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Caffeine Under Siege by the FDA

The FDA recently announced an investigation into safety issues surrounding one of the most ubiquitous and popular ingredients in consumer food products – caffeine. This is just one of several opening shots in what may become a new regulatory and litigation battleground.

Starting last year, Senators Richard Durbin and Richard Blumenthal wrote the first of several letters to the FDA requesting a safety review of caffeinated energy drinks. This March, a group of 18 public health experts wrote a detailed letter to the FDA expressing their concerns with energy drinks. In response to these requests – and reports of several deaths possibly associated with energy drinks – the FDA launched its investigation.

The current FDA safety review goes beyond the initial focus on caffeinated energy drinks and will address other food and beverage products that contain caffeine.

Caffeine is a mild stimulant naturally present in coffee beans, tea leaves, certain nuts and beans and a variety of plants. Consumed in normal quantities, caffeine modestly enhances wakefulness and elevates mood. Billions of cups of coffee and tea are consumed without untoward health effects. According to the FDA, 80 percent of adults in the U.S. consume an average of 200mg of caffeine (about two cups of coffee) per day.

The recent legal challenges are focused principally on products containing high concentrations of caffeine and products such as energy drinks that encourage rapid consumption, particularly where those products are marketed to and consumed by children and adolescents. The FDA has also expressed concern that use of caffeine as a flavor additive and stimulant has been proliferating widely to diverse food products including instant oatmeal, waffles, gum, jelly beans, marshmallows and other snacks, and that these products can contain as much caffeine as one or more cups of coffee.

For normal healthy adults, the FDA reports that consumption of 400mg per day (roughly four to five cups of coffee) has not been linked to adverse effects. There is, however, a great deal of individual variability, and the FDA states that "600mg (four to seven cups of coffee) of caffeine or more each day is too much." The FDA has not issued a recommended maximum level of caffeine for children.

About the Author

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This article was originally published by *Food Processing* on May 15, 2013.

Besides daily dosage, the public health experts who wrote to the FDA expressed concern that the physiological effects can be magnified significantly if caffeine is consumed rapidly, rather than spaced over the course of the day. These experts also note that children and adolescents have a lower threshold for potential adverse effects because they have a lower body mass than adults and because they have not developed pharmacological tolerance for caffeine.

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The public health experts point to medical data associating high doses of caffeine with cardiovascular abnormalities, including heart rhythm disturbances, new-onset seizures, neurological symptoms (nervousness, anxiety, jitters and headaches) and other adverse health effects.

So what steps can industry take to meet the legal challenges? Here are some thoughts:

- Take proactive measures to mitigate risk: Besides including caffeine in the ingredients list, companies might voluntarily add information about the amount of caffeine contained in their products. Labels could also provide warnings regarding potential adverse effects. Companies could also consider voluntarily limiting the amount of caffeine – or eliminating caffeine entirely – in products likely to be consumed by children. They might review and possibly revise advertising directed to children or that might be interpreted as encouraging excessive consumption. The American Beverage Association's "Guidance for the Responsible Labeling and Marketing of Energy Drinks" should be considered. Companies should liaise with trade associations that are meeting with the FDA so they have input into the regulatory process.

- Study the safety of caffeine: Anecdotal reports of adverse events are just that – anecdotes. Association is not proof of causation. In a recent letter, the FDA said that while its review of recently published safety studies is still ongoing, "the available studies do not indicate any new, previously unknown risks associated with caffeine consumption." Industry members should consult with toxicologists, epidemiologists and other scientists to review the relevant studies and respond to scientifically unwarranted criticisms.

- Communicate industry's point of view: There needs to be a fair and balanced discussion of the issues. It is important that regulators and the public not be unduly influenced by advocacy masquerading as science.

- Defend litigation: Monster Beverage Corp., defendant in a wrongful death lawsuit, recently issued a press release detailing medical and scientific evidence that it says demonstrate the absence of a causal link between an energy drink and a teenage consumer's cardiac death. Unmeritorious cases should be defended vigorously.