

Janet Woodcock
Acting Commissioner
U.S. Food & Drug Administration,
10903 New Hampshire Ave., HF-1
Silver Spring, MD 20993-0002
Janet.Woodcock@fda.hhs.gov

Susan T. Mayne
Director, Center for Food Safety and
Applied Nutrition, U.S. Food & Drug
Administration,
Outreach and Information Center
5001 Campus Dr., HFS-009
College Park, MD 20740-3835
Susan.Mayne@fda.hhs.gov

Conrad Choiniere, PhD
Director, Office of Analytics and Outreach,
U.S. Food & Drug Administration,
Outreach and Information Center
5001 Campus Dr., HFS-009
College Park, MD 20740-3835
conrad.choiniere@cfsan.fda.gov

Mark Moorman
Director, Office of Food Safety ,
U.S. Food & Drug Administration,
Outreach and Information Center
5001 Campus Dr., HFS-009
College Park, MD 20740-3835
Mark.Moorman@fda.hhs.gov

Judy McMeekin, PharmD
Associate Commissioner,
Office of Regulatory Affairs
U.S. Food & Drug Administration,
White Oak 31, 10903
New Hampshire Ave.,
Silver Spring, MD 20993
Judith.McMeekin@fda.hhs.gov

May 24, 2021

Re: Dangerously high levels of arsenic and lead found in many vinegar products require action by the FDA

Dear Acting Commissioner Woodcock, Directors Mayne, Choinier, and Moorman, and Associate Commissioner McMeekin:

The representatives of the undersigned consumer organizations, Empire State Consumer Project (ESCP), from Rochester, NY, and Food & Water Watch write to inform you about the alarmingly high lead and arsenic levels we have found in numerous vinegars and reductions sold in U.S. groceries. We ask the agency quickly act to protect the public, especially those at highest risk such as pregnant women and children, by establishing limits and warnings for arsenic and lead in these products.

As detailed in the attached spreadsheet and accompanying lab reports, ESCP's test results show that of the 24 samples of major brands of vinegars or vinegar reductions or glazes purchased this year in the Rochester area and online:

- Close to half (11) were contaminated with arsenic or lead;
- Seven (7) tested positive for both; and
- 10 out of 21 (47.6%) of all balsamic vinegars or vinegar reductions or glazes tested positive for either arsenic or lead.¹

All but one of the vinegar or reduction samples testing positive for either arsenic or lead were balsamics, and all were imported from Italy, Greece, or Spain.

These test results show that consumers put themselves at risk for purchasing a vinegar or vinegar reduction or glaze that is contaminated with these toxic metals, especially if it is balsamic.

In terms of arsenic, levels were very high, ranging from 70 parts per billion (ppb) to more than 1,040 ppb. To put this in perspective, at the maximum levels found in vinegar or reductions, with simply one serving (1 tablespoon), consumers would far exceed FDA's 10-ppb maximum contaminant level for 1 liter of bottled water.² At the mean levels detected (287.91 ppb), consumers would come close with two tablespoons (8.51 ppb). These levels far exceed some states' 5-ppb drinking-water standards. Lead levels were also very high, ranging from 68.6 to 127 ppb. These levels are at least twice as high as California's maximum contamination limit of 34 ppb in balsamic vinegars (under Proposition 65), therefore requiring a label warning for those products.

The ESCP testing was done to determine if levels of contaminants in balsamic vinegars were reduced since they were first identified in 2002 by the Environmental Law Foundation. This testing led to a California Proposition 65 bottle and shelf-label requirement for balsamic products.³ ESCP's new testing clearly shows that lead levels continue to be unacceptably high in many brands. Two balsamic products that were identified as having no lead or arsenic in the past had the highest for lead and arsenic in ESCP's testing—at 1040 ppb arsenic and 106 ppb lead.

The California Attorney General's database lists 24 warning notices sent to companies for lead found in balsamic vinegars as recently as 2020.⁴ There was little overlap in products eliciting those warning letters and ESCP's test results, suggesting it remains an extensive problem for the industry.

Of course, while the FDA and state-action and warning levels may be useful for making a preliminary evaluation of the problem of lead and arsenics in vinegar, it is critical to remember that these limits are not strictly based on protecting public health. Indeed, the EPA has set a goal

¹ ESCP's complete testing results, including vinaigrettes that did not have detectable levels of arsenic or lead are listed in the accompanying lab reports.

² .01 milligrams/liter. See 21 C.F.R. § 165.110(b)(4)(iii)(A) (2020). These calculations based on 67.63 U.S. tablespoons per liter.

³ Jane Kay, "Special Report: Some vinegars - often expensive, aged balsamics - contain a big dose of lead," (Nov. 9, 2009), <https://www.ehn.org/special-report-some-vinegars-often-expensive-aged-balsamics-contain-a-big-dose-of-lead-2649749136.html>

⁴ Located at <https://oag.ca.gov/prop65/60-day-notice-search> (last accessed May 24, 2021).

of *zero* ppb for inorganic arsenic in drinking water, reflecting that there is *no level* below which there is no known or expected risk to health. Similarly, California’s level for balsamic vinegar is based on a litigation settlement, and, thus, at least in part, reflects companies’ financial abilities to achieve these levels or else lose customers. As FDA recognizes, however, there is *no safe level of lead in the blood*.

We are concerned that the agency may be overlooking the contribution of vinegars and vinegar reductions to unsafe levels of arsenic and lead. FDA does not include vinegars in their Total Diet Survey. The agency’s recent tests of Italian salad dressings show only trace amounts of arsenics and lead, in line with ESCP’s testing. However, the agency is currently omitting the popular use of vinegars for salad dressing and in many other foods (*e.g.*, grilling, broiling, and marinating).

Food & Water Watch partnered with ESCP and Consumer Reports in 2011 when ESCP’s testing found arsenic in apple juices. We asked the FDA to set an arsenic limit for the products, which the agency is now finalizing. The FDA can act similarly to move the U.S. food supply towards the lowest feasible levels of toxic chemicals in Americans’ diet, including requirements for warnings, limits, and goals for lead and arsenic in commonly used items such as vinegars. Given the growing popularity of vinegars, especially balsamics, the dangerous nature of these contaminants, and the apparently extensive contamination, vinegars and reductions must be given particular attention in order to protect public health.

This is especially critical for pregnant women because both lead and arsenic can seriously damage the fetus. Exposure to arsenic *in utero* is associated with DNA damage and micronuclei in newborns. The authors of a recent study concluded that “[o]ur study clearly revealed the detrimental impacts of arsenic exposure during pregnancy which results in various types of genetic damage in newborns in a dose-dependent manner. If such damage persists, it may contribute to the initiation of cancer which may develop later in life.”⁵

Likewise, the U.S. Center for Disease Control recognize that elevated levels of lead in the blood during pregnancy can:

- Increase risk of miscarriage;
- Cause premature birth or undersized babies;
- Hurt the baby’s brain, kidneys, and nervous system; and
- Cause the child to have learning and/or behavior problems.⁶

And these contaminants are not just an issue for pregnant women. Arsenic is a cardiotoxin and as such it is particularly dangerous for the elderly, African Americans—who have higher rates of cardiovascular disease—and the many other people with kidney, cardiac,

⁵ Navasumrit, P., Chaisatra, K., Promvijit, J. *et al.* Exposure to arsenic in utero is associated with various types of DNA damage and micronuclei in newborns: a birth cohort study. *Environ Health* 18, 51 (2019). <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-019-0481-7>.

⁶<https://www.cdc.gov/nceh/lead/prevention/pregnant.htm#:~:text=If%20a%20woman%20is%20exposed,too%20early%20or%20too%20small>.

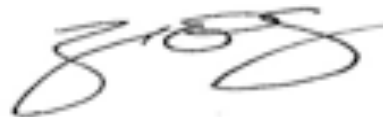
and other chronic illnesses. Lead's neurotoxic effects impact adults as well as children and can accelerate cognitive decline with age.

Since only California requires contaminant hazard labeling of balsamic vinegars, we ask FDA to protect all U.S. consumers by taking action: perform product testing and establish limits and warnings addressing lead and arsenic in in vinegars and vinegar reductions.

There is FDA precedent for this action in the Import Alerts for undeclared sulfites and legacy pesticides in vinegars. There are also alerts for arsenic in fruit juice, bottled water, and dietary supplements and for lead in candy, dried fruits, spices, dietary supplements, and other foods. These are in keeping with the agency's recently announced "Closer to Zero" action plan to reduce children's exposure to toxic elements. We believe that targeting very popular vinegar and vinegar reductions, particularly balsamics, including some with high levels of arsenic and lead, is a necessary component of an adequate action plan.

We request that you act quickly to mitigate health risks to people across the United States, especially pregnant women and children. And we look forward to hearing from you on this pressing matter. We are happy to talk to you more about this issue and invite you to please contact Carol Chittenden at ESCP at 585-831-7124 and cachitter@aol.com to schedule such a meeting.

Sincerely,



Zachary B. Corrigan
Senior Staff Attorney
Food & Water Watch

Judy Braiman, President
Carol Chittenden, Director
Empire State Consumer Project, Inc.

cc: Reps. Rosa DeLauro, Chairwoman, U.S. House Committee on Appropriations; Carolyn Maloney, Chairwoman, House Committee on Oversight and Reform; Raja

Krishnamoorthi, Chair, Subcommittee on Economic and Consumer Policy; Tony Cárdenas, the Vice Chair of the Energy and Commerce's Subcommittee on Consumer Protection and Commerce; and Joe Morelle.

Sens. Chuck Schumer, Senate Majority Leader; Kirtsen Gillibrand; Pat Leahy, Chair U.S. Senate Committee on Appropriations; Amy Klobuchar; and Tammy Duckworth.