

## Client Alert

### Study Finds Lead Contamination in Rice Imports—Could Litigation Be Close Behind?

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A recently-published Monmouth (NJ) University study claims to have detected high levels of lead in imported rice. These preliminary findings, which follow media reports last fall about arsenic contamination in rice, pose new regulatory and litigation risks for manufacturers, importers, distributors and, perhaps, even retailers of foods and other consumer and commercial products made with imported rice.

Although imports account for only seven percent of rice consumed in the U.S., imports of rice and rice flour have increased by more than 200 percent since 1999, a trend that is likely to continue as more consumers seek to limit or eliminate gluten from their diets. In addition to whole grain rice and rice flour, rice is a common ingredient in a wide array of food products, ranging from infant formula and baby food to ethnic foods. Rice and its byproducts are also often contained in non-food items such as building materials, paper, cosmetics, and hygiene products.

According to the Monmouth study's principal investigator, Dr. Tsanangurayi Tongesayi, the daily exposure level from eating the rice products analyzed in the study would be 30-60 times higher than the Food and Drug Administration's (FDA) provisional total tolerable intake (PTTI) level. The Monmouth study purports to have found elevated lead concentrations in rice imported from Bhutan, China, the Czech Republic, India, Italy, Taiwan, and Thailand. It should be noted that research is ongoing, and the study has not yet been published in a peer-reviewed journal.

In 2012, the Centers for Disease Control (CDC) estimated that 450,000 U.S. children have lead levels higher than the CDC's recommended limit. To protect consumers, FDA monitors lead content in foods, particularly those consumed by children. Although it has not yet set mandatory limits for allowable lead levels, the FDA has said it will take action against juice products if lead concentrations exceed 50 parts per billion ("ppb"), and in other food deemed to contain "too much lead."

Likewise, the Consumer Product Safety Commission (CPSC) has long imposed limits on the amount of lead in consumer products like paint, which Congress lowered in 2008 to 90 parts per million ("ppm"). Lead and arsenic are two of eight elements restricted from use in the coating and substrate of toys in both Europe and the United States, and Congress established a lead limit of 100 ppm in each accessible part of a consumer product intended or designed primarily for children age 12 or younger. State labeling laws, including California's Proposition 65 and Illinois' Lead Poisoning Prevention Act, also impose requirements on manufacturers to label certain products containing lead.

Manufacturers' obligation to guard against and warn about lead in food is currently the subject of [a high-profile Proposition 65 bench trial](#) in Alameda County, California. In that case, a plaintiff group has sued 16 baby food manufacturers—including Del Monte, Gerber, Beech-Nut, and Welch's—alleging that the manufacturers failed

to provide required Proposition 65 cancer and reproductive toxicity warnings about the presence of lead in their products. The manufacturers contend that lead occurs naturally in the soil in which the produce used in their products was grown, and cannot be mitigated. The manufacturers also assert that federal law preempts the Proposition 65 warning requirement because FDA has determined that the products at issue do not pose unacceptable risks to consumers.

The Monmouth study and an emerging body of literature on lead and arsenic in rice suggest this could be the next target of Proposition 65 and other consumer product litigation, as well as regulatory action by FDA. The near-term path may depend on both the outcome of the California baby food trial and the extent to which the conclusions from the Monmouth study are confirmed and replicated. And as FDA implements the 2011 Food Safety Modernization Act (FSMA), it is making clear its intent to hold food manufacturers responsible for the safety of the ingredients used in their products, and to determine whether they meet applicable food safety regulations.

In order to mitigate its risk, a company that imports, sells, or distributes products made from rice grown overseas should consider taking the following precautionary steps:

- Evaluate compliance protocols to ensure they are robust enough to meet new requirements under FSMA for foreign-sourced foods and ingredients.
- Determine the source of rice used in products, and ensure compliance with applicable U.S. Customs and Border Protection regulations, including country of origin declarations and labeling requirements.
- Investigate whether foreign-based suppliers are testing for lead.
- Consider conducting independent tests for lead in products with rice content.
- If lead is found, evaluate the safety risk and report all relevant findings to the appropriate federal or state authorities immediately.

Crowell & Moring attorneys are experienced in food safety compliance and litigation issues, and are available to assist you.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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