AMERICAN FROZEN FOOD INSTITUTE

Issue Brief: Heavy Metals (Lead, Arsenic, Cadmium)

Lead, arsenic, and cadmium are each present in the environment, including the water, air, soil, and foods, either as naturally occurring substances or as a result of contamination from human activity. Each has been associated with negative health effects when consumed at high levels, such as cancer and/or developmental effects. Arsenic may be present as inorganic arsenic (generally considered the more toxic form of arsenic) or organic arsenic.

Legal Framework

FDA has not established a general maximum action level for lead, arsenic, or cadmium in foods. FDA has established maximum levels in individual foods on a case-by-case basis such as in bottled water, juices, pottery and candy consumed by young children, and in the specifications for food and color additives. More information on the relevant standards appears below. In general, the presence of heavy metals in food is governed by the prohibition against introducing adulterated foods into interstate commerce. 1/

FDA has published a method of analysis of foods for arsenic, cadmium, lead, and selected other heavy metals. 2/ Since 1991, FDA has tested for total arsenic in a variety of foods, including rice and juices. 3/

Bottled Water: FDA has established the amounts of lead, arsenic, and cadmium permitted in bottled water. The allowable level for inorganic substances in bottled water are 0.010 milligrams per liter (mg/L) for arsenic and 0.005 mg/L for lead and cadmium. 4/

Food Ingredients and Color Additives: The specifications for many food additives, generally recognized as safe (GRAS) ingredients, and color additives frequently will incorporate maximum levels for heavy metals and other contaminants either in the regulation (or notification) itself or by cross reference to the Food Chemicals Codex. 5/

Candy: Additionally, the agency has published a guidance document on lead in candy likely to be consumed by small children, which recommends a maximum lead

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1/ Federal Food, Drug, and Cosmetic Act (FFDCA) § 402(a)(1); 21 U.S.C. § 342(a)(1).
2/ FDA, *Analysis of Foods for As, Cd, Cr, Hg and Pb by Inductively Coupled Plasma-Mass Spectrometry* (ICP-MS), Apr. 25, 2011, http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM272693.pdf.
3/ FDA, *Questions and Answers on Arsenic* (July 2013), http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm280202.htm.
4/ 21 C.F.R. § 165.110(b)(3)(iii)(A).
5/ *See, e.g.,* 21 C.F.R. parts 73, 74, 172, 184.

level of 0.1 ppm. 6/ FDA states that this level is considered achievable with the use of good manufacturing practices (GMPs) and to be protective of human health. In bringing enforcement actions, FDA will consider the level of lead present, the best available consumption data, and the lead exposure that would result from consumption of the product. With respect to lead-based ink on candy wrappers, if lead is found on the portion of the package that directly contacts food, or if the lead could be expected to migrate into the packaged food, the product would be viewed as adulterated.

Juice: FDA has established in guidance a level of 50 parts per billion (ppb) of lead in ready-to-drink fruit juices, including fruit nectars that are in international trade, consistent with the Codex Alimentarius Commission standard. 7/ FDA indicates it may in the future establish an action level for lead in juice at levels above 50 ppb.

Proposition 65: At the state level, lead, inorganic arsenic, and cadmium are listed under California's Proposition 65, which was adopted as a voter initiative in 1986. Lead and inorganic arsenic are listed as known to the state of California to cause both cancer and reproductive toxicity, while cadmium is listed as a reproductive toxin. If a product results in levels of dietary exposure to a listed chemical that exceed the safe harbor level, Proposition 65 requires companies to provide a "clear and reasonable" warning to consumers. 8/ California has established the following safe harbor levels of relevance here: 0.5 micrograms (µg/day) of lead, 9/ 10 µg/day of arsenic, and 4.1 µg/day of cadmium. 10/ Importantly, Proposition 65 has a bounty hunter provision that allows for private rights of action to enforce the labeling requirements.

Recent Developments

- Arsenic in Rice and Rice Products: In September 2013, FDA published the results of testing for the presence of arsenic in over 1,000 samples of rice and rice products. The agency concluded that the amount of detectable arsenic is too low to cause any immediate or short-term adverse health effects. 11/ FDA states that its work going forward will focus on management of long-term risk. FDA is currently working on a draft

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6/ FDA Guidance for Industry, *Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy* (Nov. 2006), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm077904.htm.

7/ FDA Guidance for Industry: *Juice HACCP Hazard and Controls Guidance* (Mar. 3, 2004), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm.

8/ The law also provides a very narrow exemption from the warning requirement for naturally occurring substances. The warning can be provided by various means, but for packaged foods items or other consumer products, labeling the product with the appropriate statement – e.g., "WARNING: This product contains a chemical known to the State of California to cause cancer." – is the typically utilized format.

9/ Note that there are two safe harbor levels for lead. The reproductive toxicity safe harbor is lower, so we provide this level.

10/ The level of exposure to a food is determined by multiplying the concentration of the chemical in the food by the average rate of consumption of the food for average consumers of the food over 70 years. Appropriate dietary intake surveys may be used as the basis for determining average rates of consumption of a food, and it is typically prudent to engage an expert to conduct the evaluation.

11/ FDA, *Arsenic in Rice and Rice Products* (September 2013), http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319870.htm.

quantitative risk assessment for rice and rice products anticipated to be published this year.

- Action Level for Inorganic Arsenic in Apple Juice: In July 2013, FDA published a draft guidance document proposing an action level of 10 ppb for inorganic arsenic in apple juice. 12/ This represents the level of inorganic arsenic in single-strength (ready-to-drink) apple juice that FDA considers protective of public health and achievable with the use of GMPs. FDA will initially analyze apple juice samples for total arsenic, speciating samples containing more than 10 ppb total arsenic to determine inorganic arsenic levels.

- Arsenic in Pear Juice: In February 2012, FDA published analytical testing results for arsenic in pear juice and pear juice concentrate. 13/ Of 142 samples tested, 23 had levels of inorganic arsenic at or above 23 ppb, which FDA identified in 2008 as the level of concern for inorganic arsenic in pear juice. 14/

Issues to Watch

- Draft Guidance on Arsenic in Foods: In it's 2013/2014 Regulatory Plan for Priorities, FDA lists issuing draft guidance on arsenic in other foods beyond apple juice as a priority item.

- Proposition 65 Reform: In October 2013, California passed a law to reform Proposition 65. The law provides fairly narrow relief for a limited number of situations, most of which would not be relevant to food manufacturers. 15/ Broader Proposition 65 reform would be of interest to many food companies.

- Proposition 65 Juice Case: A California Superior Court Judge has issued a tentative ruling that fruit juices, baby food, fruit cocktail, and other packaged fruit and vegetable products are not required to carry Proposition 65 warnings regarding their lead content. 16/ The case is currently under appeal.

International Perspective

12/ FDA Draft Guidance for Industry, *Arsenic in Apple Juice – Action Level* (July 2013), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm360020.htm.

13/ FDA, *Arsenic in Pear Juice Analytical Results, 2005-2011* (February 2012), http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm275452.htm.

14/ FDA, *Hazard Assessment and Level of Concern – Pear Juice* (April 2008), http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm277676.htm.

15/ The law requires potential plaintiffs to give alleged violators a notice before suing. The alleged violator would have 14 days to fix the problem, pay a $500 penalty, and so inform the potential plaintiff. This special exemption is available to restaurants that introduce the Prop 65 chemical into food through cooking processes, but it is not available to food manufacturers generally.

16/ *Environmental Law Foundation (ELF) v. Beech-Nut Corp. et al.*, Case No. RG11 597384 (Sup. Ct. Cal. Cty Alameda) (July 15, 2013).

- European Union (EU): Heavy metals are regulated in the EU as food contaminants and are subject to maximum levels set forth in Commission Regulation (EC) No 1881/2006. 17/ Section 3 of the Annex to the EU Contaminants Regulation sets maximum levels for metals in food. The levels for lead range from 0.02 mg/kg wet weight in raw milk and infant formula to 15 mg/kg wet weight in bivalve molluscs; and levels for cadmium range from 0.050 mg/kg wet weight in meat, fish, fruit, and vegetables to 3 mg/kg wet weight in food supplements. The EC has also recently proposed to revise the maximum levels for cadmium in certain foods beginning January 1, 2015. 18/ There is no maximum level set for arsenic in foods, but the European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain conducted a risk assessment on arsenic in food and recommended reducing dietary exposure to inorganic arsenic. 19/ Accordingly, the presence of arsenic in food is subject only to the general requirement to place only safe food on the market, as set forth in the EU General Food Law (Regulation (EC) No 178/2002)).

  The European Food Safety Authority's (EFSA) in its 2012 scientific opinion revised the provisional tolerable weekly intake (PTWI) of methylmercury to 1.3 µg/kg bw and set a PTWI of 4 µg/kg bw for inorganic mercury. 20/ Methylmercury is the chemical form of most concern making up more than 90 percent of the total mercury in fish and seafood. EFSA concluded that the levels of mercury in foods, other than fish and seafood, were of lower concern since they were not largely methylmercury. 21/ Additionally, EFSA plans to issue a scientific opinion on the risks and benefits of fish/seafood consumption relative to methylmercury by Dec. 31, 2014. 22/

  In 2010, EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) concluded that there is no safe threshold for lead. 23/ The CONTAM Panel considered cereals, vegetables and tap water to contribute most to dietary exposure to lead for most Europeans. Also, in 2010, the CONTAM Panel reaffirmed the previous PTWI of 2.5 µg/kg bw for cadmium. 24/ The CONTAM

17/ COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:364:0005:0024:EN:PDF

18/ The proposed amendment is available at http://register.consilium.europa.eu/doc/srv?l=EN&t=PDF&gc=true&sc=false&f=ST%205675%202014%20INIT&r=http%3A%2F%2Fregister.consilium.europa.eu%2Fpd%2Fen%2F14%2Fst05%2Fst05675.en14.pdf .

19/ EFSA, *Scientific Opinion of the CONTAM Panel: Arsenic in* Food, http://www.efsa.europa.eu/fr/efsajournal/doc/1351.pdf.

20/ http://www.efsa.europa.eu/en/topics/topic/metals.htm

21/ Opinion of the Scientific Panel on contaminants in the Food Chain of the European Food Safety Authority (EFSA) on a request from the Commission related to mercury and methylmercury in food (adopted on 24 February 2004) - http://www.efsa.eu.int/science/contam/contam_opinions/259/opinion_contam_01_en1.pdf

22/ Mandate on the risks and benefits of fish/seafood consumption as regards methylmercury - http://registerofquestions.efsa.europa.eu/raw-war/mandateLoader?mandate=M-2013-0001

23/ Scientific Opinion on Lead in Food, http://www.efsa.europa.eu/en/efsajournal/pub/1570.htm

24/ EFSA SCIENTIFIC OPINION Statement on tolerable weekly intake for cadmium - http://www.efsa.europa.eu/en/efsajournal/doc/1975.pdf; http://www.efsa.europa.eu/en/scdocs/doc/980.pdf. Reports of the Scientific Committee for Food, 36th series, Opinion of the Scientific Committee for Food on cadmium, p. 67, http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_36.pdf

Panel concluded that adverse effects are unlikely to occur at current dietary exposures. In 2009, the CONTAM Panel concluded that there is no safe threshold for arsenic. 25/

In 2001, Scientific Committee on Foods (SCF) noted levels of inorganic tin of 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may cause gastric irritation in some individuals necessitating setting lower maximum levels (MLs). 26/

Finally, EFSA has a call for continuous collection of chemical contaminants occurrence data in food and feed. 27/

- Canada: Health Canada continues to monitor the concentrations of various chemicals, including lead and arsenic, in foods through its ongoing Total Diet Study surveys and also conducts targeted surveys in specific foods. Additionally, the Canadian Food Inspection Agency carries out monitoring and surveillance work for lead and arsenic in foods, including those commonly consumed by infants and children. 28/

- United Kingdom (UK): The presence of metals in foods in the UK is covered by the EU rules referenced above. The UK previously imposed a limit of 1 mg/kg for arsenic in food with separate limits applicable to certain food categories. These regulations were revoked in 2002 as the scientific substantiation was considered outdated.

- Codex and World Health Organization (WHO): The Codex General Standard for Contaminants and Toxins in Food and Feed (Codex Stan 193-1995) provides for maximum levels of heavy metals in foods – specifically, arsenic, cadmium, lead, mercury, methylmercury, and tin. 29/ Based on the most recent Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) evaluation, health-based guidance values for these heavy metals are: no PTWI is health protective for inorganic arsenic, 25 µg/kg body weight provisional tolerable monthly intake (PTMI), no PTWI is health protective for lead, 4 µg/kg bw PTWI as inorganic mercury applies to all foods except fish and shellfish, 1.6 µg/kg bw PTWI applies to fish and shellfish, and 14 mg/kg bw PTWI as inorganic tin. The Codex Committee on Contaminants in Foods is currently revising maximum levels (MLs) for lead in selected commodities, considering appropriate MLs for cadmium in chocolate and cocoa-derived products, established MLs for arsenic in polished rice while considering an appropriate ML for arsenic in husked rice, will resume work on the draft Codex Code of Practice for the Prevention and Reduction of Arsenic

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25/ Scientific Opinion on Arsenic in Food, http://www.efsa.europa.eu/en/efsajournal/pub/1351.htm
26/ Opinion of the Scientific Committee on Food on acute risks posed by tin in canned foods (adopted on 12 December 2001) http://ec.europa.eu/food/fs/sc/scf/out110_en.pdf
27/ http://www.efsa.europa.eu/en/dataclosed/call/datex101217.htm
28/ http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/environ/lead_plomb-eng.php; http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/environ/arsenic-eng.php
29/ CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED - http://www.codexalimentarius.org/download/standards/17/CXS_193e.pdf

Contamination in Rice and will consider appropriate MLs for methylmercury in relevant fish species. 30/

AFFI Action Items

- Monitor FDA developments, including establishment of action levels and issuance of draft and final guidance on heavy metals.

- Monitor Proposition 65 reform and cases affecting the food industry.

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30/ REPORT OF THE EIGHTH SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS. 2014. - http://www.codexalimentarius.org/download/report/906/REP14_CFe.pdf