risk of BO in coffee processing workers caught media attention.[20] Lawyer advertisements followed. There are hundreds of commercial coffee processing facilities in the United States at which large volumes of beans are roasted and ground; many grocery store chains also have commercial-size roasters and grinders on site. Thus, the potential for litigation exists and should be watched.

Recommendations for Users of Diacetyl and AP

Although the science is limited, companies that handle raw diacetyl and AP, or flavors containing these ingredients, may wish to take preliminary precautions to minimize worker exposure. Current recommendations include air sampling to detect and measure potential concentrations of the chemicals, but there is no established Occupational Safety and Health Administration permissible exposure limit (PEL) or National Institute for Occupational Safety and Health recommended exposure limit (REL) for either chemical.

The NIOSH has published proposed RELs for diacetyl (5 ppb) and AP (9.3 ppb) (as a time-weighted average (TWA) for up to eight hours per day during a 40-hour workweek).[21] If elevated levels of either chemical are detected in workplace air, efforts should be undertaken to reduce the levels.

Per the NIOSH, employers can minimize occupational exposures to flavoring or flavoring ingredients by implementing standard industrial hygiene practices (in order) as listed below:[22]

- Substitution: carefully evaluate potential substitutes for toxicity and then replace with less hazardous chemicals.
- Engineering controls: use closed systems, isolation or local exhaust ventilation in order to reduce air concentration of potentially harmful chemicals.
- Administrative controls: implement good housekeeping and work practices.
- Personal protective equipment: use respirators or other appropriate equipment where needed (in addition to engineering and administrative controls).
- Employee health monitoring: continued evaluation of lung function and other clinical abnormalities is critical. Symptoms or cases should be tracked and reported to the NIOSH where appropriate.

In an attempt to minimize litigation risk, manufacturers and suppliers of potentially hazardous flavors or flavor ingredients should affix stringent warnings to the product (label, MSDS) and should consider a disclaimer that the product is not approved for inhalation. Consideration should also be given to incorporation of an indemnification clause in the sales contract or supply agreement for any flavor or flavor ingredient containing the above chemicals.

This was the first in a two-part series. In part 2 we will focus on the growing industry of e-cigarettes and how the liquids used with these devices may be the next target in diacetyl and AP litigation.

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DISCLOSURE: Jennifer Steinmetz has represented a flavor ingredient supplier in diacetyl litigation.

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[3] Morgan et al., 2008, *supra* n 2.

[4] van Rooy et al., Bronchiolitis Obliterans Syndrome in Chemical Workers Producing Diacetyl for food Flavorings, *Am. J. of Respiratory and Critical Care Medicine*, May 2007, 176: 498-504.

[5] Gaffney et al., Naturally occurring diacetyl and 2,3-pentanedione concentrations associated with roasting and grinding unflavored coffee beans in a commercial setting, *Toxicology Reports* 2, 2015, 1171-1181, at 1171-1172; see also Morgan et al., Bronchial and Bronchiolar Fibrosis in Rats Exposed to 2,3-Pentanedione Vapors: Implications for Bronchiolitis Obliterans in Humans, *Toxicologic Pathol.*, 2011, 1-18 at 1-2.

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[8] Flavorings-Related Lung Disease: Exposures to Flavoring Chemicals, *Ctrs. for Disease Control & Prevention*, (Sept. 29, 2015), <http://www.cdc.gov/niosh/topics/flavorings/exposure.html> (last accessed Aug. 11, 2016).

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[14] Bailey et al., Respiratory Morbidity in a Coffee Processing Workplace with Sentinel Obliterative Bronchiolitis Cases, *Am. J. Ind. Med.*, 2015, 58: 1235-1245.

[15] *Id.*

[16] Gaffney et al., *supra* n 5, at 1171.

[17] *Id.*

[18] *Id.* at 1178.

[19] *Id.*

[20] Coffee Workers' Concerns Brew Over Chemical's Link to Lung Disease, *the Salt*, (April 15, 2016), <http://www.npr.org/sections/thesalt/2016/04/15/474325037/coffee-workers-concerns-brew-over-chemicals-link-to-lung-disease>; see also Raquel Rutledge, Danger Brewing for Coffee Roasters, *J. Sentinel*, (Dec. 30, 2015), <http://www.jsonline.com/watchdog/watchdogreports/trouble-brewing-at-work-b99634143z1-363740781.html>.

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The Evolution Of Diacetyl-Related Litigation: Part 2

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For over a decade, plaintiffs' attorneys have targeted the flavoring chemical diacetyl in a series of national lawsuits which started when respiratory disease was discovered in nine workers at a Missouri microwave popcorn processing plant back in 2000. In recent years, however, plaintiffs have started to shift their focus to new industries and alternative chemicals. This is the second in a two-part series. Part 1 looked at the history of diacetyl litigation, along with some new players to the game. Part 2 will focus on the growing industry of e-cigarettes and how the liquids used with these devices may be the next target in diacetyl and acetyl propionyl (AP) litigation.

New Industry: E-Liquids

Use of electronic nicotine delivery systems (ENDS) has exploded since their introduction in 2007. ENDS include electronic cigarettes (e-cigarettes), vaporizers, vape pens, hookah pens and e-pipes.[1] ENDS are designed to heat up nicotine "e-liquid" into an ultrafine aerosol that consumers inhale, which is penetrated into the lungs and then exhaled, producing a visible vapor during the process (hence the term "vaping").[2] Some ENDS are prefilled, single-use and disposable. Others are refillable, including mods which are larger and allow consumers to mix different e-liquids.[3] Manufacturers range from large-player cigarette companies to small startup vaping shops that mix their own e-liquids.[4]

Over 7,000 flavored e-liquids are available for vaping in ENDS.[5] Flavors include traditional tobacco and menthol, as well as numerous candy, fruit, bakery and cocktails flavors — e.g., cotton candy, cherry, oatmeal cookie and piña colada — to name only a few. Concern has been raised that these sweet flavors appeal to young users, as e-cigarette use in high schoolers increased almost 800 percent from 2011 to 2014.[6]

Recent research has focused on determining what chemicals are contained in flavored e-liquids. In one study by Dr. Konstantinos Farsalinos — a researcher at Onassis Cardiac Surgery in Athens, Greece, and an advocate of e-cigarettes as a smoking cessation aid — 74 percent of tested sweet-flavored liquids contained diacetyl and AP (with more samples containing diacetyl).[7] Farsalinos concluded, however, that the median level of diacetyl and AP exposure from the e-liquids he tested was 100 and 10 times lower, respectively, compared to cigarette smoking.



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Nonetheless, Farsalinos has proposed that diacetyl and AP be eliminated from e-liquids to avoid unnecessary exposure.[8] In another study by Harvard researchers, diacetyl was detected in 76 percent of tested samples, including those that were not candy- or fruit-flavored.[9] AP was found in 23 of 51 flavors tested, including in 21 samples that also contained diacetyl. This shows that AP is used not only as a substitute for diacetyl, but in conjunction with it.

Attention has now turned to the potential health effects of inhaling diacetyl and AP in e-liquids. In contrast to other diacetyl and AP exposures which focused on workers, the primary health concern with e-liquids lies with consumers — including younger users who may be more susceptible to certain toxic exposures.[10] The Flavor and Extract Manufacturers Association (FEMA) warns that none of the safety assessment programs for flavors evaluate their use in products other than human food, so their results cannot be extrapolated to inhalation. FEMA further suggests that manufacturers and marketers should be ensuring the safety of e-liquid flavors when inhaled by consumers.[11]

There is little research currently available on potential health effects of inhaling flavorings in e-liquids.[12] Some studies are underway, but not completed.[13] This is partly because there has not been sufficient time for more robust epidemiology studies to be completed.[14] Even lower-tier scientific evidence is limited. A search reveals a case report about a 60-year-old male who was diagnosed with an acute inhalational lung condition related to use of an ENDS and flavored e-cigarette liquid.[15] In addition, one group of researchers concluded that e-liquids induced oxidative and inflammatory responses in mice and human lung cells, with certain sweet or fruit flavors of e-liquids reported to be stronger oxidizers than tobacco flavors.[16]

In terms of labeling, there are no requirements for manufacturers to indicate whether e-liquids contain diacetyl or AP; indeed, currently the only requirement is that ENDS products must contain a nicotine warning statement. There also are no applicable standards for the composition of e-liquids, including no governmental recommendations or restrictions on diacetyl and AP levels in e-liquids.[17] Under these circumstances, it is difficult for users to know what they are inhaling and what the potential health effect(s) may be. There is information suggesting that manufacturers may not even be aware that diacetyl or AP is in the e-liquids they have created and/or sold.[18]

As of Aug. 8, 2016, the U.S. Food and Drug Administration's regulatory authority encompasses all ENDS as well as their components and parts, which includes e-liquids. However, at present, there are no FDA proposed rules on use of flavorings in e-liquids. ENDS manufacturers — including vape shops that mix or prepare e-liquids — are required to register with the FDA by Dec. 31, 2016, and must submit an application to remain in the market within the next two years. That application must contain a listing of ingredients, including information about harmful and potentially harmful constituents (HPHCs) in tobacco products and smoke, although the established list of 93 HPHCs does not currently include diacetyl or AP. The FDA estimates that it will take an additional year to review these new tobacco product applications. In the interim, e-cigarette manufacturers can continue selling their products. [19]

E-Liquid Manufacturer Recommendations

Plaintiffs firms have begun to include information about e-cigarettes on their websites, twitter feeds and other forms of social media. There is a long line of potential parties within the distribution stream who could be targeted — from flavoring suppliers and distributors, to large cigarette companies also in the ENDS marketplace, to contract manufacturers of e-liquids, to neighborhood vaping shops mixing e-liquids in the back of their stores.

Even though there are no governing regulatory standards, those within the supply chain could potentially be subjected to lawsuits alleging that testing, labeling and/or content disclosure of e-liquids are required by tort common law, and that the failure to do so caused alleged injury, either consumer fraud or personal injury.

Indeed, there have been at least two lawsuits filed against e-cigarette manufacturers which center on a failure to disclose the presence of diacetyl/AP and warn of their associated risks. Both were putative class actions alleging consumer fraud-based claims filed in the U.S. District Court, Central District of California. *Cox v. Cuttwood LLC et al.*, 8:15-cv-01961-GW-JCG; *Greene et al. v. Five Pawns Inc.*, 8:15-cv-01859-DOC-DFM. The Cox case has been voluntarily dismissed, and the Greene case is in the initial pleadings stage.

In the next few years, the FDA may impose additional requirements relating to diacetyl and AP on e-liquid manufacturers, including with regard to testing, composition restrictions and labeling. Some manufacturers may decide not to take action unless required by the FDA. Others may decide to take voluntary steps to reduce potential tort liability. For example, manufacturers of e-liquids could consider periodically testing their products to determine the constituents and eliminate any diacetyl and AP detected, as suggested by Farsalinos.

If diacetyl and AP are not eliminated, manufacturers could consider whether to disclose their presence and possible risks to consumers, which potentially could minimize labeling claims such as those alleged in the Cox and Greene lawsuits. But cons include that any disclosures may differ from later FDA requirements, and would need to be monitored for accuracy. Also, current testing methods may not be sensitive enough to detect lower levels of these chemicals,[20] so avoidance of phrases like “diacetyl-free” may be prudent. Before taking any voluntary action, these and several additional factors should be considered as part of an individualized risk-benefit analysis.

—By Sherry Knutson and Jennifer Steinmetz, Tucker Ellis LLP

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[2] *Id.*; Barrington-Trimis et al., Flavorings in Electronic Cigarettes An Unrecognized Respiratory Health Hazard?, *JAMA*. 2014 Dec. 17; 312(23): 2493-94.

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[12] Barrington-Trimis, *supra* n 2, at 2493.

[13] Rutledge, *supra* n. 3.

[14] Barrington-Trimis, *supra* n 2, at 2494.

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[16] Lerner et al., Vapors Produced by Electronic Cigarettes and E-Juices with Flavorings Induce Toxicity, Oxidative Stress, and Inflammatory Response in Lung Epithelial Cells and in Mouse Lung, *PLoS ONE* 10(2): e0116732. Doi:10.1371/journal.pone.0116732 (Feb. 6, 2015).

[17] See FDA, Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS), *supra* n 1.

[18] See Rutledge, *supra* n. 3 (reporting on co-founder of a vape shop who did not know that one of his top-selling e-liquids contained diacetyl and AP, and who stated that he expected his flavor suppliers to alert him if diacetyl or other potentially harmful chemicals were present in the flavoring sold to his shop).

[19] FDA, Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List, <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297786.htm> (last

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[20] Rutledge, *supra* n. 3.