INITIAL STATEMENT OF REASONS

PROPOSITION 65

TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENT TO ARTICLE 5

NEW SECTION 25501.1 NATURALLY OCCURRING CONCENTRATIONS OF LISTED CHEMICALS IN UNPROCESSED FOODS

PROPOSED NATURALLY OCCURRING CONCENTRATIONS OF INORGANIC ARSENIC IN WHITE AND BROWN RICE

July 21, 2017

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Contents

Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65[1] and has the authority to promulgate and amend regulations to further the purposes of the Act. This new regulation would provide guidance for businesses and the public by establishing:

1) A new Section 25501.1 – Naturally Occurring Concentrations of Listed Chemicals in Unprocessed Foods - that would provide safe harbor values for naturally occurring levels of certain listed chemicals in specific unprocessed foods, and

2) Safe harbor concentrations for the natural background levels of inorganic arsenic in rice. The naturally occurring concentration of inorganic arsenic in rice would be established at 80 parts per billion (ppb) for white rice and 170 ppb for brown rice.

These safe harbor values would apply to all white and brown rice, regardless of the location of where the rice is grown. These values were derived using data for brown and white rice grown in California obtained from the US Food and Drug Administration (2013)[2] and using data for white rice grown in California in 2012 and 2013 obtained from the California Rice Commission[3]. In deriving these values, the extent to which inorganic arsenic in rice may result from human activity was considered.

Problem to be Addressed by the Proposed Rulemaking

The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity. Warnings are not required when exposures are sufficiently low, for

[1] Health and Safety Code, section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as “Proposition 65”. Hereafter referred to as “Proposition 65” or “the Act”.

[2] Derived by OEHHA from the United States Food and Drug Administration (US FDA, 2013). Analytical results from inorganic arsenic in rice and rice products sampling. September 2013. Data available at http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM352467.pdf.

[3] Derived by OEHHA from the California Rice Commission (CRC, 2012 and 2013). Total and inorganic arsenic levels in white rice produced in six US rice growing regions. Unpublished data received with permission from the California Rice Commission.

example when[4]:

> "An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity…"

Proposition 65 implementing regulations provide that naturally occurring chemicals in food are not considered an exposure for purposes of Proposition 65. Existing Title 27, Section 25501 provides in relevant part:

> "(a) Human consumption of a food shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the food.
>
> > (1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.
> > (2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data."

Various chemicals on the Proposition 65 list are considered naturally occurring in food, because they occur solely as a result of absorption or accumulation of the chemical from the environment in which the food is raised or grown. Although Section 25501(a) provides a general approach to establishing the "naturally occurring level" of a chemical in a food, it is difficult to make such a calculation for some chemicals, leaving the possibility that different parties may calculate naturally occurring levels of a given chemical differently, even within the same growing region.

The proposed regulation would add new Section 25501.1 - that would provide safe harbor values for naturally occurring levels of certain listed chemicals in specific foods, such as inorganic arsenic in rice. The new regulation would not

[4] Health and Safety Code, sections 25249.9(b) and 25249.10(c).

preclude a business from using other evidence, assumptions, principles or procedures consistent with Section 25501 to establish that the level of a chemical in a food is naturally occurring. However, Section 25501.1 would establish default naturally occurring concentrations for certain chemicals in specific foods that are calculated by OEHHA. In evaluating the exposure to a chemical in food for which the business is responsible, the naturally occurring concentration would be subtracted from the measured concentration in the food to determine if the food product is exempt from Proposition 65 warning requirements pursuant to Health and Safety Code section 25249.10(c).

The proposed regulation would initially provide safe harbor naturally occurring concentrations for inorganic arsenic in dry white and brown rice grain. As more fully discussed below, the soil in California naturally contains arsenic. The concentrations derived in Section 25501.1(a) take into account the possible contribution of anthropogenic sources in deriving the naturally occurring safe harbor values for the section. OEHHA anticipates adopting additional levels for other listed chemicals or types of foods over time.

Purpose

The purpose of this amendment is to add a new section to the Article 5 regulations to provide default guidance on the natural background levels of Proposition 65 chemicals in foods. It would also add a natural background level for inorganic arsenic in white and brown rice in this new section.

Development of Naturally Occurring Level for Inorganic Arsenic in Rice

OEHHA's approach to the selection of the naturally occurring concentrations for inorganic arsenic in rice is discussed below. This may or may not be the same method OEHHA would use to establish background levels for other listed chemicals, depending on the scientific information available for those chemicals.

Uptake of Inorganic Arsenic by Rice

Arsenic is an abundant metalloid found in the environment from both natural and anthropogenic sources[5,6], including geologic processes[7], pesticides[8] and arsenic-contaminated irrigation water[9]. Rice plants (*Oryza sativa*) take up arsenic from the soil during the growing process. Arsenic levels are generally more concentrated in the bran or outer coating of the rice grain. The coating is retained in brown (unpolished) rice and removed from white (polished) rice[10]. Post-harvest production processes, including parboiling and polishing, reduce the arsenic concentration in the rice grain by solubilizing arsenic that leaches out of the rice grain during boiling, or removing outer layers that can sequester arsenic[11]. This document is focused on the arsenic content of unprocessed brown and white rice. It does not cover more processed rice types, such as parboiled and instant rice.

The amount of arsenic taken up by rice varies by rice type and soil concentration[12]. Higher arsenic levels in the soil lead to greater uptake and accumulation of arsenic in the rice plant[13]. The amount and specific form of arsenic (organic vs. inorganic) in the soil depends on several factors, including

[5] Duan G, Liu W, Chen X, Hu Y and Zhu Y (2013). Association of arsenic with nutrient elements in rice plants. Metallomics 5(7):784-792.

[6] Hojsak I, Braegger C, Bronsky J, Campoy C, Colomb V, Desci T, Domellöf M, Fewtrell M, Fidler Mis N, Mihatsch W, Molgaard C and van Goudoever J (2014). Arsenic in rice-a cause for concern. A comment by the ESPGHAN committee on nutrition. J Pediatr Gastroenterol Nutr EPub 60(1):142-145.

[7] Yang N, Winkel LH and Johannesson KH (2014). Predicting geogenic arsenic contamination in shallow groundwater of south Louisiana, United States. Environ Sci Technol 48(10): 5660-6.

[8] Wang F, Chen Z, Zhang L, Gao Y and Sun Y (2006). Arsenic uptake and accumulation in rice (Oryza sativa L.) at different growth stages following soil incorporation of roxarsone and arsanilic acid. Plant Soil 285:359-367.

[9] Rahman M Azizur, Hasegawa H, Rahman MM, Rahman M Arifur and Miah MAM (2007). Accumulation of arsenic in tissues of rice plant (Oryza sativa L.) and its distribution in fractions of rice grain. Chemosphere 69:942-948.

[10] Meharg AA, Lombi E, Williams PN, Scheckel KG, Feldmann J, Raab A, Zhu Y and Islam R (2008). Speciation and localization of arsenic in white and brown rice grains. Environ Sci Technol 42:1051-1057.

[11] Rahman M Azizur, Hasegawa H, Rahman MM, Rahman M Arifur and Miah MAM (2007). Accumulation of arsenic in tissues of rice plant (Oryza sativa L.) and its distribution in fractions of rice grain. Chemosphere 69:942-948.

[12] Sommella A, Deacon C, Norton G, Pigna M, Violante A and Meharg AA (2013). Total arsenic, inorganic arsenic, and other elements concentrations in Italian rice grain varies with origin and type. Environ Pollut 181: 38-43.

[13] Zhao F, Zhu Y and Meharg AA (2013). Methylated arsenic species in rice: geographical variation, origin, and uptake mechanisms. Environ Sci Technol 47(9):3957-3966.

the amount of water in the soil and soil chemistry[14,15]. Inorganic arsenic is considered the most toxic form to humans and animals and is ubiquitous in rice plants and irrigation water[16,17].

Arsenic in rice as a result of plant uptake from the soil during the natural growing process is unavoidable. Thoroughly washing the harvested rice grains prior to cooking, increasing the volume of water in which the rice is cooked, and draining before consumption may reduce the amount of arsenic contained in the cooked rice grain[18]. The naturally occurring levels of inorganic arsenic in rice grain identified in this document are for concentrations present in the dry rice grain, before food preparation.

Anthropogenic Arsenic Contamination of Soils

A number of human activities have contributed to contamination of soils with inorganic arsenic. Relatively high anthropogenic arsenic contamination of soil can be present near arsenic smelters, in old orchards and cotton-growing regions that saw wide use of lead arsenate or other arsenical pesticides and herbicides, underneath pressure-treated wood structures, and in residential soils where Paris Green (copper acetoarsensite) was used as a pigment in wall paper and paint in the late 1800s[19,20]. One study found elevated arsenic in the upper 6-18 inches of soil in regions of Washington State affected by smelter emissions, and from the historical use of pesticides[21]. A study of play structures in Toronto, Canada, on which arsenicals had been used, indicated contamination under the structure, but not significant dispersion laterally away from the play structure[22]. A study of arsenical use in Texas employing measurements of arsenic with borings over considerable depth did not find migration of inorganic arsenic into groundwater

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[14] Linquist BA, Anders MM, Adviento-Borbe MA, Chaney RL, Nalley LL, Da Rosa EFF and van Kessel C (2015). Reducing greenhouse gas emissions, water use, and grain arsenic levels in rice systems. Glob Change Biol 21:407-417. doi: 10.1111/gcb.12701.
[15] Linquist B and Ruark M (2011). Re-Evaluating diagnostic phosphorus tests for rice systems based on soil phosphorus fractions and field level budgets. Agro J 103(2):501-508.
[16] European Food Safety Authority Panel on Contaminants in the Food Chain (CONTAM) (2009). Scientific Opinion on Arsenic in Food. EFSA Journal 7:1351.
[17] Hite AH (2013). Arsenic and rice: a call for regulation. Nutrition 29:353-354.
[18] Raab A, Baskaran C, Feldmann J and Meharg AA (2009). Cooking rice in a high water to rice ratio reduces inorganic arsenic content. J Environ Monit 11:41-44.
[19] Hughes MF, Beck BD, Chen Y, Lewis AS and Thomas DJ (2011). Arsenic exposure and toxicology: A historical perspective. Tox Sci 123(2):305-332.
[20] ATSDR (2007). Toxicological Profile for Arsenic. US Department of Health and Human Services, Public Health Service.
[21] Ibid.
[22] Ibid.

from the use of arsenical pesticides on cotton[23]. Taken together, these studies show the wide variation of inorganic arsenic contamination that can be associated with common human activities. They indicate that it is reasonable to assume that arsenical pesticide applications, particularly in arid areas, remain fairly localized to the areas in which they are applied, with the understanding that the degree of migration is a function of soil type[24]. On the other hand, emissions from smelters show regional contamination due to dispersion of the airborne emissions[25]. Table 1 summarizes the results of these studies, providing measured levels of arsenic in soil associated with legacy uses of inorganic arsenic.

Table 1. Different types of legacy inorganic arsenic contamination of soil

Source	**Setting**	**Arsenic level in soil (ppm)**
Mine or smelter wastes	Various US sites	>27,000
Abandoned mining site	Southwest England	may exceed 50,000
Copper smelter	Vicinity of Anaconda, MT, upper 2 cm of soil	126 - 236
Copper, lead, arsenic smelter	I-90 corridor in region of ASARCO smelter Washington (first 6-inch soil depth)	>20
Agricultural arsenical use	10 potato fields in Long Island, NY using sodium arsenite herbicide (0-18 cm depth)	28 - 51
	13 orchards in New York State with lead arsenate use	1.6 - 141
	Barber Orchard in NC that operated from 1908 to 1988 that used lead arsenate[26]	280 - 364

[23] Ibid.
[24] Crafts AS and Harvey WA (1955). Weed Control by Soil Sterilization. California Agricultural Experiment Station Extension Service, Division of Agricultural Services, University of California.
[25] ATSDR (2007). Toxicological Profile for Arsenic. US Department of Health and Human Services, Public Health Service.
[26] United States Environmental Protection Agency (US EPA, 2011). Explanation of Significant Difference to the Remedial Action, Barber Orchard Superfund Site, US EPA Region 4, Atlanta, GA March 2011. Available at: http://www.epa.gov/superfund/sites/rods/fulltext/e2011040003830.pdf.

Source	Setting	Arsenic level in soil (ppm)
	Former orchards in Washington State with lead arsenate use: Mean (range) surface 5-10 cm subsurface 10-50 cm	30 (2.9 - 270) 74 (32 - 180)
Pesticide manufacturing	85 homes in Middleport, NY Geometric mean (range)	21 (5 - 340)
Arsenic treated wood	32 of 217 play structures in Toronto Canada with arsenic levels exceeding soil guideline	12 - 48

Source: ATSDR Toxicological Profile for Arsenic[27]

Background Level of Arsenic in Soil

US Geological Survey Study

The US Geological Survey (USGS) conducted an expansive soil sampling study to determine the concentration of various minerals and elements, including arsenic, from 4857 sites in the conterminous United States[28]. Guidelines for sample selection were followed to ensure that samples were not collected from obviously contaminated areas. Each site was selected based on a "generalized random tessellation stratified design" to produce a spatially balanced set of sampling points, not employing a strict grid, at a density of 1 site per 1600 square kilometers. Samples were collected from three soil compartments to assess concentrations in topsoil (0-5 centimeters [cm] depth), A horizon (intermediate depth) and C horizon (greater depth, potential parent source material). USGS determined that the national average (i.e., arithmetic mean) concentration of total (organic and inorganic) arsenic is as follows: 6.4 parts per million (ppm) in topsoil, 6.6 ppm in A horizon, and 7.0 ppm in C horizon. USGS also reported the third quartiles (75th percentile), which were similar to the mean and median values. Maximum values were considerably higher at 830, 1100, and 397 ppm for topsoil, A horizon and C horizon. These values indicate that at least one site

[27] ATSDR (2007). Toxicological Profile for Arsenic. US Department of Health and Human Services, Public Health Service.
[28] USGS (2013). Geochemical and Mineralogical Data for Soils of the Conterminous United States. Data available at http://pubs.usgs.gov/ds/801/pdf/ds801.pdf.

may have had high contamination, although soils overlying arsenic-rich geologic deposits may also have high concentrations[29].

Of the 4857 sites sampled nationally, 257 sites are in California, and 33 of these fall in ten counties[30] where rice is currently grown or has traditionally been grown, based on publicly available historical land use data. Average arsenic concentrations from all samples taken in these ten California counties are similar to the national averages discussed above, with 6.2 ppm in topsoil, 7.1 ppm in A horizon and 7.0 ppm in C horizon[31]. Within each of the ten California rice-growing counties the number of sites sampled is small, precluding firm conclusions regarding the variability of arsenic in soils in these areas based on the USGS data (Table 2).

Table 2. Levels of Total Arsenic Measured in Soils in Rice-Growing Counties of California

County	No. Sites Sampled	Topsoil (ppm)		A horizon (ppm)		C horizon (ppm)	
		Mean	Range	Mean	Range	Mean	Range
Butte	3	5.97	4.6-7.2	6.67	5.2-8.6	6.70	3.2-10.3
Colusa	2	9.60	9.1-10.1	11.05	10.2-11.9	9.70	9.1-10.3
Glenn	3	4.93	3.6-6.9	9.40	6.3-15.1	11.53	8.2-16.9
Sacra-mento	4	7.88	2.9-12	7.85	2.7-12.9	7.98	3.4-12.3
Sutter	2	7.55	2.3-12.8	7.25	2.3-12.2	5.30	3.4-7.2
Yolo	3	8.77	4.9-13.1	8.73	5.8-11.5	9.73	8-11.1
Yuba	1	7.70	---	10.70	---	10.60	---
Fresno	12	5.28	2.4-11.5	5.83	2.1-11.3	5.13	2.1-10.7
Madera	1	2.20	---	2.00	---	2.00	---
Merced	2	4.00	3.6-4.4	4.40	4.2-4.6	5.55	5.5-5.6

Data source: USGS (2013) Survey[32]

[29] ATSDR (2007). Toxicological Profile for Arsenic. US Department of Health and Human Services, Public Health Service.
[30] California rice-growing counties include: Butte, Colusa, Fresno, Glenn, Madera, Merced, Sacramento, Sutter, Yolo, and Yuba.
[31] Derived by OEHHA from USGS (2013). Geochemical and Mineralogical Data for Soils of the Conterminous United States. Data available at http://pubs.usgs.gov/ds/801/pdf/ds801.pdf.
[32] Ibid.

California Department of Food and Agriculture Soil Survey

A study commissioned by the California Department of Food and Agriculture (CDFA) evaluated the toxic metal content of agricultural soil in California and the potential impact of fertilizers, which can contain trace elements such as arsenic[33]. Samples from Oxnard/Ventura, Santa Maria/San Luis Obispo Valley, Colusa/Glenn counties, Fresno, Coachella Valley, Imperial Valley, and Monterey/Salinas Valley were examined to compare arsenic concentrations in soils from uncultivated areas (i.e., baseline concentrations) to concentrations in cropland soils from the same region.

To understand changes over time in arsenic levels in soils from uncultivated areas, the study compared total arsenic from archived soil samples collected in 1967 to samples from the same locations taken in 2001. The soil in these 50 sampling locations is considered representative of the different soil profiles found in California. While there were a few site-specific differences (the 2001 arsenic levels at five individual sites were above 1967 values), 1967 and 2001 levels of arsenic across these uncultivated areas overall did not significantly differ, as shown in Table 3 below. Thus, in the event that samples from uncultivated land in a particular region were unable to be obtained in 2001, levels from the 1967 samples from uncultivated land could confidently be compared to the 2001 cropland samples instead.

Table 3. Total Arsenic Levels at 50 Locations in Uncultivated Areas in California

Year	Arsenic Levels (ppm)		
	Mean ± SD	Median	Range
1967	8.8 ± 4.3	8.5	1.8 - 20.5
2001	7.6 ± 3.7	6.5	1.8 - 16.6

Data source: CDFA Soil Survey (2004)[34]

In comparing total arsenic levels in uncultivated land (baseline concentrations) to those in cropland from the same region, the study found that some arsenic concentrations from the cropland samples were elevated above baseline levels while others were not. In the Imperial and Coachella Valleys, cropland soil arsenic levels were consistently at or lower than baseline levels, indicating no increase due to recent (i.e., post-1967) farming activity, at least in the fields sampled. Arsenic concentrations in cropland soils from Oxnard/Ventura and

[33] Chang AC, Page AL and Krage NJ (2004). Role of Fertilizer and Micronutrient Applications on Arsenic, Cadmium and Lead Accumulation on Cropland Soils in California. Final Report to CDFA. Department of Environmental Sciences, University of California at Riverside (UCR).
[34] Ibid.

Monterey/Salinas Valley also remained within baseline ranges. Arsenic levels in cropland samples from Santa Maria/San Luis Obispo Valley and Colusa/Glenn County exceeded baseline levels, and cropland levels from Fresno, while remaining within the baseline range, showed an upward trend between 1967 and 2001. However, none of the increases were so high as to indicate severe arsenic soil contamination in cropland.

While this study included two cotton-growing areas (where historical arsenical pesticide use may have occurred), Imperial Valley and Coachella Valley, and two rice-growing areas, Fresno and Colusa/Glenn counties, its utility is somewhat limited by the fact that it did not include data from several other rice-growing counties in California, nor did it include specific information about crops grown in the sampled croplands. Overall, it serves to provide a general impression of arsenic content in some California soils, and despite increases in a few cultivated areas, none of the cropland or baseline samples for any region were indicative of high arsenic contamination. Further, the soil arsenic concentrations measured in this study, even in the areas which saw increases, were similar to those measured in the USGS study.

Historical Use of Arsenical Pesticides on California Land

Analysis of historical and current land use and pesticidal practices can also inform discussion of the potential contribution of arsenic to soils from anthropogenic sources. While the registration of lead arsenate for insecticidal use was cancelled in 1988[35,36], historical use of inorganic arsenicals is associated with soil contamination[37], and as shown in Table 1, levels of inorganic arsenic in orchards and fields from legacy arsenical use can be quite high. Furthermore, while there is no current use of inorganic arsenic as a pesticide, there are a number of organic forms still registered for use in the US. Organic arsenicals were observed to be as efficacious as inorganic forms, but at lower application rates[38,39,40], and although inorganic arsenic is the predominant form in soil, organic arsenic compounds can also be found where such pesticidal

[35] US EPA (1988). Final notice of intent to cancel. Federal Register 53:24787.
[36] Peryea FJ (1998). Historical use of lead arsenate insecticides, resulting soil contamination and implications for soil. Proceedings, 16th World Congress of Soil Science, Montpelier France.
[37] Schweizer EE (1967). Toxicity of DMSA Soil Residues to Cotton and Rotational Crops. Weeds 15(1):72-76.
[38] Ibid.
[39] Hughes MF, Beck BD, Chen Y, Lewis AS and Thomas DJ (2011). Arsenic exposure and toxicology: A historical perspective. Tox Sci 123(2):305-332.
[40] Walsh LM, Sumner ME and Keeney DR (1977). Occurrence and Distribution of Arsenic in Soils and Plants. Environ Health Pers 19:67-71.

applications have occurred[41,42]. One study reported increased levels of organic arsenic in soils and groundwater adjacent to where cotton is grown[43]. In California, multiple publicly available data sources allowed the analysis of both historical agricultural land use and arsenical pesticide application.

Areas of Cotton and Rice Production in California

Growing rice in areas previously used for cotton is one noted pathway for rice contamination by arsenic, given the common past use of arsenic for soil sterilization and weevil and other pest control in cotton production[44,45]. The majority of rice produced in California, over 95%, comes from the Sacramento Valley – mainly from Colusa, Sutter, Butte, and Glenn counties[46]. Water supply is relatively plentiful in the Sacramento Valley compared to other areas with potential for rice production. The high clay content soils are ideal for rice and less favorable for other crops[47].

The early 1900s saw the beginning of continuous commercial production of cotton in the Imperial Valley, and with the start of World War I, its production expanded into the San Joaquin Valley[48]. The West was not affected by boll weevil infestations, a severe problem for cotton grown in the South. With the high cost and limited availability of water, and the development of pesticide resistance in cotton pests, much of the cotton production in the southern San Joaquin and Imperial Valleys has recently given way to more lucrative crops[49]. Nonetheless, the San Joaquin Valley has remained the main region of cotton production in the state since the 1960s, with 90% of California cotton grown in Fresno, Kern, Kings, Merced and Tulare Counties[50]. The primary rice and cotton growing counties do not overlap, as shown in Figure 1 below.

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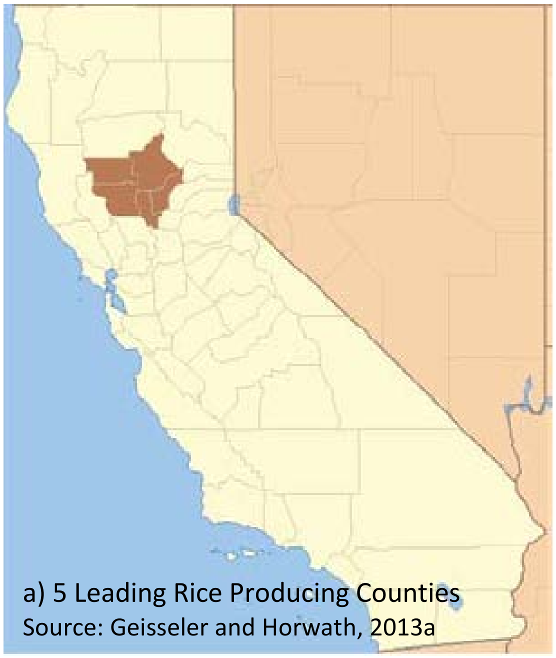
41 Hughes MF, Beck BD, Chen Y, Lewis AS and Thomas DJ (2011). Arsenic exposure and toxicology: A historical perspective. Tox Sci 123(2):305-332.
42 Woolson EA, Axley JH and Kearney PC (1971). The chemistry and phytotoxicity of arsenic in soils: I. contaminated field soils. Soil Sci Soc Amer Proc 35:938-943.
43 Bednar AJ, Garbarino JR, Ranville JF and Wildeman TR (2002). Presence of Organoarsenicals Used in Cotton Production in Agricultural Water and Soil of the Southern United States. J Agric Food Chem 50(25):7340-7344.
44 Ibid.
45 Crafts AS and Harvey WA (1955). Weed Control by Soil Sterilization. California Agricultural Experiment Station Extension Service, Division of Agricultural Services, University of California.
46 Geisseler D and Horwath WR (2013a). Rice Production in California. Fertilizer Research and Education Program, California Department of Food and Agriculture.
47 Ibid.
48 Geisseler D and Horwath WR (2013b). Cotton Production in California. Fertilizer Research and Education Program, California Department of Food and Agriculture.
49 Ibid.
50 Ibid.

Figure 1. Map of California (a) Rice and (b) Cotton Growing Counties



Orchards and Other Crops in Rice Growing Areas of California

Levels of inorganic arsenic in California rice (see below) are not indicative of high soil arsenic levels seen in abandoned orchards and potato fields, and the soils best for rice growing – clay and poorly draining – are not ideal for orchards and other crops, such as potatoes, for which inorganic arsenicals were used as herbicides, pesticides and soil sterilants. To evaluate the potential for low level, more recent exposure to organic arsenicals, OEHHA evaluated the overlap of land areas growing crops with potential for arsenic use with rice-growing areas. OEHHA also plotted the proximity of these potential arsenical use crops to the 33 USGS soil sampling sites in rice-growing counties, to provide information on possible arsenical contamination at these sites. Because use data are only available for periods near or after inorganic arsenic use was phased out during the 1980s[51], this analysis is reflective of potential contamination resulting from *organic* arsenic applications.

OEHHA identified 15 California agricultural crops[52] that have historically used arsenical pesticides using information from the California Department of Pesticide Regulation (DPR). For information on land use and historical location

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[51] Peryea FJ (1998). Historical use of lead arsenate insecticides, resulting soil contamination and implications for soil. Proceedings, 16th World Congress of Soil Science, Montpelier France.
[52] California crops queried: cotton, apples, lemons, oranges, limes, tangerines, grapefruit, grapes, peaches, pears, plums, strawberries, pomegranates, almonds and walnuts.

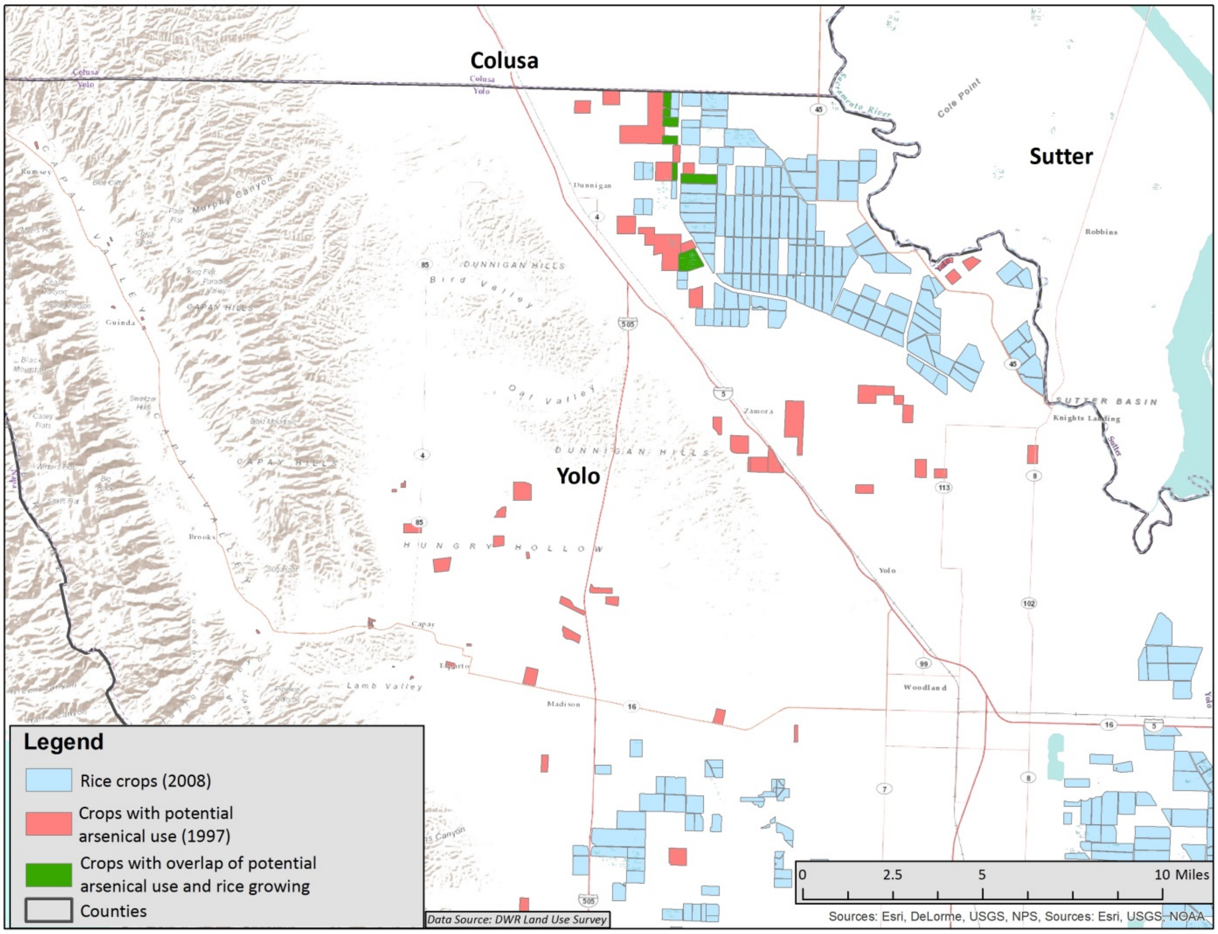
of specific crops, OEHHA queried the National Agricultural Statistics Service (NASS)[53] during the 25-year period 1985 – 2010 and California Department of Water Resources (DWR)[54] databases.

Based on the NASS and DWR historical land use databases, the overlap of rice cultivation with land that previously was used for crops upon which arsenical pesticides were potentially applied (1985-2010) was evaluated. As an example of the approach, Figure 2 shows the result for Yolo County for one time period of use. Most land areas are surveyed every 3-7 years so data may not be available for every area for each of the years queried. However, most California rice-growing areas, particularly in the northern region, are dedicated to rice and are not rotated through with other crops, even in years when rice is not grown[55]. The analysis indicated that less than 5% of recent rice-growing areas in the state overlapped with areas where crops with potential arsenical use were grown.

In some cases, such as Yolo County (Figure 2), crops that potentially used arsenical pesticides may be grown adjacent (within 0.5-1 kilometer) to rice-growing areas. Based on the data available and the consistency with which rice fields are dedicated primarily to rice, the potential contribution of arsenic from arsenical pesticides to soil levels in rice fields appears minimal by this analysis.

[53] Derived by OEHHA from the National Agricultural Statistics Service, NASS Five Year census of agriculture. Data available at http://www.agcensus.usda.gov/index.php.
[54] Derived by OEHHA from the California Department of Water Resources, Land Use Data- GIS files: 1976-2013. Data available at http://www.water.ca.gov/landwateruse/lusrvymain.cfm.
[55] Geisseler D and Horwath WR (2013a). Rice Production in California. Fertilizer Research and Education Program, California Department of Food and Agriculture.

Figure 2. Map of Northern Yolo County, California: Rice and Crops with Potential Arsenical Use[56]



Map of Northern Yolo County, California, a major rice-growing area, showing growing areas for crops with potential arsenical use (1997) and rice (2008) with few areas of overlap. Source: Created by OEHHA using NASS and DWR Databases.[57,58]

The possible use of organic arsenical pesticides at the 33 USGS sampling sites in rice-growing counties was also evaluated. Each sampling site from USGS represented approximately 1 square kilometer. To account for some irregularities in resolution and surveying practices used in the data gathering process, an approximate 5 kilometer radius around each sampling site was evaluated. ZIP code locations were identified for each soil sampling site based

[56] California crops queried: cotton, apples, lemons, oranges, limes, tangerines, grapefruit, grapes, peaches, pears, plums, strawberries, pomegranates, almonds and walnuts.
[57] Derived by OEHHA from the National Agricultural Statistics Service, NASS Five Year census of agriculture. Data available at http://www.agcensus.usda.gov/index.php.
[58] Derived by OEHHA from the California Department of Water Resources, Land Use Data- GIS files: 1976-2013. Data available at http://www.water.ca.gov/landwateruse/lusrvymain.cfm.

on the longitudinal and latitudinal coordinates provided in the USGS study. The DPR[59] database was then queried for the use of arsenical pesticides in those ZIP codes during the years of 1990-2010 (data prior to 1990 is not included in the database). When results indicated arsenical pesticide use in a given ZIP code, the crops on which they were used were also indicated in the DPR database.

Of the 33 USGS sites queried in rice-growing regions, 18 were in ZIP codes where organic arsenical pesticides were applied. While some sampling sites fell in areas where crops with potential arsenical pesticide use were grown, most did not. The sampling sites were often near active rice-growing areas, and away from areas where crops with potential arsenical use were grown. Total arsenic soil levels did not appear to correspond to areas with confirmed arsenical pesticide use. Thus although arsenical pesticide use may contribute to total arsenic in soil at sampling sites with confirmed use, this analysis suggests that that contribution does not appear to be significant in California rice-growing regions. Variation in total arsenic soil levels appeared to be more a factor of local geography, with the seven northern California rice-growing counties (Butte, Colusa, Glenn, Sacramento, Sutter, Yolo and Yuba) having slightly higher levels of total arsenic (mean: 8.2 ppm, range: 2.3-16.9 ppm, 18 sites) compared with the 3 southern counties (Fresno, Madera and Merced) (mean: 5.1 ppm, range: 2.0-11.5 ppm, 15 sites)[60] as shown in Table 2.

Overall the evaluation of the potential arsenic contamination in rice-growing soils suggests very limited possible contributions from arsenicals. Less than 5% of the current areas in California where rice is grown overlapped with cropland with the potential for arsenical use. Also, an analysis of the possible arsenical pesticide contamination at USGS sampling sites in rice-growing areas showed limited potential arsenic contamination.

Contributions of Arsenic from Water

Globally, the use of water that contains high levels of arsenic to irrigate rice fields is a major health concern and contributes to elevated levels of arsenic in rice[61]. Internationally, in some areas rice is irrigated with groundwater sources, some of which can be heavily contaminated with arsenic from geologic processes[62]. In

[59] Derived by OEHHA from the California Department of Pesticide Regulation, Pesticide Use Reports: 1990-2010. Data available at http://calpip.cdpr.ca.gov/main.cfm.
[60] Derived by OEHHA from USGS (2013). Geochemical and Mineralogical Data for Soils of the Conterminous United States. Data available at http://pubs.usgs.gov/ds/801/pdf/ds801.pdf.
[61] Newbigging AM, Paliwoda RE and Le XC (2015). Rice: Reducing arsenic content by controlling water irrigation. J Environ Sci 30:129-131.
[62] Yang N, Winkel LH and Johannesson KH (2014). Predicting geogenic arsenic contamination in shallow groundwater of south Louisiana, United States. Environ Sci Technol 48(10): 5660-6.

certain areas of Bangladesh where rice paddies were irrigated with arsenic-contaminated water, soil arsenic levels were observed to be substantially elevated, as were levels in the rice grain[63]. In the US, rice is typically irrigated with surface water that generally contains low levels of arsenic[64], and the low levels of arsenic in California soils do not suggest significant contributions of arsenic in water to soil. Consistent with the naturally occurring regulation, irrigation is not considered a human activity unless it involves the addition of chemicals to the irrigated water used on crops[65].

Measurements of Arsenic in US and California Rice

As noted above, the bran or outer coating is retained in brown rice, giving brown rice its color and less polished texture[66]. Arsenic, including the inorganic form, collects in the bran coating during the growing process at higher concentrations than in the rest of the grain, resulting in generally higher concentrations of total and inorganic arsenic in brown rice when compared to white rice. OEHHA conducted an analysis of arsenic levels in US and California rice. This analysis was also informed by a similar analysis conducted by the University of California (UC), Davis, under contract with OEHHA[67].

The US Food and Drug Administration (US FDA) collected samples from rice packaged for sale within the US market and measured total and inorganic arsenic levels. Rice samples were identified by country (e.g. China, India) or state of origin (e.g. California, Arkansas) and variety or type of rice (e.g. brown, medium grain) and analyzed for both total and inorganic arsenic levels[68]. The California Rice Commission (CRC) also provided data on arsenic levels in samples of California-produced white rice. The California-produced rice samples from the CRC and US FDA data were combined to form the California data set[69].

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63 Meharg AA and Rahman MM (2003). Arsenic contamination of Bangledesh paddy field soils: implications for rice contribution to arsenic consumption. Environ Sci Technol 37:229-234.
64 Smedley PL and Kinniburg DG (2002). A review of the source, behavior and distribution of arsenic in natural waters. Appl Geochemistry 17(5):517-568.
65 California Code of Regulations, Title 27, Section 25501(a)(3).
66 Batres-Marquez AP, Jensen HH and Upton J (2009). Rice Consumption in the United States: Recent Evidence from Food Consumption Surveys. J Am Diet Assoc. 109(10):1719-1727.
67 Mann S (2014). Is observed background level of arsenic in the rice plant due to anthropogenic sources? Final Report to the California Environmental Protection Agency Office of Environmental Health Hazard Assessment Contract: OEHHA13-S13. Department of Environmental Toxicology, University of California, Davis.
68 Derived by OEHHA from US FDA (2013). Analytical results from inorganic arsenic in rice and rice products sampling. September 2013. Data available at http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM352467.pdf.
69 Derived by OEHHA from CRC (2012 and 2013). Total and inorganic arsenic levels in white rice produced in six U.S. rice growing regions. Unpublished data received with permission from the California Rice Commission.

Data for total arsenic, inorganic arsenic, and the ratio of inorganic arsenic to arsenic for each sample of California rice are tabulated in Appendix A.

For the California data set, there were 31 brown rice samples and 113 white rice samples with average (i.e., arithmetic mean) total arsenic concentrations of 0.17 ppm for brown rice and 0.09 ppm for white rice. Average and median inorganic arsenic concentrations in this data set were 0.13 ppm for brown rice and 0.06 ppm for white rice. Values one standard deviation above these values for inorganic arsenic were 0.17 ppm for brown rice and 0.08 for white rice. These results, along with the ranges for inorganic arsenic, are shown in Table 4 below.

Table 4. Arsenic Levels in California Brown and White Rice

Rice Type	**Number of Samples**	**Total Arsenic (ppm)**	**Inorganic Arsenic (ppm)**		
		Mean ± SD	**Mean ± SD**	**Median**	**Range**
Brown	31	0.17 ± 0.04	0.13 ± 0.04	0.13	0.03 - 0.20
White	113	0.09 ± 0.04	0.06 ± 0.02	0.06	0.02 - 0.10

Data source: US FDA (2013) and CRC (2012, 2013)[70]

OEHHA also analyzed the US FDA and CRC data on total and inorganic arsenic concentrations[71] for all samples of rice grown in the US. These data are also included in Appendix A. Excluding the California samples leaves a total of 346 samples of white rice produced in five US states[72] and 47 brown rice samples produced in three US states. The average total arsenic concentrations were 0.30 ppm for brown rice and 0.21 ppm for white rice; the average inorganic arsenic concentrations were 0.16 ppm for brown rice and 0.09 ppm for white rice. The arsenic concentrations shown in Table 4 for California-grown rice are somewhat lower than the values representing the other US rice-growing states ($p < 0.01$). Similar concentrations of inorganic arsenic in US rice have been reported in the scientific literature for brown and white rice at 0.17 ppm and 0.11 ppm, respectively[73].

[70] Ibid.
[71] Derived by OEHHA from US FDA (2013). Analytical results from inorganic arsenic in rice and rice products sampling. September 2013. Data available at http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM352467.pdf.
[72] Arkansas, Louisiana, Mississippi, Missouri and Texas.
[73] Meharg AA, Lombi E, Williams PN, Scheckel KG, Feldmann J, Raab A, Zhu Y and Islam R (2008). Speciation and localization of arsenic in white and brown rice grains. Environ Sci Technol 42:1051-1057.

OEHHA also evaluated the ratio of inorganic to total arsenic in both brown and white rice. The ratio of inorganic arsenic to the total arsenic concentrations in the US rice samples ranged from 20-100% for brown rice (US FDA data) (mean: 65%, median: 64%, 95% upper bound: 89%) and 12-100% for white rice (US FDA and CRC data) (mean: 53%, median: 51%, 95% upper bound: 89%). This approximately 10% difference at the mean in the ratio of inorganic to total arsenic concentration between brown and white rice has been reported in the scientific literature[74,75]. The variability in the ratio appears to be driven primarily by the amount of organic arsenic present in the rice, as the levels of inorganic arsenic are less variable than total arsenic for the US rice samples from different areas.

Naturally Occurring Inorganic Arsenic in Rice

Reviewing relatively recent and historical information on arsenical pesticide use, it is reasonable to assume that the majority of arsenic in California soil in rice-growing areas is naturally occurring. The mean value of inorganic arsenic in California white rice is 0.06 ppm, or 60 ppb; 80 ppb is one standard deviation above this value. The mean value for brown rice is 0.13 ppm, or 130 ppb; 170 ppb is one standard deviation above this value. Since there is natural variation in the levels of arsenic in rice, these values that are one standard deviation from the mean are selected as the safe harbor naturally occurring levels of inorganic arsenic for these types of rice. Values toward the extreme of the distribution are not selected because of potential arsenic contribution from historical anthropogenic sources. The value for white rice is the same as the 80 ppb proposed by UC Davis[76], which did not provide separate values for white and brown rice.

The mean and median values for inorganic arsenic were very similar within each data set (brown, white rice), indicating relatively little skewness in the measured values. The ratio of inorganic to total arsenic was variable in US rice, and thus total arsenic does not provide a reliable basis for estimating inorganic levels. OEHHA also considered estimating levels of arsenic in rice from soil levels using uptake transfer factors. However, these factors vary across studies and also did not provide reliable estimates.

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[74] Ibid.

[75] Williams PN, Raab A, Feldmann J and Meharg AA (2007). Market basket survey shows elevated levels of As in South Central US processed rice compared to California: consequences for human dietary exposure. Environ Sci Technol 41(7):2178-83.

[76] Mann S (2014). Is observed background level of arsenic in the rice plant due to anthropogenic sources? Final Report to the California Environmental Protection Agency Office of Environmental Health Hazard Assessment Contract: OEHHA13-S13. Department of Environmental Toxicology, University of California, Davis.

These proposed safe harbor naturally occurring levels for inorganic arsenic would apply to all rice, independent of location of production. Within the United States, naturally occurring levels of arsenic in soil appear similar to levels in California soils, as indicated by findings from the USGS survey.

Necessity

Over the years, stakeholders have requested assistance in determining background levels of naturally occurring chemicals in foods. The addition of Section 25501.1, which will provide safe harbor concentration values for naturally occurring chemicals in foods addresses this concern. Further, the initial entries for inorganic arsenic in brown and white rice address a specific, ongoing concern. In particular, arsenic has been the subject of numerous enforcement actions under the Act. There has been a divergence of opinion as to whether certain concentrations can be considered naturally occurring, and should not therefore be considered an exposure for purposes of Proposition 65. The regulated community has sought more clarity in the implementation of the naturally occurring provision of the Act, and the values for arsenic proposed in this rulemaking provide greater clarity.

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements pursuant to sections 11346.3(b)(1)(A) through (D):

Creation or elimination of jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California. The proposed regulation will increase clarity for the regulated community by establishing background levels for arsenic occurring naturally in rice. This will assist the regulated community in determining whether an “exposure” occurs for purposes of the Act.

Creation of new businesses or elimination of existing businesses within the State of California

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. The proposed regulation will increase clarity for the regulated community as to the implementation of the naturally occurring provision of the Act.

Expansion of businesses currently doing business within the State of California

This regulatory action will not impact the expansion of businesses within the State of California. The proposed regulation will increase clarity for the regulated community as to the implementation of the naturally occurring provision of the Act.

Benefits of the proposed regulation to the health and welfare of California residents, worker safety, and the state's environment

OEHHA has concluded that the public and the regulated community would benefit from increased clarity by the adoption of background levels for arsenic occurring naturally in rice. This will assist the regulated community in determining whether an "exposure" occurs for purposes of the Act. The health and welfare of California residents will benefit from the ability to make informed decisions from relevant warnings.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

To derive the naturally occurring level of inorganic arsenic in rice, OEHHA reviewed and relied upon a number of reports, articles, and data sets, as described below. Seven studies were used to understand occurrence and sources of arsenic in the environment:

- Duan G, Liu W, Chen X, Hu Y and Zhu Y (2013). Association of arsenic with nutrient elements in rice plants. Metallomics 5(7):784-792.
- European Food Safety Authority Panel on Contaminants in the Food Chain (CONTAM) (2009). Scientific Opinion on Arsenic in Food. EFSA Journal 7:1351.
- Hite AH (2013). Arsenic and rice: a call for regulation. Nutrition 29:353-354.
- Hojsak I, Braegger C, Bronsky J, Campoy C, Colomb V, Desci T, Domellöf M, Fewtrell M, Fidler Mis N, Mihatsch W, Molgaard C and van Goudoever J (2014). Arsenic in rice-a cause for concern. A comment by the ESPGHAN committee on nutrition. J Pediatr Gastroenterol Nutr EPub 60(1):142-145.
- Rahman M Azizur, Hasegawa H, Rahman MM, Rahman M Arifur and Miah MAM (2007). Accumulation of arsenic in tissues of rice plant (Oryza sativa L.) and its distribution in fractions of rice grain. Chemosphere 69:942-948.

- Wang F, Chen Z, Zhang L, Gao Y and Sun Y (2006). Arsenic uptake and accumulation in rice (Oryza sativa L.) at different growth stages following soil incorporation of roxarsone and arsanilic acid. Plant Soil 285:359-367.
- Yang N, Winkel LH and Johannesson KH (2014). Predicting geogenic arsenic contamination in shallow groundwater of south Louisiana, United States. Environ Sci Technol 48(10): 5660-6.

Ten reports and studies were used in consideration of sources of soil contamination:

- ATSDR (2007). Toxicological Profile for Arsenic. US Department of Health and Human Services, Public Health Service.
- Bednar AJ, Garbarino JR, Ranville JF and Wildeman TR (2002). Presence of Organoarsenicals Used in Cotton Production in Agricultural Water and Soil of the Southern United States. J Agric Food Chem 50(25):7340-7344.
- Crafts AS and Harvey WA (1955). Weed Control by Soil Sterilization. California Agricultural Experiment Station Extension Service, Division of Agricultural Services, University of California.
- Hughes MF, Beck BD, Chen Y, Lewis AS and Thomas DJ (2011). Arsenic exposure and toxicology: A historical perspective. Tox Sci 123(2):305-332.
- Peryea FJ (1998). Historical use of lead arsenate insecticides, resulting soil contamination and implications for soil. Proceedings, 16th World Congress of Soil Science, Montpelier France.
- Schweizer EE (1967). Toxicity of DMSA Soil Residues to Cotton and Rotational Crops. Weeds 15(1):72-76.
- United States Environmental Protection Agency (1988). Final notice of intent to cancel. Federal Register 53:24787.
- US EPA (2011). Explanation of Significant Difference to the Remedial Action, Barber Orchard Superfund Site, US EPA Region 4, Atlanta, GA March 2011. Available at: http://www.epa.gov/superfund/sites/rods/fulltext/e2011040003830.pdf.
- Walsh LM, Sumner ME and Keeney DR (1977). Occurrence and Distribution of Arsenic in Soils and Plants. Environ Health Pers 19:67-71.
- Woolson EA, Axley JH and Kearney PC (1971). The chemistry and phytotoxicity of arsenic in soils: I. contaminated field soils. Soil Sci Soc Amer Proc 35:938-943.

Four studies were used to understand how contaminated water contributes to soil arsenic concentrations:

- Meharg AA and Rahman MM (2003). Arsenic contamination of Bangledesh paddy field soils: implications for rice contribution to arsenic consumption. Environ Sci Technol 37:229-234.
- Newbigging AM, Paliwoda RE and Le XC (2015). Rice: Reducing arsenic content by controlling water irrigation. J Environ Sci 30:129-131.
- Smedley PL and Kinniburg DG (2002). A review of the source, behavior and distribution of arsenic in natural waters. Appl Geochemistry 17(5):517-568.
- Yang N, Winkel LH and Johannesson KH (2014). Predicting geogenic arsenic contamination in shallow groundwater of south Louisiana, United States. Environ Sci Technol 48(10): 5660-6.

Four studies were used to understand how arsenic is taken up into rice plants and grains:

- Linquist B and Ruark M (2011). Re-Evaluating diagnostic phosphorus tests for rice systems based on soil phosphorus fractions and field level budgets. Agro J 103(2):501-508.
- Linquist BA, Anders MM, Adviento-Borbe MA, Chaney RL, Nalley LL, Da Rosa EFF and van Kessel C (2015). Reducing greenhouse gas emissions, water use, and grain arsenic levels in rice systems. Glob Change Biol 21:407-417. doi: 10.1111/gcb.12701.
- Sommella A, Deacon C, Norton G, Pigna M, Violante A and Meharg AA (2013). Total arsenic, inorganic arsenic, and other elements concentrations in Italian rice grain varies with origin and type. Environ Pollut 181: 38-43.
- Zhao F, Zhu Y and Meharg AA (2013). Methylated arsenic species in rice: geographical variation, origin, and uptake mechanisms. Environ Sci Technol 47(9):3957-3966.

Six studies helped inform discussion of differences in arsenic concentrations due to rice type and/or preparation:

- Batres-Marquez AP, Jensen HH and Upton J (2009). Rice Consumption in the United States: Recent Evidence from Food Consumption Surveys. J Am Diet Assoc. 109(10):1719-1727.
- Mann S (2014). Is observed background level of arsenic in the rice plant due to anthropogenic sources? Final Report to the California Environmental Protection Agency Office of Environmental Health Hazard Assessment Contract: OEHHA13-S13. Department of Environmental Toxicology, University of California, Davis.

- Meharg AA, Lombi E, Williams PN, Scheckel KG, Feldmann J, Raab A, Zhu Y and Islam R (2008). Speciation and localization of arsenic in white and brown rice grains. Environ Sci Technol 42:1051-1057.
- Raab A, Baskaran C, Feldmann J and Meharg AA (2009). Cooking rice in a high water to rice ratio reduces inorganic arsenic content. J Environ Monit 11:41-44.
- Rahman M Azizur, Hasegawa H, Rahman MM, Rahman M Arifur and Miah MAM (2007). Accumulation of arsenic in tissues of rice plant (Oryza sativa L.) and its distribution in fractions of rice grain. Chemosphere 69:942-948.
- Williams PN, Raab A, Feldmann J and Meharg AA (2007). Market basket survey shows elevated levels of As in South Central US processed rice compared to California: consequences for human dietary exposure. Environ Sci Technol 41(7):2178-83.

Three reports were used to analyze background levels of arsenic in California soils:

- Agency for Toxic Substances and Disease Registry (ATSDR, 2007). Toxicological Profile for Arsenic. US Department of Health and Human Services, Public Health Service.
- Chang AC, Page AL and Krage NJ (2004). Role of Fertilizer and Micronutrient Applications on Arsenic, Cadmium and Lead Accumulation on Cropland Soils in California. Final Report to CDFA. Department of Environmental Sciences, University of California at Riverside (UCR).
- United States Geological Survey (USGS, 2013). Geochemical and Mineralogical Data for Soils of the Conterminous United States. Data available at http://pubs.usgs.gov/ds/801/pdf/ds801.pdf.

Four studies were used to understand rice and other crop production in California:

- Bednar AJ, Garbarino JR, Ranville JF and Wildeman TR (2002). Presence of Organoarsenicals Used in Cotton Production in Agricultural Water and Soil of the Southern United States. J Agric Food Chem 50(25):7340-7344.
- Crafts AS and Harvey WA (1955). Weed Control by Soil Sterilization. California Agricultural Experiment Station Extension Service, Division of Agricultural Services, University of California.
- Geisseler D and Horwath WR (2013a). Rice Production in California. Fertilizer Research and Education Program, California Department of Food and Agriculture.

- Geisseler D and Horwath WR (2013b). Cotton Production in California. Fertilizer Research and Education Program, California Department of Food and Agriculture.

Three databases were used to show land use and pesticide use in/near areas where rice is grown in California:

- California Department of Pesticide Regulation, Pesticide Use Reports: 1990-2010. Data available at http://calpip.cdpr.ca.gov/main.cfm.
- California Department of Water Resources, Land Use Data- GIS files: 1976-2013. Data available at http://www.water.ca.gov/landwateruse/lusrvymain.cfm.
- National Agricultural Statistics Service, NASS Five Year census of agriculture. Data available at http://www.agcensus.usda.gov/index.php.

Finally, two datasets were used to analyze naturally occurring inorganic arsenic levels in rice:

- CRC (2012 and 2013). Total and inorganic arsenic levels in white rice produced in six U.S. rice growing regions. Unpublished data received with permission from the California Rice Commission.
- US FDA (2013). Analytical results from inorganic arsenic in rice and rice products sampling. September 2013. Data available at http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Metals/UCM352467.pdf.

A reference list is included in this Initial Statement of Reasons as Appendix B. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

Benefits of the Proposed Regulation

Regulated businesses will likely benefit from the proposed regulation because it would provide guidance about naturally occurring levels of arsenic in certain foods by establishing default naturally occurring concentrations for that chemical in rice. The health and welfare of California residents will likely benefit by increasing the public's ability to make informed purchasing decisions using the warnings they receive for certain foods.

The implicit net benefit of Proposition 65 and the proposed regulation is based on the stated desire of Californians to be informed of exposures to chemicals that are known to cause cancer or reproductive harm, as evidenced by the passage of Proposition 65 by the voters in 1986.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

A number of alternatives to the regulation were proposed during the pre-regulatory workshop and the public comment period that followed. One suggestion was to "adopt the FDA and USDA standard tolerances for lead and other contaminants in food." OEHHA notes that currently there are no established federal tolerances for arsenic in food products, and that tolerances are not typically set based on the consideration of naturally occurring levels. Formerly, US FDA had set a tolerance for arsenic which applied only to food-producing animals treated with arsenical veterinary drugs; however, as of the close of 2015, there are no FDA-approved, arsenic-based drugs for use in food producing animals[77]. US FDA has recently proposed a limit (100 ppb) for inorganic arsenic that will apply only to infant rice cereal[78], but this proposal has not yet been adopted.

It was suggested that OEHHA address varying levels of arsenic in soils in growing regions around the US and world in deriving the proposed naturally occurring levels. The findings of the USGS survey indicated that naturally occurring levels of arsenic in US soils appear similar to levels in California soils. The OEHHA-derived safe harbor values for naturally occurring levels of inorganic arsenic in rice are based on California rice data which appears to have minimal contributions from anthropogenic sources. The California rice data have concentrations that are similar to but slightly lower than those measured by US FDA and CRC in rice grown in five other US states. The use of arsenical pesticides in these other areas of the US where rice is grown and the potential for contributions that may have resulted in slightly higher levels compared to California could not be evaluated due to lack of readily available data.

Another suggested alternative related to addressing variability was to "incorporate two standard deviations to the mean results". OEHHA feels that

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[77] US FDA (2015). FDA Announces Pending Withdrawal of Approval of Nitarsone. Accessed April 11, 2017. Available at:
https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm440668.htm
[78] US FDA (2016). FDA Proposes Limit For Inorganic Arsenic In Infant Rice Cereal. Accessed: April 11, 2017. Available at:
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm493740.htm

providing one value rather than a range of values (from two standard deviations below the mean to two standard deviations above the mean) provides a clearer guideline for affected parties and is consistent with the manner in which action levels and tolerances for chemicals in food are set in the US (e.g., US FDA[79]) and internationally (e.g., World Health Organization [WHO][80]). The choice of a value one standard deviation above the mean accounts for natural variability of arsenic. A related suggestion to account for variability was to set the naturally occurring allowance using the highest detected levels of the results that OEHHA reviewed. Selecting the highest detected levels would result in OEHHA promulgating a "naturally occurring level" of inorganic arsenic in rice that would be significantly higher than the actual naturally occurring levels in most rice. An elevated "naturally occurring" level could also conflict with food-safety standards. More specifically, a naturally occurring level based on the highest detected levels would allow a background level for inorganic arsenic in rice greater than twice the limit proposed by US FDA for infant rice cereal, which is primarily composed of rice (260 ppb compared to 100 ppb). The values derived by OEHHA are closer to the value proposed by US FDA. OEHHA also considered estimating levels of arsenic in rice from soil levels using uptake transfer factors. However, these factors vary across studies and also did not provide reliable estimates.

OEHHA has initially determined that none of the reasonable alternatives described above would be more effective in carrying out the purpose for which Proposition 65 is proposed, or would be as effective and less burdensome to affected private persons or businesses than the proposed action, or would be more cost effective to affected private persons or businesses and equally effective in implementing the statutory policy or other provision of law.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, would be more effective in carrying out the proposed action, or would

[79] US FDA (2000). Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. Accessed: April 13, 2017. Available at: https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm077969.htm

[80] Codex Alimentarius Commission. 2015. Codex general standard for contaminants and toxins in food and feed (CODEX STAN 193–1995). pp.34-51

be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any mandatory requirements on small businesses. Proposition 65 expressly exempts businesses with less than 10 employees[81] from the requirements of the Act. In addition, proposed Section 25501.1 is specifically designed to lessen the existing burdens on businesses that are subject to the requirements of the Act by establishing default (safe harbor) naturally occurring levels for inorganic arsenic in white and brown rice.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed action does not impose any new requirements upon private persons or business but rather provides guidance for businesses by establishing safe harbor naturally occurring levels for inorganic arsenic in white and brown rice.

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulations do not duplicate and will not conflict with federal regulations.

[81] Health and Safety Code, section 25249.11(b).

Appendix A: Arsenic in Rice Data

These data tables contain values for total arsenic, inorganic arsenic and the ratio of inorganic to total arsenic in rice from: 1) US Food and Drug Administration (US FDA, 2013), for white and brown rice, and 2) California Rice Commission (CRC, 2012 & 2013) for white rice.

White Rice

FDA 2013, Arkansas (N=89)						
Total As (ppm)	Inorganic As (ppm)	Ratio Inorganic to Total		Total As (ppm)	Inorganic As (ppm)	Ratio Inorganic to Total
0.220	0.055	0.250		0.220	0.097	0.441
0.130	0.057	0.438		0.230	0.097	0.422
0.231	0.058	0.251		0.222	0.097	0.437
0.108	0.062	0.574		0.223	0.098	0.439
0.197	0.063	0.320		0.193	0.099	0.513
0.124	0.071	0.573		0.227	0.101	0.445
0.172	0.071	0.413		0.262	0.103	0.393
0.198	0.075	0.379		0.263	0.103	0.392
0.185	0.076	0.411		0.200	0.104	0.520
0.180	0.077	0.428		0.192	0.107	0.557
0.158	0.078	0.494		0.234	0.110	0.470
0.152	0.078	0.513		0.210	0.111	0.529
0.160	0.079	0.494		0.234	0.111	0.474
0.155	0.079	0.510		0.241	0.112	0.465
0.224	0.081	0.362		0.240	0.115	0.479
0.186	0.081	0.435		0.196	0.120	0.612
0.188	0.082	0.436		0.261	0.121	0.464
0.193	0.082	0.425		0.265	0.127	0.479
0.160	0.082	0.513		0.306	0.128	0.418
0.168	0.083	0.494		0.188	0.054	0.287
0.185	0.083	0.449		0.199	0.056	0.281
0.179	0.083	0.464		0.148	0.063	0.426
0.228	0.085	0.373		0.127	0.064	0.504
0.170	0.085	0.500		0.156	0.064	0.410
0.202	0.085	0.421		0.233	0.074	0.318
0.237	0.085	0.359		0.153	0.077	0.503
0.158	0.085	0.538		0.182	0.077	0.423
0.177	0.086	0.486		0.200	0.078	0.390
0.153	0.086	0.562		0.167	0.087	0.521
0.167	0.087	0.521		0.190	0.090	0.474
0.276	0.087	0.315		0.196	0.090	0.459
0.188	0.087	0.463		0.189	0.093	0.492
0.200	0.088	0.440		0.239	0.094	0.393
0.242	0.088	0.364		0.187	0.094	0.503
0.194	0.089	0.459		0.192	0.095	0.495
0.172	0.089	0.517		0.184	0.096	0.522
0.184	0.089	0.484		0.273	0.099	0.363
0.210	0.090	0.429		0.239	0.101	0.423
0.248	0.090	0.363		0.207	0.101	0.488
0.216	0.091	0.421		0.198	0.102	0.515

0.182	0.091	0.500		0.316	0.112	0.354
0.271	0.093	0.343		0.258	0.113	0.438
0.208	0.095	0.457		0.324	0.126	0.389
0.213	0.095	0.446		0.334	0.174	0.521
0.150	0.095	0.633				

FDA 2013, California (N=64)						
Total As (ppm)	**Inorganic As (ppm)**	**Ratio Inorganic to Total**		**Total As (ppm)**	**Inorganic As (ppm)**	**Ratio Inorganic to Total**
0.053	0.027	0.509		0.118	0.065	0.551
0.099	0.050	0.505		0.117	0.066	0.564
0.099	0.052	0.525		0.116	0.066	0.569
0.101	0.052	0.515		0.119	0.069	0.580
0.103	0.056	0.544		0.108	0.074	0.685
0.054	0.039	0.722		0.134	0.078	0.582
0.089	0.045	0.506		0.120	0.079	0.658
0.089	0.046	0.517		0.135	0.087	0.644
0.104	0.047	0.452		0.130	0.088	0.677
0.084	0.050	0.595		0.155	0.100	0.645
0.090	0.051	0.567		0.079	0.052	0.658
0.081	0.052	0.642		0.099	0.054	0.545
0.092	0.052	0.565		0.104	0.056	0.538
0.091	0.053	0.582		0.112	0.064	0.571
0.099	0.054	0.545		0.103	0.065	0.631
0.093	0.054	0.581		0.107	0.070	0.654
0.105	0.054	0.514		0.103	0.072	0.699
0.083	0.054	0.651		0.170	0.072	0.424
0.086	0.055	0.640		0.109	0.073	0.670
0.099	0.055	0.556		0.105	0.079	0.752
0.099	0.056	0.566		0.117	0.081	0.692
0.094	0.056	0.596		0.148	0.081	0.547
0.076	0.058	0.763		0.180	0.081	0.450
0.092	0.060	0.652		0.141	0.087	0.617
0.099	0.060	0.606		0.170	0.088	0.518
0.116	0.061	0.526		0.151	0.088	0.583
0.105	0.061	0.581		0.130	0.094	0.723
0.113	0.062	0.549		0.146	0.099	0.678
0.105	0.062	0.590		0.118	0.100	0.847
0.091	0.062	0.681		0.113	0.102	0.903
0.092	0.062	0.674		0.127	0.102	0.803
0.127	0.063	0.496		0.115	0.102	0.887

FDA 2013, Louisiana (N=35)						
Total As (ppm)	**Inorganic As (ppm)**	**Ratio Inorganic to Total**		**Total As (ppm)**	**Inorganic As (ppm)**	**Ratio Inorganic to Total**
0.314	0.068	0.217		0.322	0.109	0.339
0.123	0.072	0.585		0.221	0.112	0.507
0.173	0.076	0.439		0.186	0.113	0.608
0.226	0.078	0.345		0.268	0.114	0.425
0.236	0.079	0.335		0.253	0.116	0.458
0.258	0.081	0.314		0.220	0.136	0.618
0.173	0.083	0.480		0.134	0.064	0.478
0.252	0.087	0.345		0.256	0.082	0.320
0.379	0.089	0.235		0.143	0.095	0.664
0.220	0.089	0.405		0.174	0.098	0.563
0.192	0.089	0.464		0.186	0.101	0.543
0.222	0.091	0.410		0.213	0.103	0.484
0.188	0.095	0.505		0.251	0.105	0.418
0.230	0.098	0.426		0.212	0.109	0.514
0.290	0.098	0.338		0.259	0.110	0.425
0.166	0.100	0.602		0.232	0.112	0.483
0.285	0.102	0.358		0.250	0.137	0.548
0.260	0.102	0.392				
FDA 2013, Texas (N=25)						
0.177	0.066	0.373		0.225	0.108	0.480
0.458	0.068	0.148		0.220	0.111	0.505
0.171	0.072	0.421		0.343	0.150	0.437
0.270	0.081	0.300		0.652	0.078	0.120
0.185	0.085	0.459		0.644	0.080	0.124
0.242	0.090	0.372		0.656	0.082	0.125
0.329	0.097	0.295		0.717	0.084	0.117
0.305	0.099	0.325		0.613	0.097	0.158
0.383	0.103	0.269		0.630	0.101	0.160
0.780	0.105	0.135		0.616	0.102	0.166
0.529	0.106	0.200		0.616	0.102	0.166
0.365	0.106	0.290		0.612	0.109	0.178
0.270	0.106	0.393				
CRC 2012, Arkansas, Arkansas (N=19)						
0.210	0.080	0.381		0.150	0.080	0.533
0.190	0.040	0.211		0.120	0.080	0.667
0.210	0.070	0.333		0.120	0.090	0.750
0.270	0.120	0.444		0.140	0.090	0.643
0.240	0.110	0.458		0.160	0.130	0.813
0.180	0.090	0.500		0.170	0.090	0.529
0.190	0.080	0.421		0.180	0.080	0.444
0.140	0.090	0.643		0.150	0.090	0.600
0.210	0.100	0.476		0.240	0.110	0.458
0.170	0.110	0.647				

CRC 2012. Butte, California (N=25)						
Total As (ppm)	**Inorganic As (ppm)**	**Ratio Inorganic to Total**		**Total As (ppm)**	**Inorganic As (ppm)**	**Ratio Inorganic to Total**
0.070	0.040	0.571		0.060	0.040	0.667
0.110	0.070	0.636		0.090	0.070	0.778
0.080	0.060	0.750		0.080	0.050	0.625
0.090	0.080	0.889		0.090	0.050	0.556
0.110	0.070	0.636		0.050	0.040	0.800
0.070	0.050	0.714		0.070	0.050	0.714
0.110	0.080	0.727		0.100	0.060	0.600
0.090	0.060	0.667		0.060	0.050	0.833
0.070	0.060	0.857		0.090	0.060	0.667
0.090	0.060	0.667		0.070	0.040	0.571
0.100	0.060	0.600		0.060	0.040	0.667
0.060	0.050	0.833		0.060	0.040	0.667
0.080	0.050	0.625				
CRC 2012, Acadia, Louisiana (N=19)						
0.170	0.070	0.412		0.290	0.050	0.172
0.140	0.060	0.429		0.210	0.060	0.286
0.130	0.030	0.231		0.140	0.070	0.500
0.180	0.040	0.222		0.200	0.070	0.350
0.190	0.050	0.263		0.210	0.080	0.381
0.150	0.060	0.400		0.190	0.080	0.421
0.210	0.050	0.238		0.160	0.070	0.438
0.250	0.060	0.240		0.170	0.070	0.412
0.280	0.060	0.214		0.110	0.060	0.545
0.270	0.090	0.333				
CRC 2012, Washington, Mississippi (N=19)						
0.100	0.050	0.500		0.080	0.050	0.625
0.080	0.040	0.500		0.080	0.070	0.875
0.100	0.060	0.600		0.080	0.080	1.000
0.100	0.060	0.600		0.090	0.070	0.778
0.140	0.070	0.500		0.120	0.090	0.750
0.090	0.060	0.667		0.120	0.090	0.750
0.120	0.060	0.500		0.110	0.080	0.727
0.080	0.060	0.750		0.100	0.070	0.700
0.110	0.090	0.818		0.100	0.060	0.600
0.110	0.080	0.727				
CRC 2012, Pemiscot, Missouri (N=19)						
0.060	0.030	0.500		0.030	0.030	1.000
0.040	0.020	0.500		0.040	0.030	0.750
0.050	0.030	0.600		0.060	0.050	0.833
0.060	0.040	0.667		0.060	0.040	0.667
0.060	0.040	0.667		0.070	0.060	0.857
0.040	0.030	0.750		0.060	0.040	0.667
0.040	0.030	0.750		0.040	0.030	0.750
0.050	0.030	0.600		0.040	0.020	0.500
0.060	0.040	0.667		0.040	0.030	0.750
0.060	0.030	0.500				

Total As (ppm)	Inorganic As (ppm)	Ratio Inorganic to Total	Total As (ppm)	Inorganic As (ppm)	Ratio Inorganic to Total
CRC 2012. Colorado, Texas (N=19)					
0.280	0.070	0.250	0.150	0.040	0.267
0.240	0.060	0.250	0.120	0.050	0.417
0.240	0.050	0.208	0.200	0.080	0.400
0.200	0.050	0.250	0.210	0.080	0.381
0.170	0.050	0.294	0.180	0.080	0.444
0.160	0.050	0.313	0.180	0.060	0.333
0.180	0.040	0.222	0.170	0.060	0.353
0.170	0.050	0.294	0.170	0.050	0.294
0.220	0.070	0.318	0.170	0.050	0.294
0.200	0.070	0.350			
CRC 2013, Arkansas. Arkansas (N=24)					
0.260	0.110	0.423	0.280	0.150	0.536
0.340	0.140	0.412	0.330	0.140	0.424
0.440	0.140	0.318	0.250	0.120	0.480
0.330	0.130	0.394	0.310	0.120	0.387
0.260	0.130	0.500	0.180	0.060	0.333
0.370	0.110	0.297	0.280	0.100	0.357
0.250	0.150	0.600	0.300	0.110	0.367
0.310	0.130	0.419	0.310	0.140	0.452
0.200	0.080	0.400	0.160	0.080	0.500
0.330	0.120	0.364	0.170	0.060	0.353
0.390	0.210	0.538	0.290	0.090	0.310
0.250	0.110	0.440	0.320	0.070	0.219
CRC 2013, Butte, California (N=24)					
0.040	0.030	0.750	0.050	0.050	1.000
0.050	0.040	0.800	0.040	0.030	0.750
0.030	0.020	0.667	0.030	0.020	0.667
0.040	0.040	1.000	0.040	0.040	1.000
0.030	0.020	0.667	0.040	0.030	0.750
0.040	0.030	0.750	0.040	0.030	0.750
0.040	0.030	0.750	0.040	0.030	0.750
0.040	0.030	0.750	0.040	0.030	0.750
0.050	0.030	0.600	0.030	0.030	1.000
0.040	0.030	0.750	0.030	0.030	1.000
0.050	0.040	0.800	0.040	0.030	0.750
0.040	0.030	0.750	0.030	0.030	1.000
CRC 2013, Acadia, Louisiana (N=24)					
0.250	0.120	0.480	0.140	0.050	0.357
0.220	0.130	0.591	0.090	0.080	0.889
0.250	0.120	0.480	0.100	0.050	0.500
0.230	0.120	0.522	0.150	0.080	0.533
0.150	0.060	0.400	0.210	0.110	0.524
0.120	0.050	0.417	0.230	0.120	0.522
0.140	0.060	0.429	0.220	0.100	0.455
0.100	0.090	0.900	0.210	0.100	0.476
0.110	0.080	0.727	0.160	0.070	0.438
0.100	0.080	0.800	0.160	0.070	0.438
0.100	0.080	0.800	0.210	0.110	0.524
0.090	0.070	0.778	0.170	0.090	0.529

CRC 2013, Washington, Mississippi (N=24)						
Total As (ppm)	**Inorganic As (ppm)**	**Ratio Inorganic to Total**		**Total As (ppm)**	**Inorganic As (ppm)**	**Ratio Inorganic to Total**
0.110	0.080	0.727		0.080	0.090	1.125
0.120	0.100	0.833		0.080	0.090	1.125
0.160	0.100	0.625		0.080	0.070	0.875
0.200	0.150	0.750		0.170	0.120	0.706
0.100	0.100	1.000		0.110	0.120	1.091
0.120	0.110	0.917		0.120	0.100	0.833
0.160	0.110	0.688		0.170	0.120	0.706
0.180	0.140	0.778		0.190	0.130	0.684
0.080	0.080	1.000		0.130	0.110	0.846
0.080	0.080	1.000		0.120	0.100	0.833
0.110	0.100	0.909		0.110	0.080	0.727
0.090	0.080	0.889		0.080	0.090	1.125
CRC 2013. Pemiscot, Missouri (N=6)						
0.060	0.040	0.667		0.050	0.040	0.800
0.040	0.030	0.750		0.050	0.050	1.000
0.050	0.040	0.800		0.040	0.030	0.750
CRC 2013, Colorado, Texas (N=24)						
0.310	0.200	0.645		0.430	0.260	0.605
0.310	0.110	0.355		0.400	0.130	0.325
0.380	0.110	0.289		0.470	0.170	0.362
0.330	0.190	0.576		0.360	0.100	0.278
0.320	0.140	0.438		0.260	0.170	0.654
0.380	0.160	0.421		0.230	0.080	0.348
0.420	0.140	0.333		0.250	0.150	0.600
0.330	0.070	0.212		0.240	0.090	0.375
0.330	0.090	0.273		0.330	0.140	0.424
0.330	0.110	0.333		0.390	0.120	0.308
0.490	0.230	0.469		0.300	0.120	0.400
0.430	0.130	0.302		0.270	0.110	0.407

Brown Rice

FDA 2013, Arkansas (N=27)						
Total As (ppm)	Inorganic As (ppm)	Inorganic As/ Total As		Total As (ppm)	Inorganic As (ppm)	Inorganic As/ Total As
0.206	0.108	0.524		0.277	0.147	0.531
0.168	0.109	0.649		0.209	0.153	0.732
0.283	0.112	0.396		0.206	0.159	0.772
0.161	0.119	0.739		0.288	0.163	0.566
0.208	0.120	0.577		0.319	0.164	0.514
0.228	0.120	0.526		0.271	0.169	0.624
0.205	0.124	0.605		0.219	0.172	0.785
0.225	0.124	0.551		0.222	0.172	0.775
0.191	0.124	0.649		0.269	0.173	0.643
0.223	0.130	0.583		0.310	0.178	0.574
0.234	0.133	0.568		0.313	0.179	0.572
0.291	0.135	0.464		0.223	0.183	0.821
0.286	0.135	0.472		0.291	0.195	0.670
0.207	0.140	0.676				
FDA 2013, California (N=31)						
0.086	0.066	0.767		0.142	0.137	0.965
0.084	0.087	1.036		0.194	0.146	0.753
0.178	0.092	0.517		0.146	0.147	1.007
0.161	0.105	0.652		0.187	0.150	0.802
0.057	0.034	0.596		0.195	0.152	0.779
0.114	0.082	0.719		0.197	0.152	0.772
0.150	0.088	0.587		0.202	0.155	0.767
0.131	0.100	0.763		0.242	0.159	0.657
0.144	0.108	0.750		0.183	0.161	0.880
0.142	0.114	0.803		0.186	0.163	0.876
0.147	0.118	0.803		0.194	0.163	0.840
0.159	0.120	0.755		0.191	0.166	0.869
0.162	0.120	0.741		0.180	0.187	1.039
0.198	0.123	0.621		0.219	0.193	0.881
0.187	0.123	0.658		0.269	0.202	0.751
0.149	0.125	0.839				
FDA 2013, Louisiana (N=4)						
0.253	0.138	0.545		0.308	0.160	0.519
0.318	0.152	0.478		0.349	0.249	0.713
FDA 2013, Texas (N=16)						
0.241	0.125	0.519		0.423	0.167	0.395
0.301	0.130	0.432		0.630	0.168	0.267
0.342	0.147	0.430		0.264	0.170	0.644
0.328	0.153	0.466		0.850	0.171	0.201
0.315	0.153	0.486		0.312	0.197	0.631
0.677	0.154	0.227		0.356	0.207	0.581
0.303	0.157	0.518		0.430	0.218	0.507
0.394	0.163	0.414		0.394	0.235	0.596

Appendix B: Reference List

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