Final Statement of Reasons
Title 27, California Code of Regulations

Amendments to Article 5

New Section 25501.1

Naturally Occurring Concentrations of

Listed Chemicals in Unprocessed Foods

Naturally Occurring Concentrations of

Inorganic Arsenic in White and Brown Rice

SUMMARY

The Office of Environmental Health Hazard Assessment (OEHHA) published the Initial Statement of Reasons (ISOR) for this action on July 21, 2017. No public hearing was requested for this regulatory proposal. The 45-day comment period closed on September 7, 2017. OEHHA received five comments from the following organizations:

- Agricultural Council of California and California Farm Bureau Federation (Ag Council/Farm Bureau)
- California Rice Commission (CRC)
- Environmental Research Center, Inc. (ERC)
- Grocery Manufacturers' Association (GMA)
- Lundberg Family Farms (Lundberg)

PEER REVIEW

To comply with Health and Safety Code section 57004, OEHHA in November 2017 provided the ISOR for the proposed naturally occurring concentrations of inorganic arsenic in white and brown rice to three subject-matter experts for peer review. The peer reviewers, who each submitted comments, were:

- Dr. Rebecca Neumann, Department of Civil and Environmental Engineering, University of Washington
- Dr. Matthew Polizzotto, Department of Earth Sciences, University of Oregon, and Department of Crop and Soil Sciences, North Carolina State University
- Dr. Angelia Seyfferth, Department of Plant and Soil Sciences, University of Delaware

UPDATE OF INITIAL STATEMENT OF REASONS

An update of the Initial Statement of Reasons is not necessary because no changes from the originally proposed amendments have been made.

SUMMARY AND RESPONSE TO RELEVANT COMMENTS RECEIVED

A summary of the comments received throughout this rulemaking process that are relevant to the rulemaking is provided below, along with OEHHA's responses to those comments.

PUBLIC COMMENTS

1. Comment (Ag Council/Farm Bureau): Supports the proposed regulation developing background concentrations of arsenic in rice. Commenters appreciate OEHHA's recognition that the approach taken in determining arsenic concentrations in rice may not be the same approach taken when establishing background levels for other chemicals. The agricultural community appreciates these efforts, which are viewed as a positive first step in creating more useful regulations related to naturally occurring chemicals.

Response: Comment noted. No change to the proposed regulation was made based on this comment.

2. Comment (CRC): Supports the proposed regulation. States that the guidance provided by this proposed regulation is necessary for the agricultural community to effectively communicate with consumers about raw agricultural commodities.

Response: Comment noted. No change to the proposed regulation was made based on this comment.

3. Comment (ERC): The new section is arguably ambiguous as to the intended scope of the naturally occurring concentrations. While ERC believes that concentrations would only apply to rice grain consumed whole or used in its entirety as an ingredient in unprocessed food, some stakeholders may argue that the naturally occurring concentrations should apply to ingredients derived from rice grain (such as rice protein) that are present as ingredients in food. Regulation would benefit from clarification to avoid unnecessary future disputes as to scope of the regulation.

Response: OEHHA disagrees that the scope of the regulation is ambiguous. Proposed Section 25501.1 simply provides concentration levels at which certain chemicals in unprocessed foods are deemed to be naturally occurring. This regulation should be read in the context of Section 25501, which describes in more detail the circumstances under which a chemical is deemed to be “naturally occurring” and thus not an exposure for purposes of the Act. Section 25501.1 provides clarity by interpreting the existing provision in Section 25501(a)(2), that allows businesses to determine background levels for listed chemicals. As stated in the ISOR for the regulation (pages 4-5):

> “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 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).”

Other provisions of the regulations address the situation where a food is added to another consumer product (see Section 25501(b)). Such determinations are outside the scope of the present rulemaking. No change to the proposed regulation was made based on these comments.

4. Comment (GMA): Supports the naturally occurring concentration of inorganic arsenic in white and brown rice, and supports and incorporates by reference comments made by CRC.

Response: Comment noted. No change to the proposed regulation was made based on this comment.

5. Comment (Lundberg): Supports comments submitted by CRC. Supports proposal to add new provision to regulations. Levels provide adequate "safe harbor" under Proposition 65 and are consistent with the scientific research on this topic.

Response: Comment noted. No change to the proposed regulation was made based on this comment.

PEER REVIEW COMMENTS

1. Comment (Dr. Rebecca Neumann, Dr. Angelia Seyfferth): Both peer reviewers provided comments regarding inorganic arsenic accumulation in the bran layer of the rice grain.

Dr. Rebecca Neumann suggested including citation(s), such as Meharg *et al*. (2008) and Rahman *et al*. (2007), both cited elsewhere in the ISOR, to support the statement that inorganic arsenic collects in the outer bran layer of the rice grain. Dr. Neumann stated:

> "The assumption/conclusion that arsenic accumulates in the bran of rice grain is correct based on a number of different published studies. However, the [Initial Statement of Reasons] does not directly reference any study to support the statement on page 6 that, 'Arsenic levels are generally more concentrated in the bran or outer coating of the rice grain.' The lack of references on this point within the [Initial Statement of Reasons] give the incorrect impression that knowledge of where arsenic accumulates in the grain is not well-established."

Dr. Angelia Seyfferth stated that studies are emerging that show that organic arsenic species, particularly dimethylarsinic acid, accumulate in the endosperm of the rice grain whereas inorganic arsenic is localized to the bran. Dr. Seyfferth suggested OEHHA ensure the ISOR correctly states that *inorganic* arsenic is more concentrated in the bran layer.

Response: OEHHA agrees that: i) it is well-established that inorganic arsenic accumulates in the bran layer of rice grains, ii) Meharg *et al*. (2008) and Rahman *et al.* (2007) support this conclusion, and iii) that the ISOR could have been clearer in conveying this. The pertinent language on page 6 of the ISOR[1] reads as follows:

> "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

[1] OEHHA (2017). Initial Statement of Reasons, 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. Available from: https://oehha.ca.gov/media/downloads/crnr/07212017arsenicisor.pdf

> from white (polished) rice[2]. 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[3]."

The second and third sentences in this passage were meant to elaborate on and provide support for the first sentence.

OEHHA agrees that *inorganic* arsenic accumulates in the bran layer of rice grains, and that Meharg *et al*. (2008) and Rahman *et al*. (2007) explicitly support the well-established finding that 'inorganic arsenic levels are generally more concentrated in the bran or outer coating of the rice grain'.

No change to the proposed regulation was made based on this comment.

2. Comment (Dr. Matthew Polizzotto, Dr. Rebecca Neumann): Dr. Polizzotto asked that OEHHA verify that rice grown in California is typically irrigated with surface water since groundwater may have elevated levels of arsenic. Dr. Neumann asked that OEHHA consider and discuss further the impacts of cultivar and water management strategy on the amount of arsenic taken up into rice grains.

Response: The majority of California rice is produced in the Sacramento Valley, and is mostly irrigated by surface water[4,5]. Groundwater may be used during droughts or at farms without access to surface water[6]. Surface water in the Sacramento Valley, generally has significantly lower levels of arsenic than groundwater[7].

Rice growing involves cycles of flooding and drying the fields. The frequency and duration of flooding practices varies by rice producer, taking into account seasonal

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[2] 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.

[3] 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.

[4] CH2MHill and Plantierra (2013). Rice-Specific Groundwater Assessment Report. Prepared for the Central Valley Regional Water Quality Control Board on behalf of the California Rice Commission, July 2013. Available online at: https://www.waterboards.ca.gov/rwqcb5/water_issues/irrigated_lands/regulatory_information/rice_growers_sacvalley_wdrs/2013july_crc_gar_final.pdf

[5] CH2MHill, Davids Engineering and MBK Engineers (2011). Efficient Water Management for Regional Sustainability in the Sacramento Valley, prepared for Northern California Water Association, available online at: https://www.norcalwater.org/wp-content/uploads/2012/01/Technicalreport-jul2011.pdf

[6] See Lundberg Farms website at http://www.lundberg.com/info/faq/#/farming-practices

[7] Thatcher E, Porta L, and Bundy S (2014). Arsenic in Groundwater, Soil and Surface Water in Rice-growing Areas of the Sacramento Valley. Prepared for the California Rice Commission by CH2MHill.

precipitation, pest management, crop yield, and need for and timing of fertilizer applications. The cycling between wet and dry field conditions alters the redox chemical environment of the soil, potentially influencing the proclivity of the rice plant to take up arsenic[8,9]. Enhanced flooding conditions favor anaerobic, reductive soil conditions (as opposed to oxidative soil conditions) that can lead to increased inorganic arsenic uptake in the rice plant[10].

Several factors influence the arsenic levels in rice plants grown in a given field. However, in-field studies and analysis of arsenic levels in commercially harvested rice cultivars suggest that certain cultivars may take up less total arsenic or have higher ratios of inorganic to organic arsenic. The cultivar genotype, in combination with soil type and soil chemistry, can be associated with either lower or higher arsenic levels[11]. Some japonica rice cultivars tend to have lower levels of arsenic in comparison to indica rice cultivars. Selection of lower arsenic cultivars, in combination with arsenic-lowering irrigation practices, may reduce the overall arsenic levels in the rice cultivated[12].

No change to the proposed regulation was made based on this comment.

3. Comment (Dr. Rebecca Neumann): Reviewer suggested including citation(s) supporting the statement that soils best suited to rice growing are not ideal for orchards and other crops. Reviewer stated, "it is unclear how OEHHA determined that rice field soils are not good for other crops."

Response: OEHHA notes the sentence in the ISOR[13] identified by the reviewer (ISOR, page 14, first paragraph) is a restatement of information from an earlier paragraph (ISOR, page 13, second paragraph, last sentence: "The high clay content soils [in areas where rice is grown in California] are ideal for rice and less favorable for other crops[14]"). OEHHA also notes that the appropriate citation (Geisseler and Horwath, 2013a) is provided with the first appearance of the statement on page 13.

8 Thatcher E, Porta L, and Bundy S (2014). Arsenic in Groundwater, Soil and Surface Water in Rice-growing Areas of the Sacramento Valley. Prepared for the California Rice Commission by CH2MHill.
9 Kabata-Pendias A (2001). "Chapter 10: Elements of Group V; Part II: Arsenic". In *Trace Elements in Soils and Plants*. Third Edition. Boca Raton, FL: CRC Press. Available from: http://base.dnsgb.com.ua/files/book/Agriculture/Soil/Trace-Elements-in-Soils-and-Plants.pdf. pp 239-246.
10 Xu XY, McGrath SP, Meharg AA, and Zhao FJ (2008). Growing Rice Aerobically Markedly Decreases Arsenic Accumulation. Environ Sci Technol 42:5574-5579.
11 Ye, XX, Sun B, and Yin YL (2012). Variation of As concentration between soil types and rice genotypes and the selection of cultivars for reducing As in the diet. Chemosphere 87:384-389.
12 Hua B, Yan W, Wang J, Deng B, and Yang J (2011). Arsenic Accumulation in Rice Grains: Effects of Cultivars and Water Management Practices. Environ Engineer Sci 28 (8):591-596.
13 OEHHA (2017). Full citation provided in footnote 1.
14 Geisseler D and Horwath WR (2013a). Rice Production in California. Fertilizer Research and Education Program, California Department of Food and Agriculture.

No change to the proposed regulation was made based on this comment.

4. Comment (Dr. Rebecca Neumann): Reviewer stated: "OEHHA concluded that historical inorganic arsenic application on present day rice fields did not occur because present day rice soils do not have the high soil arsenic levels seen in abandoned orchards and potato fields […]." Reviewer further stated, "It is unclear what sources are being used to set the standard for soil concentrations in orchards/potato fields that received inorganic arsenic application."

Response: The first paragraph on page 14 of the ISOR[15] states: "Levels of inorganic arsenic in California rice (see below [Table 4]) are not indicative of high soil arsenic levels seen in abandoned orchards and potato fields..." This statement represents an inference made by OEHHA after comparing arsenic levels measured in California-grown rice, presented in Table 4[16] of the ISOR[17] (page 19) and soil arsenic levels reported for abandoned orchards and potato fields, and presented in Table 1 of the ISOR (pages 8-9). While OEHHA acknowledges that complex factors influence the amount of inorganic arsenic taken up by rice from the soil[18], OEHHA infers that the relatively low levels of inorganic arsenic measured in California-grown rice indicate that this rice is not being grown in highly contaminated soils.

No change to the proposed regulation was made based on this comment.

5. Comment (Dr. Rebecca Neumann, Dr. Angelia Seyfferth): Reviewers suggested including historic cropping data in the analysis and maps showing potential for overlap of areas where crops with possible arsenical pesticide use are grown with areas where rice is grown, and clarifying the choice of date range used in the analysis of crop overlap.

Dr. Seyfferth stated, "[U]sing historical data on past inorganic arsenical use could be informative to understand whether the arsenic in soils is from past arsenical use."

Dr. Neumann stated, "[H]istorical cropping of cotton is also important to evaluate, because historical use of arsenicals was prevalent," and went on to discuss how including this data in Figure 1 of the ISOR[19] would make it possible "to visually see any potential overlap between a *[sic]* land areas that support cotton at any point in the past (for which data are available) with land areas currently supporting rice production."

[15] OEHHA (2017). Full citation provided in footnote 1
[16] The appendix provides the raw data used to calculate the statistics presented in Table 4.
[17] OEHHA (2017). Full citation provided in footnote 1.
[18] OEHHA (2017). Full citation provided in footnote 1. Pages 6-7.
[19] OEHHA (2017). Full citation provided in footnote 1. Page 14

Response: OEHHA notes that limitations in the availability and quality of cropping data, historical and recent, dictated the time range analyzed for potential overlap of crops with possible arsenical pesticide use (including cotton)[20] and rice growing regions presented in the ISOR[21].

Most land areas in California are surveyed for use by the California Department of Water Resources (DWR) every 3 to 7 years[22], and there are little data available for the five counties of interest for overlap analysis[23] prior to 1985. DWR began collecting land use records in 1976, and while there are records for the "Legal Delta" region during that year, the region, defined by DWR as covering parts of Alameda, Contra Costa, Sacramento, San Joaquin, Solano, and Yolo counties, does not cover much of the area of interest for overlap analysis. However, in looking at the DWR land use data from 1976, OEHHA determined that there was no spatial overlap between crops identified as having the potential for either inorganic or organic arsenical pesticide use and any rice crops in the region in subsequent years. The next year of DWR data available in the area of interest for overlap analysis was 1989, when records for Yolo County were collected. These data, and data collected in the area of interest in the years that followed, were included in OEHHA's original overlap analysis discussed in the ISOR.

Data collected by the National Agricultural Statistics Service (NASS)[24] also informed the overlap analysis presented in the ISOR. The NASS has collected annual land use data via satellite imagery since 1997, however this data is less useful than the DWR data since, due to the nature of satellite data collection, the resolution is not as precise. NASS data were used when needed to supplement and cross-check the DWR data used in OEHHA's overlap analysis of areas where crops with possible arsenical pesticide use are grown and rice growing regions.

The range of years analyzed for potential overlap between crops with possible arsenical pesticide use and rice growing regions reflects the time period during which the most geographically appropriate and robust land use data are available.

Finally, while Figure 1 on page 14 of the ISOR indicates there is no overlap between the current five leading rice-producing counties and the current five leading cotton-

[20] As stated in Footnote 52 of the Initial Statement of Reasons: California crops queried: cotton, apples, lemons, oranges, limes, tangerines, grapefruit, grapes, peaches, pears, plums, strawberries, pomegranates, almonds and walnuts.
[21] OEHHA (2017). Full citation provided in footnote 1.
[22] Data available from: https://www.water.ca.gov/Programs/Water-Use-And-Efficiency/Land-And-Water-Use/Land-Use-Surveys
[23] OEHHA (2017), full citation provided in footnote 1. Page 14, Figure 1 identifies the 5 leading rice producing counties in California to be Colusa, Sutter, Butte, Glenn, and Yolo. Page 13 states that over 95% of California-grown rice comes from the Sacramento Valley – mainly Colusa, Sutter, Butte, and Glenn counties, citing Geisseler and Horwath (2013a) [full citation provided in footnote 14].
[24] Available from: https://nassgeodata.gmu.edu/CropScape/

producing counties in California, as already noted, the crops queried for the overlap analysis did include cotton[25].

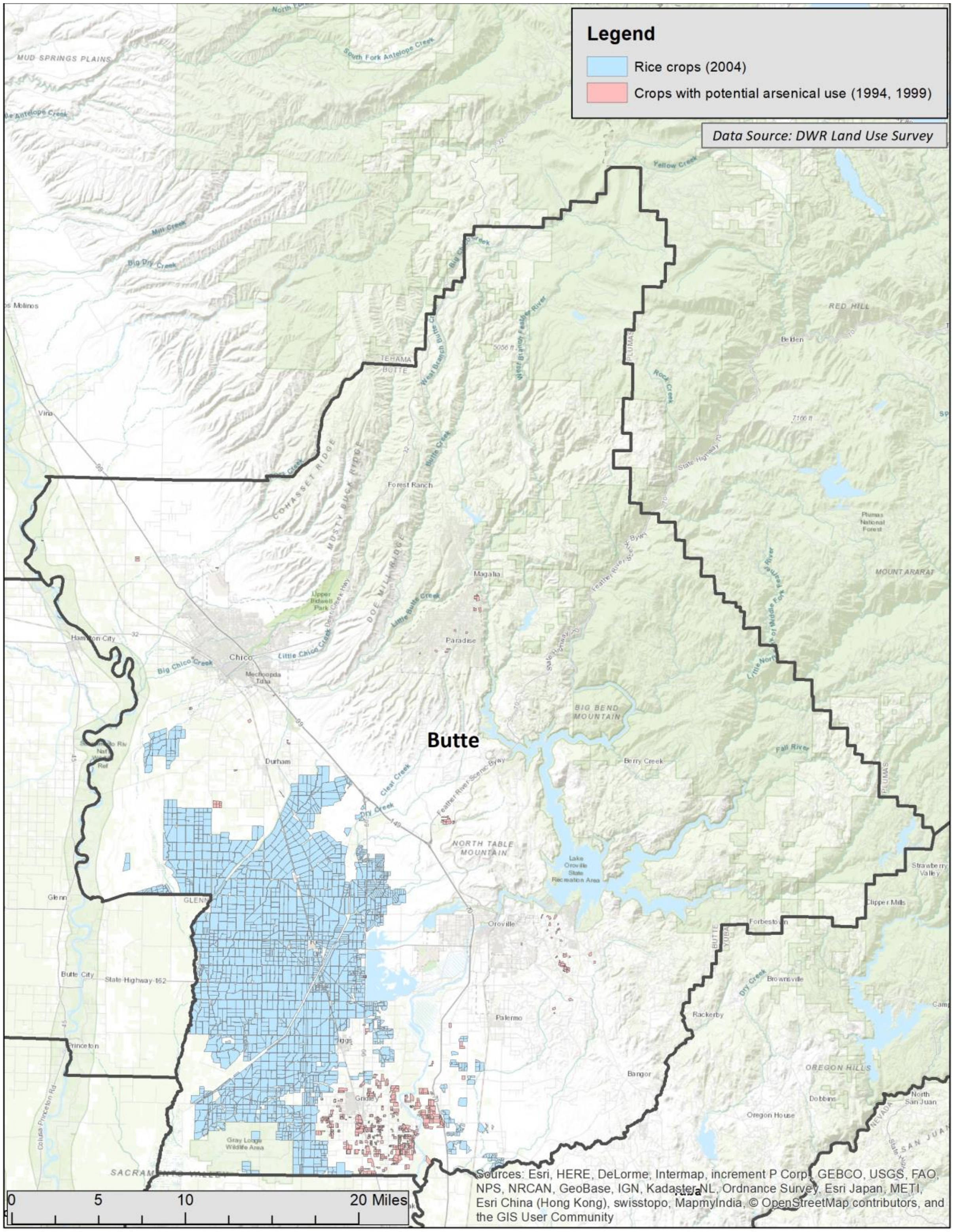
No change to the proposed regulation was made based on this comment.

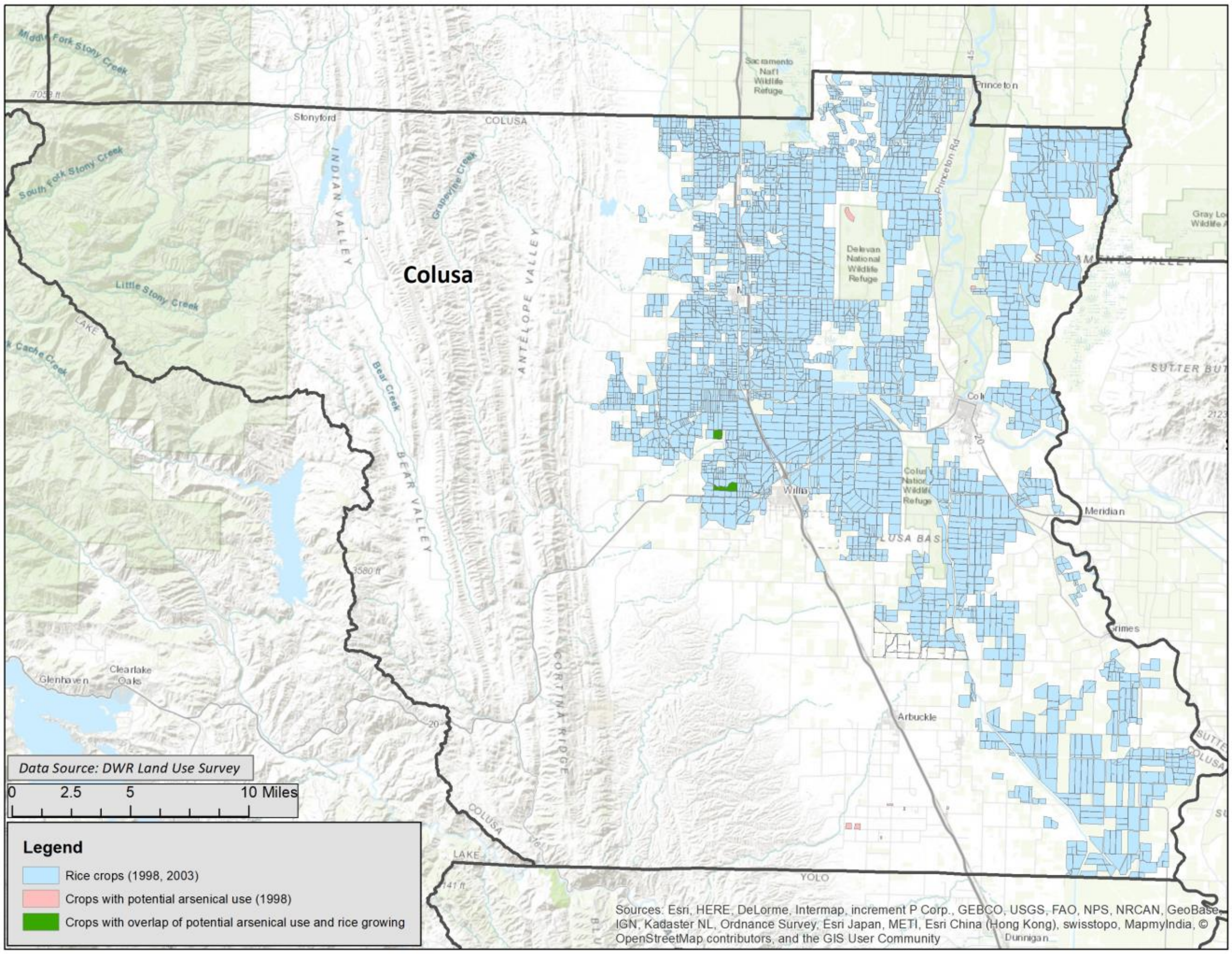
6. Comment (Dr. Rebecca Neumann): Reviewer suggested including a regional-level map showing all areas that grew any crops with potential for arsenic use at any point between 1985 and 2010 against current-day rice-growing areas.

Response: As discussed in the ISOR, the majority of rice produced in California comes from the Sacramento Valley[26]. OEHHA's analysis indicated that less than 5% of recent rice-growing areas in California overlapped with areas where crops with potential inorganic or organic arsenical use were grown. OEHHA's analysis also indicated that of the primary California rice-growing counties, Yolo County possessed the greatest opportunity for this type of overlap; a map of Yolo county was presented in the ISOR to show the geographical relationship between these two particular land uses, and it is clear from the map that areas with potential for overlap are minimal. In the six most recent annual reports by the California Department of Food and Agriculture[27], the top rice-producing county in California has consistently been Colusa and the next top-producing county has been either Butte or Sutter. Below, OEHHA has provided maps for Butte, Colusa, and Sutter counties similar to that which appeared in the ISOR for Yolo County, and, as with Yolo County, the potential for overlap is minimal. The total measured overlap was 0.0 mi^2 for Butte County, 0.4 mi^2 for Colusa County, 0.7 mi^2 for Sutter County, and 1.0 mi^2 for Yolo County.

No change to the proposed regulation was made based on this comment.

[25] As stated in Footnote 52 of the Initial Statement of Reasons: California crops queried: cotton, apples, lemons, oranges, limes, tangerines, grapefruit, grapes, peaches, pears, plums, strawberries, pomegranates, almonds and walnuts.
[26] OEHHA (2017). Full citation provided in footnote 1.
[27] Annual reports available from: https://www.cdfa.ca.gov/statistics/


Legend
Rice crops (2004)
Crops with potential arsenical use (1994, 1999)
Data Source: DWR Land Use Survey
Butte
Chico
Paradise
Oroville
Durham
Lake Oroville State Recreation Area
0
5
10
20 Miles
Sources: Esri, HERE, DeLorme, Intermap, increment P Corp., GEBCO, USGS, FAO, NPS, NRCAN, GeoBase, IGN, Kadaster NL, Ordnance Survey, Esri Japan, METI, Esri China (Hong Kong), swisstopo, MapmyIndia, © OpenStreetMap contributors, and the GIS User Community


Colusa
Data Source: DWR Land Use Survey
0 2.5 5 10 Miles
Legend
Rice crops (1998, 2003)
Crops with potential arsenical use (1998)
Crops with overlap of potential arsenical use and rice growing
Sources: Esri, HERE, DeLorme, Intermap, increment P Corp., GEBCO, USGS, FAO, NPS, NRCAN, GeoBase, IGN, Kadaster NL, Ordnance Survey, Esri Japan, METI, Esri China (Hong Kong), swisstopo, MapmyIndia, © OpenStreetMap contributors, and the GIS User Community
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Princeton
Meridian
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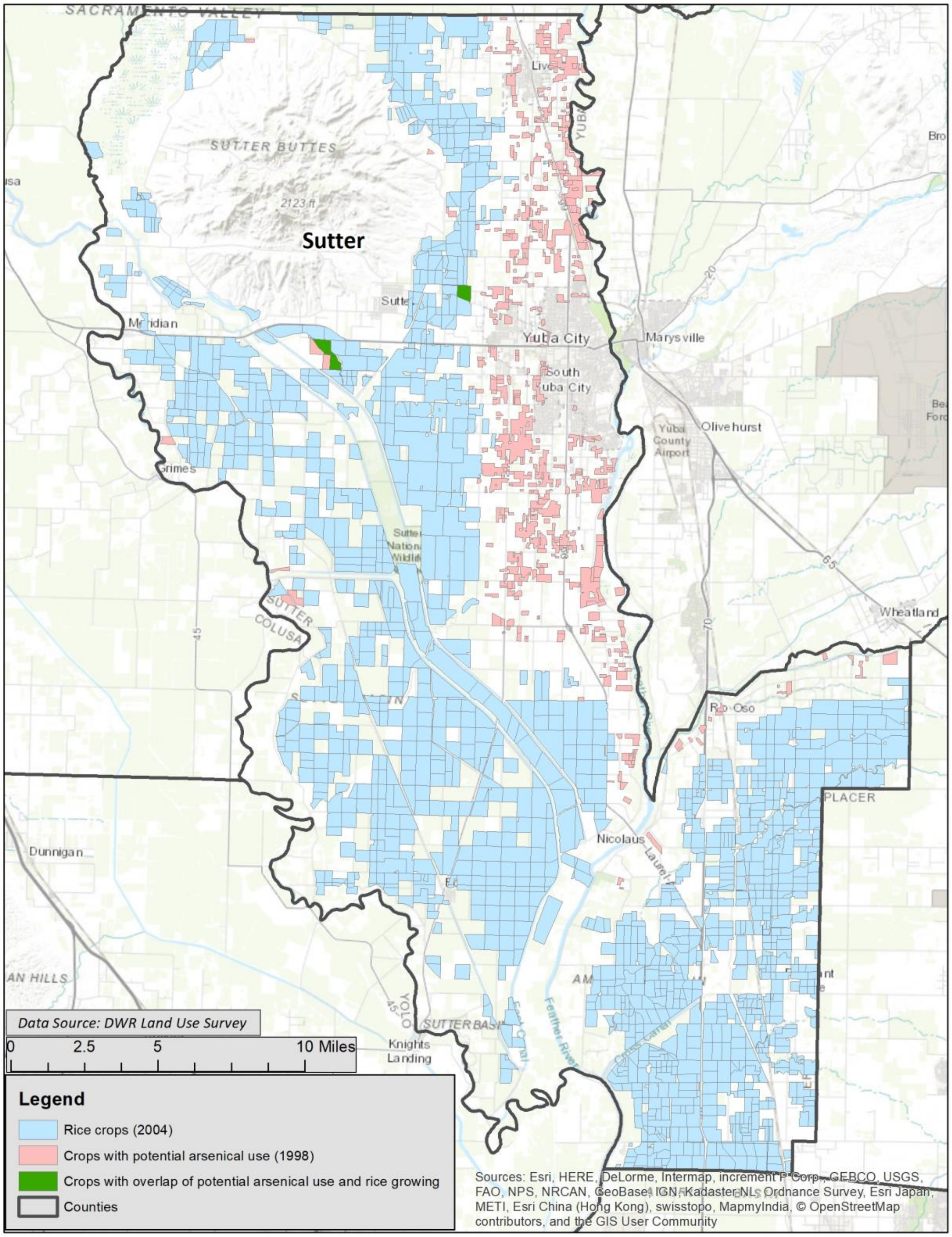
Delevan National Wildlife Refuge
Sacramento Nat'l Wildlife Refuge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Olivehurst
Yuba County Airport
Wheatland
Nicolaus
Dunnigan
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YOLO
Feather River
Data Source: DWR Land Use Survey
0
2.5
5
10 Miles
Legend
Rice crops (2004)
Crops with potential arsenical use (1998)
Crops with overlap of potential arsenical use and rice growing
Counties
Sources: Esri, HERE, DeLorme, Intermap, increment P Corp., GEBCO, USGS, FAO, NPS, NRCAN, GeoBase, IGN, Kadaster NL, Ordnance Survey, Esri Japan, METI, Esri China (Hong Kong), swisstopo, MapmyIndia, © OpenStreetMap contributors, and the GIS User Community

7. Comment (Dr. Rebecca Neumann): Reviewer suggested a clarifying statement regarding use of organic arsenic data for overlap analysis: "Because use data are only available for periods near or after inorganic arsenic use was phased out during the 1980s, this analysis is reflective of potential contamination resulting from *organic* arsenic applications." Reviewer stated that it is unclear whether organic arsenic application was actually tracked.

Response: As indicated in responses to peer review comments 5 (above) and 9 (below) and as discussed in the ISOR (see pages 14-17), pesticide use data for both inorganic and organic arsenicals were used to inform OEHHA's analysis of the potential for spatial overlap of cultivation of crops with possible arsenical pesticide use and cultivation of rice (1985-2010). The 15 California agricultural crops identified[28] as historically being associated with arsenical pesticide use in California (either inorganic or organic arsenicals) were the crops that were included in the analysis. The sentence from the ISOR (see page 14) quoted by the reviewer is the last sentence of the paragraph, and was meant to reflect all the points made in that paragraph: i) the relatively low levels of inorganic arsenic measured in California-grown rice indicate that this rice is not being grown in highly contaminated soils, such as those used previously as orchards or potato fields, ii) the type of soils best for rice growing are not ideal for orchards, potatoes, and other crops for which inorganic arsenical pesticides may have been used, iii) inorganic arsenical pesticide use was phased out during the 1980s, and iv) robust, crop-specific California pesticide use data became available starting near or after the phase-out of inorganic arsenicals. The statement quoted by the reviewer was intended to indicate that OEHHA's analysis of historical cultivation of crops with potential arsenical pesticide use from the period 1985-2010 is reflective *primarily* of potential contamination resulting from organic arsenic applications.

No change to the proposed regulation was made based on this comment.

8. Comment (Dr. Rebecca Neumann): Reviewer suggests including reference(s) supporting the statement that "crops that potentially used arsenical pesticides may be grown adjacent 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."

Response: The statement (see page 15 of the ISOR) identified by the reviewer is OEHHA's conclusion, based on OEHHA's own analyses. These analyses are

[28] As indicated in Footnote 52 of the Initial Statement of Reasons, the 15 California crops identified as having possible inorganic or organic arsenical pesticide use were cotton, apples, lemons, oranges, limes, tangerines, grapefruit, grapes, peaches, pears, plums, strawberries, pomegranates, almonds and walnuts.

described in the text that precedes this statement, and for which an example result (i.e., mapping of land use in Yolo County) is shown in Figure 2 of the ISOR[29].

No change to the proposed regulation was made based on this comment.

9. Comment (Dr. Rebecca Neumann): Reviewer suggested clarifying descriptions of the two different approaches used in section 'Orchards and other crops in rice growing areas in California.' Reviewer stated:

> "It is unclear why OEHHA used a different approach to evaluate the possibility of arsenical soil applications at the USGS soil sampling sites than was used to evaluate the possibility of arsenical soil applications within present day rice growing areas (i.e., the crop-area overlap approach). The crop-area overlap approach would enable OEHHA to look for overlap between the USGS soil sampling sites and land areas that have supported crops with potential for arsenical use," and,
> "[S]ome explanation is warranted as to why one approach was chosen over the other in the two different analyses."

Response: OEHHA notes that while an example of how the data were mapped using just one of the approaches was presented in the ISOR[30], mapping informed both approaches. OEHHA discusses the details of each approach below.

In the first approach, OEHHA evaluated the possibility for overlap of land areas growing crops with potential for arsenic use with rice-growing areas. As discussed in the responses to peer review comments 5 and 7 above, this method involved identifying 15 California agricultural crops that have historically been associated with the use of either inorganic or organic arsenical pesticides, obtaining information on land use and historical location of these crops, and mapping the data to evaluate overlap of the area where these crops were grown with current rice-growing areas. As shown and discussed in the ISOR and in the responses to comments 11 and 12 below, OEHHA determined that the potential for overlap was very low.

In the second approach, OEHHA mapped the proximity of arsenical (inorganic or organic) pesticide use to the 33 USGS soil sampling sites that were located in 10 California (current or historical) rice-growing counties, to provide information on possible arsenical contamination at these sites. This method involved determining ZIP Code

[29] OEHHA (2017). Full citation provided in footnote 1.
[30] OEHHA (2017). Full citation provided in footnote 1. Page 16.

locations[31] for each soil site sampled in the USGS study, and querying the California Department of Pesticide Regulation's (CDPR) Pesticide Use Reporting (PUR) database to ascertain whether or not arsenical pesticides were used in those ZIP Codes. As discussed in the ISOR[32], OEHHA's analysis found that of the 33 USGS sampling sites which fell in rice-growing ZIP Codes, 18 fell in ZIP Codes where crops with potential arsenical pesticide use were grown. However, most of the sampling sites themselves were far from land devoted to crops with arsenical use.

The first approach was meant to determine whether California rice has been or is currently grown in or adjacent to areas that might have had soil arsenic contamination due to past cropping of agricultural commodities associated with arsenical pesticide use. As stated in the ISOR and above, OEHHA determined through mapping of land use data that there is minimal potential for overlap.

The second approach was meant to determine if areas near the 33 USGS sampling sites that fell in rice-growing ZIP Codes might have been contaminated due to arsenical pesticide use. As stated in the ISOR and above, OEHHA's analysis through mapping showed that the sampling sites were often near active rice-growing areas and away from areas where crops with potential arsenical use were grown; because of this, an overlap analysis at these particular sampling sites was not informative and thus was not discussed at length. OEHHA's primary conclusions from this analysis were (i) 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 and (ii) variation in total arsenic soil levels appeared to be more a factor of local geography (see Table 2 on page 10 as well as page 17 of the ISOR[33]).

No change to the proposed regulation was made based on this comment.

10. Comment (Dr. Matthew Polizzotto): Reviewer suggested including areas used in turf grass production and golf courses for overlap analysis. Reviewer stated that organic arsenicals are used in these areas and studies have shown off-target arsenic accumulation following application to turf and golf courses, and noted that organic arsenic has the potential to transform into inorganic forms after application to soil.

[31] By querying CalPIP (http://calpip.cdpr.ca.gov/main.cfm) for PUR records rather than making a special data request through CDPR, OEHHA sought to ensure the reproducibility of its analysis by members of the public; at the time of OEHHA's analysis, the finest scale available for locations associated with PUR records obtained through CalPIP was ZIP Code.
[32] OEHHA (2017). Full citation provided in footnote 1. Page 17.
[33] OEHHA (2017). Full citation provided in footnote 1.

Response: In querying the California Department of Pesticide Regulation (DPR) Pesticide Use Reporting (PUR) database, OEHHA did not find any information to support including California golf courses and turf grass production operations in the overlap analysis.

OEHHA queried the PUR database and determined that there are no records which report inorganic or organic arsenical pesticide use for the site code corresponding to golf courses. According to DPR, it is possible that other site codes, such as the broad category "landscape maintenance", might have been reported for uses that actually occurred on golf courses, but it would be difficult or impossible to ascertain whether records reporting other site codes actually correspond to pesticide uses on golf courses. Furthermore, specific location information is not available for any PUR records with site codes corresponding to golf courses and landscape maintenance[34].

Including areas used in turf grass production in an overlap analysis has similar obstacles. According to DPR, until recently, the site code corresponding to turf/sod has been used for both turf/sod production and for other turf applications such as parks, cemeteries, golf courses, and others. In March 2018, DPR designated a new site code specifically for turf/sod production, but for past data it would not be possible to discern which records actually correspond to turf/sod production. That being said, a query of the site codes that DPR suggested may have been used for turf/sod production applications in the past yielded just five records pertaining to arsenical pesticides; all five were for application of the organic arsenical calcium acid methane arsonate (CAMA) to areas with site code "ornamental turf". Unfortunately, "ornamental turf" is a broad category that may or may not refer to actual production operations so it is unknown if these five records can accurately be attributed to turf/sod production. Moreover, detailed location information is not provided for these records[35]. Incidentally, these records correspond to uses in Santa Barbara County, which has had minimal if any rice production, so the specific areas in Santa Barbara County corresponding to the five records are highly unlikely to overlap with current rice-growing areas.

[34] Non-production agricultural use of pesticides, such as use on golf courses, is reported to county agricultural commissioners in California, and this information, with only county of use specified in terms of location, is later provided to CDPR and recorded in the PUR database. This is in contrast to production agricultural use records, for which detailed location information down to the square mile is provided to CDPR and available from the PUR database.

[35] Records using the site code "ornamental turf" are considered "non-production agriculture" and only county of use is reported for these records (see footnote 34).

In summary, there are no data that suggest a need to include golf courses and areas of turf grass production in an analysis of potential overlap with rice-growing areas. No change to the proposed regulation was made based on this comment.

11. Comment (Dr. Rebecca Neumann): Reviewer suggested including additional data measuring inorganic arsenic levels in rice from the surveys conducted by Consumer Reports.

Response: The reviewer refers to data collected by the Consumer Reports organization during two investigations[36,37] into levels of inorganic arsenic in rice and other foodstuffs. While some new data were used for the 2014 document from Consumer Reports, the majority of the data used therein are comprised of i) data reported by the US Food and Drug Administration (US FDA), and thus already included in OEHHA's analysis, and ii) data already used for the 2012 document from Consumer Reports, which is discussed below. All of the data used for the 2014 document from Consumer Reports, including the genuinely new data, are only available from Consumer Reports in summary form[38]; lacking the actual raw data, OEHHA is unable to include the new data in its analysis. In contrast, the raw data used for the 2012 document from Consumer Reports are readily available[39], and the remainder of this response will focus on that data.

Including the 2012 Consumer Reports data for rice grown in California would add a total of three values each to the total number of measurements for brown and white rice. The inorganic arsenic levels measured in California rice samples by Consumer Reports in 2012 were similar to the levels measured in California rice samples and reported by US FDA and CRC. As indicated in the ISOR, the naturally occurring levels of inorganic arsenic in rice proposed by OEHHA are based on analysis of those US FDA and CRC data for California rice. OEHHA has determined that including the three additional data points for brown rice and the three additional data points for white rice from the 2012 Consumer Reports document would not change the proposed values for naturally occurring levels of inorganic arsenic in white rice or brown rice[40]. In addition, OEHHA notes that the mean and standard deviation of the inorganic arsenic levels in US-grown

[36] Consumer Reports (2012). Arsenic in your food. Accessed: December 22, 2017. Available from: https://www.consumerreports.org/cro/magazine/2012/11/arsenic-in-your-food/index.htm

[37] Consumer Reports (2014). How much arsenic is in your rice? Accessed: December 22, 2017. Available from: https://www.consumerreports.org/cro/magazine/2015/01/how-much-arsenic-is-in-your-rice/index.htm

[38] Summary data available from: http://greenerchoices.org/wp-content/uploads/2016/08/CR_FSASC_Arsenic_Analysis_Nov2014.pdf

[39] Data available from: https://www.consumerreports.org/content/dam/cro/magazine-articles/2012/November/Consumer%20Reports%20Arsenic%20in%20Food%20November%202012_1.pdf

[40] The proposed naturally occurring levels of inorganic arsenic reflected one standard deviation above the mean. Including the data from the 2012 Consumer Reports document yields rounded values that are identical to the originally proposed rounded values.

white and brown rice measured by Consumer Reports in 2012 were also similar to those for US-grown white and brown rice from the US FDA and CRC data reported in the ISOR[41] (page 19, third paragraph). No change to the proposed regulation was made based on this comment.

12. Comment (Dr. Matthew Polizzotto): Reviewer indicated that OEHHA ensure that the analytical methods used by the US FDA and CRC to measure arsenic in rice are consistent for grouping and combining the data sets.

Response: The data on arsenic levels in brown rice came exclusively from US FDA, so the remainder of this response will address the appropriateness of combining the US FDA and CRC data for California-grown white rice.

According to the US FDA report on arsenic in rice and rice products[42], total arsenic concentrations in market samples of rice grown in California (as well as other parts of the US) were determined using inductively coupled plasma-mass spectrometry (ICP-MS) after acid hydrolysis. Speciated arsenic concentrations (i.e., measurements that distinguish inorganic arsenic from organic arsenic) were measured by US FDA using high performance liquid chromatography-inductively coupled plasma-mass spectrometry (HPLC-ICP-MS).

According to CRC, the same methods developed and used by US FDA in its report on arsenic in rice and rice products were used to measure total and inorganic arsenic concentrations in the rice data provided to OEHHA by CRC. Namely, ICP-MS was used to determine total arsenic concentrations and HPLC-ICP-MS was used to determine speciated arsenic concentrations.

OEHHA notes that the analytical methods and equipment used by both the US FDA and the CRC measured ranges of inorganic arsenic levels in California-grown rice that were narrow and similar to one another (US FDA: range = 0.02 ppm to 0.10 ppm; CRC: range = 0.02 ppm to 0.08 ppm). Given that the two data sets were measured using the same methods and show a similar range of values, combining the data for further analysis appears warranted. No change to the proposed regulation was made based on this comment.

13. Comment (Dr. Rebecca Neumann, Dr. Angelia Seyfferth, Dr. Matthew Polizzotto): Each of the reviewers commented on setting the proposed naturally

[41] OEHHA (2017). Full citation provided in footnote 1.
[42] US FDA (2016). Arsenic in Rice and Rice Products Risk Assessment Report. Available from: https://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM486543.pdf

occurring level of arsenic in rice at one standard deviation above the mean. Dr. Rebecca Neumann commented that OEHHA should include better justification for this approach. Dr. Matthew Polizzotto stated that OEHHA's approach is appropriate and reflects natural variability in concentrations while also omitting outliers that may be a consequence of localized anthropogenic soil contamination. Dr. Angelia Seyfferth commented that OEHHA should consider increasing the limits to two standard deviations above the mean to account for potential variability in extraction efficiencies in the processes used to determine inorganic arsenic concentrations.

Response: Each of the reviewers had a different position on this issue.

With regard to Dr. Seyfferth's comments on potential variability in inorganic arsenic extraction efficiencies, a review of the analytical methodology employed to generate the data analyzed by OEHHA indicates that the potential variability is minimal. Specifically, the inorganic arsenic concentrations in rice were determined by a validated method that incorporates quality assurance/quality control procedures and performance acceptance criteria, including analysis of standardized reference materials as well as fortified analytical materials, for which the control limit for recovery is 100 ± 20%[43]. OEHHA sought to account for natural variability that can be attributed to several factors that influence uptake of arsenic into rice plants[44]. OEHHA also considered the fact that the potential for some anthropogenic contribution could not be entirely ruled out. There are different approaches that can be taken to account for these important issues, and as discussed in the ISOR[45], OEHHA elected to set the proposed naturally occurring level of arsenic in rice at one standard deviation above the mean as best accounting for natural variability in inorganic arsenic concentrations in rice, while minimizing the contribution of outliers that may reflect localized anthropogenic soil contamination.

No change to the proposed regulation was made based on this comment.

14. Comment (Dr. Rebecca Neumann, Dr. Matthew Polizzotto Dr. Angelia Seyfferth): There is growing evidence that climate conditions influence how much arsenic is taken up by rice plants, and the conditions leading to transformation of

[43] Kubachka KM, Shockey NV, Hanley TA, Conklin SD, and Heitkemper DT (2012). Elemental Analysis Manual: Section 4.11: Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination. Version 1.1 (November 2012). Retrieved from https://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM479987.pdf
[44] OEHHA (2017). Full citation provided in footnote 1.
[45] *Ibid.*

inorganic arsenic to organic arsenic and vice-versa, and the influence thereof on concentrations of different arsenic species in soils and rice.

Response: OEHHA acknowledges the comments and noted in response to comment 2 a variety of conditions that may affect arsenic concentration in rice. Ultimately, as discussed in the ISOR (page 19), arsenic concentrations in rice cultivated in California do not show much variability, and on average are somewhat lower than the values measured in the other US rice-growing states.

15. Comment (Dr. Angelia Neumann): Even if arsenic in rice is naturally occurring, it is not necessarily at a 'safe' level, and the international standard for arsenic in food (200 ppb from the Codex Alimentarius) is far above the safe harbor limits proposed in the OEHHA report.

Response: This comment does not constitute an objection or recommendation specifically directed at the proposed action. The United Nations Codex Alimentarius level of 200 ppb was adopted in 2015[46] for polished rice, that is, milled or white rice from which all or part of the bran and germ have been removed. This compares with the naturally occurring safe harbor concentration of inorganic arsenic in white rice being established by OEHHA in regulation of 80 parts per billion (ppb). Codex did not adopt a value for husked/brown rice. The OEHHA regulation is adopting a naturally occurring inorganic arsenic safe harbor concentration of 170 ppb for brown rice. The OEHHA safe harbor values would apply to all white and brown rice, regardless of the location of where the rice is grown.

DOCUMENTS RELIED UPON

The National Agricultural Statistics Service, NASS Five Year census of agriculture[47] database referenced in the ISOR[48] was accessed for the purpose of mapping rice data from 2014. Images of maps generated from the data accessed are included on the CD in the rulemaking file that contains documents relied upon.

The content of the documents from the California Rice Commission (CRC, 2012 and 2013) that OEHHA relied upon in the ISOR[49] is contained in Appendix A of the ISOR[50]. These documents are not included on the CD in the rulemaking file that contains documents relied upon.

ALTERNATIVES DETERMINATION

In accordance with Government Code section 11346.9(a)(4), OEHHA has determined

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[46] Codex Alimentarius Commission (2015). Codex general standard for contaminants and toxins in food and feed (CODEX STAN 193–1995), p. 39.
[47] Data available at http://www.agcensus.usda.gov/index.php
[48] OEHHA (2017). Full citation provided in footnote 1. Page 26.
[49] *Ibid*.
[50] OEHHA (2017). Full citation provided in footnote 1. Page 30.

that no alternative would be more effective in carrying out the purpose for which the regulations were proposed; would be as effective in carrying out the purpose and less burdensome to affected private persons, than the proposed action; or would be more cost-effective to affected private persons in implementing the statutory policy or other provision of law. During the pre-regulatory workshop and comment period that followed, a number of alternatives were proposed. One suggestion was to "adopt the Food and Drug Administration (US FDA) and United States Department of Agriculture (USDA) standard tolerances for lead and other contaminants in food." As OEHHA noted in the ISOR for this rulemaking, currently there are no established federal tolerances for arsenic in food products, and tolerances are not typically set based on consideration of naturally occurring levels of chemicals in foods. Formerly, US FDA set a tolerance for arsenic which applied only to food-producing animals treated with arsenical veterinary drugs; however, since the end of 2015, there are no longer US FDA-approved, arsenic-based drugs for use in food producing animals[51]. US FDA recently proposed a limit (100 ppb) for inorganic arsenic that will apply only to infant rice cereal[52], 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 OEHHA-derived safe harbor values for naturally occurring levels of inorganic arsenic in rice are based on California rice data which appear 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 believes that 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[53]) and internationally (e.g., World Health

[51] US FDA (2015). FDA Announces Pending Withdrawal of Approval of Nitarsone. Accessed April 11, 2017. Available from: https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm440668.htm
[52] US FDA (2016). FDA Proposes Limit for Inorganic Arsenic in Infant Rice Cereal. Accessed: April 11, 2017. Available from: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm493740.htm
[53] US FDA (2000). Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed. Accessed: April 13, 2017. Available from:

Organization [WHO][54]). 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. 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. No other reasonable alternatives were proposed during the 45-day comment period for this rulemaking.

LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm077969.htm

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