



November 12, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-D-0322

Comments to FDA on Draft Guidance for Industry on Arsenic in Apple Juice: Action Level

To United States Food and Drug Administration (FDA):

Center for Food Safety (CFS) submits the following comments on behalf of itself and its members in response to FDA's "Draft Guidance for Industry on Arsenic in Apple Juice: Action Level" (Draft Guidance).

CFS is a nonprofit public interest advocacy organization dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies and promoting sustainable agriculture. As a membership organization, CFS represents 360,000 farmer and consumer members who reside in every state across the country, and who support safe, sustainable food systems.

CFS and its members believe it is imperative that FDA regulate the presence of arsenic in our food supply to protect consumers from its detrimental health effects. FDA's Draft Guidance represents an important first step in effective regulation, but FDA must do more to adequately protect public health. First, because arsenic is present in a variety of foods and through the environment, FDA should act through regulation rather than a nonbinding "action level." Second, given arsenic's well-documented prevalence in our food supply, FDA should take into account the multiple sources of arsenic to which consumers may be exposed, and set enforcement standards based on cumulative arsenic exposure accordingly. Finally, regardless of the means by which FDA sets arsenic standards for apple juice, it should strictly and strongly enforce them.

Arsenic Exposure Presents a Significant Threat to Public Health

Arsenic is an odorless and tasteless semi-metal element in the periodic table. It occurs naturally in the environment as an element of the earth's crust, and is found in rocks, soil, water, air, plants, and animals. Arsenic can be released into the environment through natural activities such as volcanic action, erosion of rocks, and forest fires, or through human actions. Arsenic can appear in inorganic and organic forms; elemental arsenic combines with other elements such as

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oxygen, chlorine, and sulfur to form inorganic arsenic compounds.

At one time organic arsenic was considered less toxic than inorganic arsenic and safe at low levels, but its toxicity is now well-documented. Recent studies show that organic arsenic can easily convert to inorganic arsenic in the environment and in the body when ingested by humans and animals. Some organic forms of arsenic created by the body's metabolism appear to be more toxic than inorganic arsenic.

Inorganic arsenic is a known human carcinogen. The association between inorganic arsenic and cancer is well-documented. As early as 1879, high rates of lung cancer in Saxony miners were attributed in part to inhaled arsenic. By 1992, the combination of evidence from Taiwan and elsewhere was sufficient to conclude that ingested inorganic arsenic, such as is found in contaminated drinking water and food, was likely to increase the incidence of several internal cancers. In addition to being a carcinogen, arsenic can cause diabetes and cardiovascular disease.¹ It can also contribute to declines in intellectual function and can decrease a body's ability to respond to viruses. The scientific link to skin and lung cancers is particularly strong and longstanding,² and evidence suggests that arsenic may cause liver, bladder, kidney, and colon cancers as well.

An increased risk of cancer is not the only adverse impact of arsenic; it affects nearly all organ systems by targeting ubiquitous enzyme reactions in cells.³ Studies of in-utero exposure to arsenic indicate that early life exposures to compounds can alter susceptibility of endocrine and reproductive organs. Long-term exposure to arsenic can also cause hyperpigmented skin, skin nodules, and vessel disease, and appears to heighten the risk of death from high blood pressure and heart disease. People repeatedly exposed to arsenic also have an increased risk of diabetes.⁴

Arsenic is not poisonous to everyone to the same degree. Children, infants, and fetuses are among those most vulnerable to arsenic's toxic effects. This is due to differences in arsenic metabolism between adults and those very early in life. Moreover, arsenic and its organic metabolites easily pass through the placenta.⁵ Carcinogens like arsenic are generally more potent in early life exposures. Following its review of twenty-three peer-reviewed studies of cancer incidence over fifty years, the United States Environmental Protection Agency (EPA) concluded that infants up to age two are, on average, ten times more vulnerable to carcinogenic chemicals than adults, and for some cancer-causing agents are up to sixty-five times more vulnerable.

¹ Jason Roberge et al., Presence of Arsenic in Commercial Beverages, 5 Am. J. of Env'tl. Sci. 688, 688-694 (2009).

² See, e.g., Int'l Agency for Research on Cancer, World Health Organization, *Some Metals and Metalloid Compounds: Summary of Data Reported and Evaluation*, 23 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 39 (1980), available at <http://monographs.iarc.fr/ENG/Monographs/vol23/volume23.pdf>.

³ Subcomm. to Update the 1999 Arsenic in Drinking Water Report et al., Nat'l Research Council, *Arsenic in Drinking Water: 2001 Update* (National Academy Press 2001), available at http://www.nap.edu/catalog.php?record_id=10194; M. Nathaniel Mead, *Arsenic: In Search of an Antidote to a Global Poison*, 113 Env'tl. Health Persp. A378, A378-86 (2005).

⁴ Subcomm. on Arsenic in Drinking Water et al., Nat'l Research Council, *Arsenic in Drinking Water* (National Academy Press 1999), available at http://www.nap.edu/catalog.php?record_id=6444; Subcomm. to Update the 1999 Arsenic in Drinking Water Report et al., *supra* note 3.

⁵ Subcomm. to Update the 1999 Arsenic in Drinking Water Report et al., *supra* note 3; Mead, *supra* note 3.

Children ages two to five are three times more vulnerable to carcinogens than adults.⁶ In addition, evidence now indicates that arsenic is a potent disruptor of hormone function at extremely low levels of exposure, altering the way in which hormones transmit information between cells.⁷ Recently, a delayed response in developing immunity to the H1N1 virus was attributed to arsenic exposure in drinking water.⁸ Scientists continue to discover new and increasingly dangerous health impacts not previously considered from arsenic exposure.

Historically, arsenic compounds were used in many industries, including as a preservative in pressure-treated lumber; as a preservative in animal hides; as an additive to lead and copper for hardening; in glass manufacturing; in pesticides; in animal agriculture; and as arsine gas, to enhance junctions in semiconductors. The United States has cancelled the approvals of some of these uses, such as arsenic-based pesticides, for health and safety reasons. Some of these cancellations were based on voluntary withdrawals by producers. For example, manufacturers of arsenic-based wood preservatives voluntarily withdrew their products in 2003 due to safety concerns, and EPA signed the cancellation order. In the Notice of Cancellation Order, EPA stated that it considered the voluntary move a positive step, especially for the nation's children, because it "believes that reducing the potential residential exposure to a known human carcinogen is desirable."⁹ However, arsenic is an element—it does not degrade or disappear. Therefore, despite efforts to reduce the amount of arsenic in the environment, residual arsenic remains and poses health risks to consumers.

The international community has already recognized the detrimental health effects of consuming arsenic through food. Since scientific studies and reports first provided conclusive evidence of arsenic toxicity in staple foods and beverages, arsenic tolerance levels have been a subject of public outrage. In response to the public's concern, food safety regulators around the world have acted to make consumers aware of its effects. In 2010, for example, the European Food Safety Authority (EFSA) issued warnings to consumers about the risks of inorganic arsenic in food¹⁰ and the EFSA panel on contaminants in the food chain (CONTAM) recommended that consumers reduce dietary exposure to inorganic arsenic. CONTAM found that consumers of large amounts of rice, such as certain ethnic groups, and consumers of algae-based products are especially at risk of increased arsenic exposure "[b]ecause of the high percentage of water used to prepare fruit and vegetable juices, soft drinks and alcoholic beverages,"¹¹ and "all those

⁶ Risk Assessment Forum Technical Panel, U.S. Env'tl. Prot. Agency, *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*, EPA/630/R-03/003F (Mar. 2005), available at http://www.epa.gov/ttnatw01/childrens_supplement_final.pdf.

⁷ Mead, *supra* note 3; Ronald C. Kaltreider et al., *Arsenic Alters the Function of the Glucocorticoid Receptor as a Transcription Factor*, 109 *Env'tl. Health Persp.* 245, 245-51 (2001); Jack E. Bodwell et al., *Arsenic at Very Low Concentrations Alters Glucocorticoid Receptor (GR)-Mediated Gene Activation but not GR-Mediated Gene Repression: Complex Dose-Response Effects Are Closely Correlated with Levels of Activated GR and Require a Functional GR DNA Binding Domain*, 17 *Chem. Research in Toxicology* 1064 (2004).

⁸ Courtney D. Kozul et al., *Low-Dose Arsenic Compromises the Immune Response to Influenza A Infection in Vivo*, 117 *Env'tl. Health Persp.* 1441, 1441-47 (2009).

⁹ Response to Requests to Cancel Certain Chromated Copper Arsenate (CCA) Wood Preservative Products and Amendments to Terminate Certain Uses of other CCA Products, 68 *Fed. Reg.* 17366, 17367 (Apr. 9, 2003).

¹⁰ European Food Safety Auth. Panel on Contaminants in the Food Chain (CONTAM), European Food Safety Auth. (EFSA), *Scientific Opinion on Arsenic in Food*, 7 *EFSA J.* 1351 (2009), available at <http://www.efsa.europa.eu/en/efsajournal/doc/1351.pdf>.

¹¹ *Id.* (internal quotations omitted).

categories have also been included in the list of the major contributors to inorganic arsenic exposure”¹² in addition to water.

Consumers Are Exposed to Arsenic Through a Variety of Food Sources

Both inorganic and organic arsenic are found across a variety of commonly-consumed foods. In fact, in addition to apple and fruit juices, arsenic is most commonly found in rice, seaweed, seafood, infant formulas containing brown rice syrup, and meat. Chicken and rice, especially, are widely-consumed American staple foods.

First, with regard to apple juice, a 2012 Consumer Reports study that tested apple juice samples for arsenic revealed “total arsenic levels that exceeded federal drinking-water standards”¹³ set by the EPA and followed by FDA. The report noted that while levels of arsenic in various servings of apple juice may vary, children are consistently exposed due to the volume of apple juice they consume; “[o]ne in four toddlers 2 and younger and 45 percent of children ages 3 to 5 drink 7 or more ounces of juice a day.”¹⁴ In response to public outrage over arsenic exposure, in 2012 United States Representatives Frank Pallone and Rosa DeLauro introduced H.R. 3984, the Arsenic Prevention and Protection from Lead Exposure in Juice Act of 2012, otherwise known as the APPLE Juice Act of 2012. The legislation would require FDA to issue regulations setting tolerance levels for arsenic and lead in fruit juices within two years.¹⁵

Second, with regard to chicken, a study released on May 10, 2013, by researchers at the Johns Hopkins Center for a Livable Future at the Bloomberg School of Public Health (the 2013 Study) confirms that arsenic-containing compounds and inorganic arsenic are present in both raw and cooked chicken breast. Most of the arsenic in chicken meat can be traced back to the routine addition of arsenicals to animal feed.¹⁶ Arsenic-containing feed additives are approved for both non-therapeutic and therapeutic uses in the U.S. poultry industry; the thousands of animal feeding operations in the U.S. can use arsenic-containing feed additives to increase weight gain, improve feed efficiency, and improve pigmentation in animals¹⁷ or to prevent and control disease among animals that are raised in crowded, stress-inducing conditions that promote disease. In the 2013 Study, the arsenical Roxarsone was detected in half of the conventional chicken meat samples and one of 13 conventional “antibiotic-free” samples, and conventional samples had higher inorganic arsenic concentrations than “antibiotic-free” and organic samples. Perhaps most concerning, total arsenic and inorganic arsenic concentrations were significantly higher in cooked samples than raw meat samples.

The results of the 2013 Study strongly suggest that the use of arsenic-containing compounds in poultry feed contributes to dietary inorganic arsenic exposure in consumers of conventionally-produced chickens. These results confirmed FDA’s earlier acknowledgement that

¹² *Id.*

¹³ Consumer Reports, *Arsenic in your juice: How much is too much? Federal limits don’t exist*, Consumer Reports Magazine, Jan. 2012, available at <http://www.consumerreports.org/cro/magazine/2012/01/arsenic-in-your-juice/index.htm>.

¹⁴ *Id.*

¹⁵ H.R. 3984, 112th Cong. (2012).

¹⁶ See generally, Ctr. for Food Safety, *Factory Farms: Arsenic*, May 2013, available at http://www.centerforfoodsafety.org/files/arsenic_fact-sheet_33897.pdf.

¹⁷ 21 C.F.R. § 558.530.

arsenic-based feed additives raised concerns of “completely avoidable exposure to a carcinogen.”¹⁸

In September 2013, in response to litigation initiated by CFS, FDA announced that it is in the process of voluntarily withdrawing three arsenic-based feed additives from the market.¹⁹ However, FDA has yet to take public action to formally withdraw approval for these three additives, and a fourth arsenic-based additive remains on the market pending further study by FDA. As a result, poultry continues to serve as a source of arsenic exposure.

This is significant because chicken and turkey represent the first and fourth most heavily-consumed foods in the United States, respectively. Chicken presents a notable risk due to the sheer volume of its consumption in the United States. From 1966 to 2000, annual chicken consumption rose 253 percent, from 32.1 to 81.2 pounds per person.²⁰ However, data from the United States Department of Agriculture indicate that African Americans eat about twenty percent more chicken than does the United States population as a whole. Similarly, due to their small size, toddlers eating chicken baby food may ingest chicken at substantially higher-than-average levels, on a weight-adjusted basis. For these subgroups, arsenic ingestion from contaminated chicken may be substantially higher than average. One in 100 Americans now eats more than three-quarters of a pound (>350 grams) of chicken per day. This person could be expected to ingest 32.5 to 47.07 micrograms of total arsenic per day from chicken alone. One in 1000 Americans eats at least one and one-third pounds of chicken per day. For an average-sized person, this could translate into 56.8 to 82.3 micrograms of total arsenic per day, more arsenic than the average American is estimated to receive from all dietary sources.²¹

A third concerning source of arsenic is rice, also an American staple food. In 2011, tests performed by Dartmouth College’s Children’s Environmental Health and Disease Prevention Center indicated that consuming slightly more than one-half cup of cooked rice per day resulted in total urinary arsenic concentrations nearly equal to consuming a liter of water containing the maximum amount of arsenic allowable in public drinking water. In 2012, Consumer Reports also found significant and worrisome levels of both inorganic and organic arsenic in virtually every one of the 200 rice samples it tested, including organic rice baby cereal, rice breakfast cereals, brown rice, and white rice.²² According to Consumer Reports, inorganic arsenic, which is “the predominant form of arsenic in most of the 65 rice products . . . analyzed, is ranked by the International Agency for Research on Cancer (IARC) as one of more than 100 substances that

¹⁸ Press Release, U.S. Food and Drug Admin., FDA: Pfizer will voluntarily suspend sale of animal drug 3-Nitro (June 8, 2011), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258342.htm>.

¹⁹ Letter from Michael R. Taylor, U.S. Food and Drug Admin. Deputy Commissioner for Foods and Veterinary Medicine, to Paige M. Tomaselli and David Wallinga (Sept. 30, 2012) (on file with author).

²⁰ David A. Taylor, *Funky Chicken: Consumers Exposed to Arsenic in Poultry*, 112 *Envtl. Health Persp.* A50, A50-51 (2004) (reviewing Tamar Lasky et al., *Mean Total Arsenic Concentrations in Chicken 1989-2000 and Estimated Exposures for Consumers of Chicken*, 112 *Envtl. Health Persp.* 18, 18-21 (2004)).

²¹ Tamar Lasky et al., *Mean Total Arsenic Concentrations in Chicken 1989-2000 and Estimated Exposures for Consumers of Chicken*, 112 *Envtl. Health Persp.* 18, 18-21 (2004).

²² Consumer Reports, *Arsenic in your food: Our findings show a real need for federal standards for this toxin*, *Consumer Reports Magazine*, Nov. 2012, *available at* <http://www.consumerreports.org/cro/arsenicinfood.htm>.

are Group 1 carcinogens.”²³ The results of the report “suggest many people in the U.S. may be exposed to potentially harmful levels of arsenic through rice consumption.”²⁴

Rice is a significant source of arsenic due to how it is grown. It is one of the plants that most effectively absorbs “arsenic from soil or water . . . because it is one of the only major crops grown in water-flooded conditions, which allow arsenic to be more easily taken up by its roots and stored in the grains.”²⁵ According to Consumer Reports, “[i]n the U.S. . . . about 15 percent of rice acreage [i]s in California, 49 percent in Arkansas, and the remainder in Louisiana, Mississippi, Missouri, and Texas. That south-central region of the country has a long history of producing cotton, a crop that was heavily treated with arsenical pesticides for decades in part to combat the boll weevil beetle,”²⁶ which has led to increased arsenic exposure of the rice plants. Consequently, the level of inorganic arsenic in rice from these regions is high;²⁷ American-grown rice contains 1.4 to 5 times more arsenic on average than rice from Europe, India, and Bangladesh.²⁸

As a result of the increasingly alarming reports of arsenic in rice, in September 2012 Representatives DeLauro, Pallone, and Nita Lowey introduced the R.I.C.E Act (Reducing food-based Inorganic and organic Compounds Exposure Act) in Congress.²⁹ A full year later, in September 2013, FDA announced its plan to “assess the potential health risk from long-term exposure to the arsenic in rice and foods made with [rice],”³⁰ following its release of “the analytical results of approximately 1,100 new samples of rice and rice products as part of a major effort to understand and manage possible arsenic-related risks associated with the consumption of these foods in the U.S. marketplace.”³¹ Suzanne Fitzpatrick, Senior Advisor for Toxicology in FDA’s Center for Food Safety and Applied Nutrition, noted that “[t]his is a daunting task, with one complicating factor being the sheer volume of rice products,” because “there are different varieties and hundreds of products made with rice.”

Finally, drinking water is a major source of arsenic exposure.³² EPA sets an enforceable regulation for arsenic, called a maximum contaminant level (MCL). Recognizing the health problems of arsenic in drinking water, EPA in 2001 lowered the MCL from fifty parts per billion

²³ *Id.*

²⁴ *Id.* (internal citations omitted).

²⁵ *Id.*

²⁶ *Id.*

²⁷ See Consumer Reports, *Results of our tests of rice and rice products*, 2012, available at http://www.consumerreports.org/content/dam/cro/magazine-articles/2012/November/Consumer%20Reports%20Arsenic%20in%20Food%20November%202012_1.pdf.

²⁸ Mark Peplow, *US rice may carry an arsenic burden*, Nature News (2005), available at <http://www.nature.com/news/2005/050801/full/news050801-5.html>.

²⁹ H.R. 6509, 112th Cong. (2012).

³⁰ Suzanne Fitzpatrick, *Next Steps on Arsenic and Rice*, FDA Voice Blog (Sept. 12, 2013), <http://blogs.fda.gov/fdavoic/index.php/2013/09/next-steps-on-arsenic-and-rice/#sthash.d0pvZzDh.dpuf>.

³¹ U.S. Food and Drug Admin., *Arsenic in Rice and Rice Products*, <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319870.htm> (last visited Nov. 12, 2013); see also U.S. Food and Drug Admin., *Analytical Results from Inorganic Arsenic in Rice and Rice Products Sampling*, <http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM352467.pdf> (last visited Nov. 12, 2013).

³² See Press Release, U.S. Food and Drug Admin., *FDA Warns Again About Arsenic in Mineral Water* (Mar. 24, 2007), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108875.htm>.

(ppb) to ten ppb. The National Academies of Science estimate that Americans who drink water contaminated with arsenic at the ten ppb level—numbering thirteen million in 2001—have a greater than 1-in-300 risk of developing cancer during their lifetime.³³ In its determination of an MCL for arsenic, EPA cited studies proving that “[c]hronic oral exposure to elevated levels of inorganic arsenic has resulted in gastrointestinal effects, anemia, peripheral neuropathy, skin lesions, hyperpigmentation, and liver or kidney damage in humans . . . while ingestion of inorganic arsenic by humans has been linked to a form of skin cancer and also to bladder, liver, and lung cancer. EPA has classified inorganic arsenic as a human carcinogen.”³⁴ In addition, it recognized that “[i]ngested inorganic arsenic can cross the placenta in humans, exposing the fetus to the chemical” and causing birth defects.³⁵ Based on EPA’s standard for drinking water, FDA has also set a standard of ten ppb for arsenic in bottled water.

FDA Should Regulate Based on Cumulative Arsenic Exposure

As EPA has recognized, “[f]or most people, diet is the largest source of arsenic exposure.”³⁶ The high levels of arsenic present in the foregoing staple foods and beverages add substantially to individual arsenic exposure for the great majority of American consumers. Although individually the foods may be safe to eat in moderation, they are often consumed in combination, thereby presenting a risk of cumulative arsenic exposure that could reach dangerous levels.

FDA’s proposed action level for inorganic arsenic in apple juice of ten ppb is insufficient to address the cumulative health hazards that both organic and inorganic arsenic pose to consumers. Even if such a standard were protective of consumers whose only source of arsenic is apple juice, it would still be insufficient to protect consumers who consume apple juice in addition to other staples such as water, rice, and chicken. Where, as here, consumers are likely to be exposed to a toxin from multiple sources, strict regulation of *cumulative* exposure is vital to protecting public health.

Basing tolerance levels on cumulative, rather than product-specific, exposure to toxins is already standard practice in other areas of food regulation. For example, under the Food Quality Protection Act (FQPA), EPA is required to assess the cumulative risks of pesticides that share a common mechanism of toxicity, or act the same way in the body, when setting food tolerance levels:

In assessing cumulative risks, EPA evaluates the potential for people to be exposed to more than one pesticide at a time from a group with an identified common mechanism of toxicity. These cumulative assessments consider exposures from food, drinking water, and residential sources. The Agency also incorporates regional exposures from residential and drinking water sources since this is the most appropriate way to account for the considerable variation in potential

³³ See Sonya Lunder and Dawn Undurraga, *Getting Arsenic out of Your (and Your Kids’) Diet*, Enviroblog (Sept. 20, 2012), <http://www.ewg.org/enviroblog/2012/09/getting-arsenic-out-your-and-your-kids-diet>.

³⁴ U.S. Env’tl. Prot. Agency, Arsenic Compounds: Revised Hazard Summary (Dec. 2012), *available at* <http://www.epa.gov/ttnatw01/hlthef/arsenic.html>.

³⁵ *Id.*

³⁶ *Id.*

exposures across the country. EPA's cumulative assessments, therefore, approximate as closely as possible people's actual exposures and potential risks resulting from current uses of these pesticides in different parts of the country.³⁷

FDA should similarly recognize the various exposure mechanisms in the American diet and regulate arsenic accordingly, based on its cumulative risks. FDA is well aware that arsenic is present in many foods that comprise an otherwise healthy diet, and that consumers are apt to be exposed to arsenic through a variety of sources. In light of this reality, standards based on cumulative exposure are necessary to prevent consumption of "safe" limits of arsenic in individual products that may, in the aggregate, amount to dangerous levels.

In addition, FDA should consider populations who are at greater risk of dietary arsenic exposure and ensure that its standard for arsenic in apple juice is protective of those populations. As explained above, certain segments of the American public are exposed to more arsenic than others, and children and the elderly are more susceptible to arsenic toxicity than adults. This is especially relevant with regard to apple juice, since "[t]he beverages with the highest levels of arsenic (apple and grape juice) tend to be consumed by the young and the elderly, individuals that may be more vulnerable to over exposure of heavy metals."³⁸ In order to adequately protect the public, FDA must establish standards that take the vulnerability and dietary habits of these populations into account.

FDA Should Act Through Regulation Rather than Action Levels

FDA has the authority to issue binding regulations setting limits on arsenic levels in apple juice pursuant to 21 C.F.R. § 109.6. In contrast to regulations, action levels "are not binding on the courts, the public (including food and feed producers), or the agency (including individual FDA employees)," and "do not have the 'force of law' of substantive rules."³⁹ FDA's present course of action is to promote what amounts to voluntary measures for industry to implement as the solution to a significant hazard; its Draft Guidance serves as a mere recommendation, and does not impose legally-enforceable mandates on food producers to reduce arsenic levels in apple juice. Voluntary oversight schemes such as this have an abysmal record of failure, in part because they do not create any incentive to change within the regulated industries. In the case of arsenic exposure, the public cannot afford for FDA to let protective measures fail.

In the face of significant public health risks and broad-source, long-term exposure to arsenic across the water and food supply, FDA should act with the full force of law when setting limits on arsenic by setting standards through binding regulations. Such action would be consistent with Congress's mandate in the APPLE Juice Act of 2012, which would require FDA to issue tolerances for apple juice through notice-and-comment rulemaking pursuant to 21 U.S.C. § 346. Even more importantly, it would be consistent with the Administrative Procedure Act (APA), which guarantees members of the public a right to have their comments considered and addressed as part of FDA's decision-making process.⁴⁰ On such an important matter of public

³⁷ U.S. Env'tl. Prot. Agency, Assessing Pesticide Cumulative Risk, <http://www.epa.gov/opp00001/cumulative/> (last visited Nov. 12, 2013) (emphasis added).

³⁸ Roberge, *supra* note 1, at 693.

³⁹ Action Levels for Added Poisonous or Deleterious Substances in Food, 53 Fed. Reg. 5043 (Feb. 19, 1988).

⁴⁰ See 5 U.S.C. § 553.

health that significantly affects consumers across the country, FDA should enact regulations with the force of law that are finalized “pursuant to the statutory procedural minimum” required by the APA.⁴¹

FDA Should Strongly Enforce Standards for Arsenic in Apple Juice

If FDA chooses to proceed without issuing regulations for arsenic limits in apple juice, it should begin enforcing its action levels immediately and applying them stringently. FDA’s current system of testing has proven ineffective at reducing arsenic levels in apple juice. Although “FDA has been testing for arsenic in apple juice and other fruit juices for decades as part of FDA programs that look for harmful substances in food,”⁴² it has acknowledged that its current scheme does not adequately protect the public:

The juice sold by any one company can be made from concentrate that is literally sourced throughout the world, including U.S. domestic sources. . . . Testing a small number of samples of different brands of juice only provides a snapshot in time of how much arsenic was in a particular lot of juice. Without a long term survey of many lots of juice from different companies, there is not sufficient data to say one company has lower amounts of arsenic in its juice than any other company.⁴³

By FDA’s own account, sporadic testing does not provide the necessary information to reduce arsenic levels in various apple juice products over the long-term. Moreover, levels of arsenic vary across brands, “which is likely due to the source of ingredients coming from different locations.”⁴⁴ The sampling results show that apple juice producers fail to voluntarily monitor for toxic arsenic levels in their products.

Accordingly, if FDA chooses not to enact binding regulations on industry that would mandate a reduction of arsenic levels in apple juice, it must police the industry by acting expeditiously and often to enforce its action levels. In lieu of a regulatory scheme that legally requires producers to market safe food and beverages, close and effective monitoring and enforcement action on the part of FDA is currently the public’s best defense against unnecessary and dangerous exposure to arsenic.

Conclusion

The scientific data in FDA’s own Draft Guidance acknowledges the serious health risks associated with exposure to arsenic in apple juice. In light of these risks, CFS urges FDA to take immediate and legally-binding action to address the cumulative levels of arsenic to which consumers are regularly exposed through food and beverages.

⁴¹ See *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979).

⁴² U.S. Food and Drug Admin., Questions & Answers: Apple Juice and Arsenic: What is the FDA doing to protect the public against arsenic in fruit juice?, <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm271595.htm> (last visited Nov. 12, 2013).

⁴³ U.S. Food and Drug Admin., Questions & Answers: Apple Juice and Arsenic: Can consumers choose apple juice with less arsenic by looking at where it is made?, <http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm271595.htm> (last visited Nov. 12, 2013).

⁴⁴ Roberge, *supra* note 1, at 693.

Thank you for the opportunity to provide comments.

Respectfully Submitted,

A handwritten signature in blue ink that reads "Paige M. Tomaselli". The signature is written in a cursive style with a period at the end.

Paige Tomaselli
Senior Staff Attorney