OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Naturally Occurring Lead in Certain Candies

Candies Flavored with Chili and/or Tamarind

Technical Support Document for proposed adoption of Title 27 of the California Code of Regulations, Chapter 3, Section 28500

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Reproductive and Cancer Hazard Assessment Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

PREFACE

Health and Safety Code Section 110552 requires the Office of Environmental Health Hazard Assessment (OEHHA), in consultation with the California Department of Public Health (CDPH) and the Office of the Attorney General, to make a determination of “naturally occurring levels” of lead in candy containing chili and tamarind. Pursuant to this requirement, OEHHA is proposing to add Title 27 of the California Code of Regulations, Chapter 3: Naturally Occurring Lead in Candy, section 28500, Naturally Occurring Levels of Lead in Candy. This new section would establish naturally occurring levels of lead in candies flavored with chili and tamarind. This technical support document lays out the analysis supporting the proposed levels.

The process for developing the proposed regulation started in 2007 when OEHHA initiated a process to determine “naturally occurring levels” of lead in candy containing chili and tamarind. The process included public workshops in 2008 in Los Angeles and San Diego, and a data call-in request in order to obtain relevant information from the public. OEHHA also met with federal, state, and local agencies, researchers, and industry representatives. Finally, OEHHA conducted a study of lead in chili peppers sampled from California markets. Due to resource constraints, OEHHA and the consulting agencies were unable to complete the process at that time.

On March 14, 2017, OEHHA received a petition from Lexington Law Group on behalf of the Center for Environmental Health asking that “OEHHA formally commence the regulatory process to issue regulations pursuant to Health & Safety Code §110552 setting a ‘naturally occurring’ lead level in candy containing chili and tamarind.” OEHHA held a hearing July 6, 2017 in response to this petition and solicited comments regarding the petition and potential rulemaking. March 2019 OEHHA initiated a rulemaking to establish a level for naturally occurring lead in candies flavored with chili and/or tamarind. A workshop on the proposed rule was held May 22, 2019. Information pertinent to establishing the level was received during the public comment period and workshop.

OEHHA has completed its evaluation of the available data relevant to the determination of the level of naturally occurring lead in candy containing chili and tamarind. The additional data submitted to OEHHA in the spring of 2019 are included in the analysis. OEHHA is now restarting the rulemaking process.

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INTRODUCTION

Health and Safety Code Section 110552[1] requires the Office of Environmental Health Hazard Assessment (OEHHA), in consultation with the California Department of Public Health (CDPH) and the California Office of the Attorney General, to determine "naturally occurring levels" of lead in candy containing chili and tamarind. Pursuant to this requirement, OEHHA is proposing to add a new chapter and section to Title 27 of the California Code of Regulations, Chapter 3, section 28500, Naturally Occurring Levels of Lead in Candy. This new section would establish naturally occurring levels of lead in candies flavored with chili and tamarind. This technical support document provides the scientific support for the proposed levels.

In 2007, OEHHA initiated a process to determine "naturally occurring levels" of lead in candy containing chili and tamarind. This process included coordination of public workshops and a data call-in request in order to obtain relevant information from the public, as well as consultations with federal, state, and local agencies, researchers, and industry representatives. OEHHA also conducted a study of lead in chili peppers sampled from a California agricultural field and from California markets.

APPROACH

OEHHA developed an ingredient-based approach to estimate the sum of naturally occurring lead in candy containing chili and tamarind, based on an evaluation of the level of naturally occurring lead plausibly contributed by a given ingredient and amounts of each such ingredient typically present in candies. The overall approach is to:

- Identify candies flavored with chili or tamarind,
- Identify other ingredients, other than chili and tamarind, that may substantially contribute to naturally occurring lead in these candies,
- Evaluate the level of naturally occurring lead that could reasonably be contributed by each such ingredient, and
- Estimate the level of naturally occurring lead in these candies by accounting for the amount contributed by each lead-containing ingredient typically present in the candies.

Each of the following has been identified as a potential contributor to naturally occurring lead in candies flavored with chili and/or tamarind:

- Chili peppers and chili powder[2]

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[1] Created by Assembly Bill 121 (Vargas, Adulterated Candy: Maximum Allowable Lead Levels, Chapter 707, Statutes of 2005)

[2] "Chili powder" here refers to a product made primarily from milled chili peppers of the genus *Capsicum*, rather than the commonly available spice mix also called chili powder containing milled chili peppers together with other ingredients, e.g., cumin, oregano, and garlic.

- Tamarind
- Food-grade salt
- Sugar
- Food-grade silicon dioxide
- Food-grade titanium dioxide

This applies to all candies flavored with chili and/or tamarind, with the exception of chocolate candies, which are outside the scope of the proposed regulation and this supporting analysis.

Health and Safety Code, section 110552[3], subsection (c)(3) provides:

> "…lead in candy is only naturally occurring to the extent that it is not avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible. The producer and manufacturer of candy and candy ingredients shall at all times use quality control measures that reduce the natural chemical contaminants to the 'lowest level currently feasible' as this term is used in subsection (c) of Section 110.110 of Title 21 of the Code of Federal Regulations. The 'naturally occurring level' of lead shall not include any lead in an ingredient resulting from agricultural equipment, fuels used on or around soils or crops, fertilizers, pesticides or other materials that are applied to soils or crops or added to water used to irrigate soils or crops."

For each substance identified as a potential contributor of naturally occurring lead in candies flavored with chili or tamarind, OEHHA has determined a level of lead plausibly considered to be naturally occurring consistent with section 110552.

NATURALLY OCCURRING LEAD IN INDIVIDUAL CANDY INGREDIENTS

1. **Chili Peppers and Chili Powder**

Chili powder is a popular ingredient in a variety of candies, especially Mexican-style candy, with formulations provided to OEHHA by candy manufacturers including as much as 15% chili powder in sugar-based candies and 30% chili powder in salt-based, powdered candies (Ahn 2008; Mastrorocco 2008). In these products, fresh chili pepper is typically dried and milled into powder before being mixed with other ingredients for candy processing. Most chili peppers used for the flavoring of candies appear to be varieties, or cultivars, of the *longum* group of the species *Capsicum annuum* (*C. annuum L.*). Varieties include Guajillo, Anaheim, Arbol, Ancho and Chilaca chili

[3] Hereinafter HSC section 110552 or section 110552.

peppers[4] (Miller, 2019; Zavala, 2019). These chili peppers may be used alone or in combination to create specific flavor profiles.

Several potential pathways by which lead could become associated with the fruiting part of a chili plant prior to harvest have been identified, including root uptake from soil and water, air deposition, and deposition from irrigation water. The potential for chili pepper plants to take up lead from soil and for lead to be transported to the edible fruit has been investigated in studies with varieties of *C. annuum L.* These varieties were studied using sufficient experimental designs to evaluate the potential for lead uptake (Antonious and Kochhar 2009; Hao et al. 2011). Briefly, these studies involved the analysis of lead in chili pepper fruits following growth of the chili pepper plants under controlled conditions in soils with known levels of lead present (ranging from 0.7 parts per million [ppm][5] to 1,010 ppm lead). In the Antonious and Kochhar (2009) study of chili pepper plants grown in soil with 0.7 ppm lead, no lead was detected in the fruits of *C. annuum L* (or in the fruits of *C. chinense* and *C. frutescens*, two other widely cultivated species of chili peppers included in that study).

In the Hao et al. (2011) study of *C. annuum L.* chili pepper plants grown in soils with higher levels of lead contamination, i.e., 74.6 ppm lead ('slightly contaminated soil') and 1010 ppm lead ('heavily contaminated soil'), some uptake of lead into the chili pepper fruits was observed. Specifically, the level of lead in the chili pepper fruits ranged from 0.034 to 0.09 ppm for plants grown in soil containing 74.6 ppm lead and from 0.055 to 0.19 ppm for plants grown in soil containing 1010 ppm lead, across the *C. annuum L* varieties tested. These studies indicate that while uptake and transport of lead from soil to the edible fruit of *C. annuum L.* chili pepper plants can occur, this mechanism is not expected to result in detectable levels of lead in chili peppers when plants are grown in soil without significant lead contamination.

Lead present in chili peppers, including dried peppers and chili powders, can also result from contamination as the chili is harvested, transported, dried, and processed. For example, during transport unwashed fresh chili peppers may become contaminated with materials, including soils, which contain substantial levels of lead. Elevated levels of lead may occur in soil as a result of past use of leaded gasoline. When chili peppers are dried prior to milling into chili powder, the drying and processing stages are also potential opportunities for contamination. Studies reported to OEHHA in 2007 and 2008 by candy manufacturers (The Hershey Company, Mars Inc.[6]) as well as a study conducted by OEHHA, discussed further below, have demonstrated that washing chili peppers, both fresh and dried, prior to further processing can significantly reduce the

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[4]Transcripts from the OEHHA Public Workshop[s] in the Matter of Adulterated Candy: Maximum Allowable Lead Levels, held March 5, 2008 in San Diego (p. 58) and March 6, 2008 in Los Angeles (p. 89).

[5] ppm on a weight/weight basis, i.e, equivalent to micrograms per gram (µg/g).

[6] In 2007 and 2008 subsidiaries of Mars Inc, Masterfoods USA, and Mars Snackfood US, provided data to OEHHA. References to data and information provided by Mars Inc to OEHHA encompasses information provided by its subsidiaries.

level of lead in dried whole chili peppers and in chili powder made from the washed and dried peppers.

Studies of lead in chili peppers and chili powder report data on both dry and wet weight bases. Reduction of moisture content from the fresh chili pepper, as in dried chili peppers and chili powder, concentrates non-water components of the pepper, which would include lead, if present.

Naturally Occurring Lead in Chili Peppers and Chili Powder: Relevant Data

Levels of Lead in Chili Peppers, Related Peppers, and Chili Powder

I. OEHHA Study of Lead in Fresh and Dried Chili Peppers

OEHHA conducted a multi-part study of lead in chili peppers originating from California and Mexico. In this study, OEHHA determined lead content in fresh and dried Anaheim chili peppers, and in pre-dried guajillo chili peppers. All pepper samples were stored in labeled plastic freezer bags and taken for analysis to the National Food Laboratory (NFL) located at the time in Dublin, California. NFL followed standard protocols to prepare, extract, and analyze the chili peppers by inductively coupled plasma mass spectrometry (ICP/MS). The limit of detection (LOD) for lead was 0.01 ppm.

- In part A of the study, lead content was determined in Anaheim chili peppers collected directly from a Southern California agricultural field, and in fresh Anaheim chili peppers obtained from produce markets in Northern California and grown in either California or Mexico.
- In part B of the study, lead content was determined in oven-dried Anaheim chili peppers obtained from markets in Northern California as fresh peppers, grown in either California or Mexico.
- In part C of the study, the effect of washing the fresh Anaheim chili peppers on lead content in fresh and oven-dried peppers was investigated in Mexican-grown peppers obtained from produce markets in Northern California.
- In part D of the study, lead content was determined in pre-dried guajillo peppers obtained from a Northern California market and grown in Mexico, and the effect of washing on the lead content of dried peppers was investigated.

Part A of the OEHHA study was conducted in May 2007. The goal was to determine lead content in fresh Anaheim chili peppers from California and Mexico.

i. Part A of the OEHHA Study: Samples

In Part A of the OEHHA study, field and market samples of fresh Anaheim chili peppers were obtained. Forty-eight chili peppers were collected directly from an agricultural field in Southern California and were combined to create composite samples for analysis. Each composite sample consisted of four fresh chili peppers (> 100 g). A total of 10 composite samples were designated for lead analysis. The remaining 2 composite samples were designated for moisture content analysis. An additional 240 fresh

Anaheim chili peppers, grown in California and Mexico, were obtained from ten Northern California area produce markets and were combined to create composite samples for analysis. Each composite sample consisted of four fresh chili peppers (>100 g). A total of 50 composite samples were designated for lead analysis. An additional 10 composite samples were designated for moisture content analysis.

ii. Part A of the OEHHA Study: Sample Treatment and Analysis

Chili peppers were initially cleaned by NFL to remove soil, dust, and other surface contamination by being washed with water containing mild detergent (1% Cole-Parmer Micro-90) and rinsed with deionized water, with residual moisture carefully removed with laboratory-grade wipes. All samples designated for lead analysis were analyzed by ICP/MS.

iii. Part A of the OEHHA Study: Results

An average moisture content of 91.84% (standard deviation = 0.819%) was determined for fresh, Anaheim chili peppers using the designated composite samples (n = 12). Lead was not detected in any of the composite samples of fresh, field-sampled (n = 10) chili peppers. Lead was not detected in any of the composite samples of fresh, market-sampled (n = 50) chili peppers. These results are presented in Table 1.

Table 1. Lead Levels in Fresh, Mild Detergent-Washed and Rinsed Anaheim Peppers from Part A of the OEHHA Study

Type	Sample Origin	No. Samples	Lead# (ppm)	Sampling Dates
Field-sampled peppers	California	10*	ND**	May 2007
Market-sampled peppers	California	10*	ND**	May 2007
Market-sampled peppers	Mexico	40*	ND**	May 2007

* Composite samples, not individual chili peppers. Each composite sample consisted of four individual peppers.

** Not detected, LOD = 0.01 ppm. Lead was not detected in any of the composite samples.

Wet weight

Part B of the OEHHA study was conducted in October 2007. The goal was to investigate whether the process of drying chili peppers affects the level of lead in peppers that do not contain detectable lead (above 0.01 ppm) when fresh.

i. Part B of the OEHHA Study: Samples

Sixteen fresh Anaheim chili peppers were obtained from a Northern California market. Each chili was cut in half, with one half contributed to a composite sample designated to remain as fresh chili pepper and the other half contributed to a composite sample designated for further processing by oven-drying. Each composite sample consisted of eight fresh chili pepper halves (> 100 g). Two composite samples of undried chili and two composite samples of oven-dried chili were designated for lead analysis.

ii. Part B of the OEHHA Study: Sample Treatment and Analysis

The chili peppers were initially cleaned by NFL to remove soil, dust, and other surface contamination by washing with water containing mild detergent, rinsing with deionized water, and drying with laboratory-grade wipes. Individual chili peppers were then cut in half, with each half placed into paired composite samples. For each of these paired sets of samples (two pairs, for a total of four composite samples), one was analyzed for lead without further processing (n = 2 composite samples), while the other was first oven-dried overnight, and then ground into powder prior to analysis. All samples designated for lead analysis were analyzed by ICP/MS.

iii. Part B of the OEHHA Study: Results

Lead was not detected in either the fresh (n = 2) composite or dried (n = 2) composite chili pepper samples. These results are presented in Table 2.

Table 2. Lead Levels in Mild Detergent-Washed and Rinsed Anaheim Peppers from Part B of the OEHHA Study

Type	Sample Origin	No. Samples	Lead (ppm)	Sampling Dates
Fresh, not dried peppers	Mexico	2*	ND**,#	Oct. 2007
Oven-dried peppers (dried from fresh peppers)	Mexico	2*	ND**,##	Oct. 2007

* Composite samples, eight chili pepper halves per sample.
** Not detected, LOD = 0.01 ppm.
# Wet weight
Dry weight

Part C of the OEHHA study was conducted in November 2007. The goal was to investigate the effect of washing the fresh Anaheim chili peppers on lead content in fresh and oven-dried peppers.

i. Part C of the OEHHA Study: Samples

Fresh Anaheim chili peppers of Mexican origin were sampled from three Northern California markets and were combined to create composite samples for analysis. Each initial composite sample consisted of eight fresh chili peppers (> 100 g). A total of 18 composite samples were created.

ii. Part C of the OEHHA Study: Sample Treatment and Analysis

The 18 composite samples were split into three groups, with composite samples in each group subjected to one of three different washing treatments:

- No washing treatment (n = 6 composite samples)
- Rinsed with deionized water (n = 6 composite samples)
- Washed with water containing mild detergent and rinsed with deionized water as in Parts A and B of the study (n = 6 composite samples)

One of the six composite samples in each treatment group was reserved for moisture analysis (n = 3 composite samples). The remaining 15 composite samples were further processed prior to lead analysis. Following the respective washing treatments, individual chili peppers from each composite sample were cut in half, with one half of each chili pepper forming composite sample “A”, and the other half of each chili pepper forming composite sample “B”, as illustrated in Figure 1. As indicated in Figure 1, composite samples with the “A” suffix were analyzed fresh for lead content without further processing, while composite samples with the “B” suffix were first oven-dried overnight, and then ground into powder prior to analysis for lead. All samples designated for lead analysis were analyzed by ICP/MS.

iii. Part C of the OEHHA Study: Results

Lead was not detected in either fresh (n = 15) or dried (n = 15) chili pepper subsamples. For fresh peppers, an average moisture content of 91.99% (standard deviation = 0.885%) was determined using the three designated composite samples. This is very similar to the average moisture content of 91.84% determined in Part A of the OEHHA study. For the oven-dried peppers, an average moisture content of 4.09% (standard deviation = 1.272%) was determined using the three designated composite samples. At an average moisture content of 4.09% in the oven-dried chili peppers, lead in the fresh, undried chili would be expected to fall below 0.001 ppm. Table 3 presents these results.

Figure 1. Diagram of Part C Study Design

In this figure, the prefix "X" indicates the six composite samples of peppers that did not receive a washing treatment ("Unwashed"), the prefix "Y" indicates the six composite samples of peppers that were rinsed only with water ("Water Rinsed"), and the prefix "Z" indicates the six composite samples of peppers that were washed with mild detergent and then rinsed ("Detergent Washed"). The suffix "A" indicates halves of individual peppers within a composite sample that were analyzed fresh and the suffix "B" indicates halves of individual peppers within a composite sample that were analyzed after oven-drying and grinding.

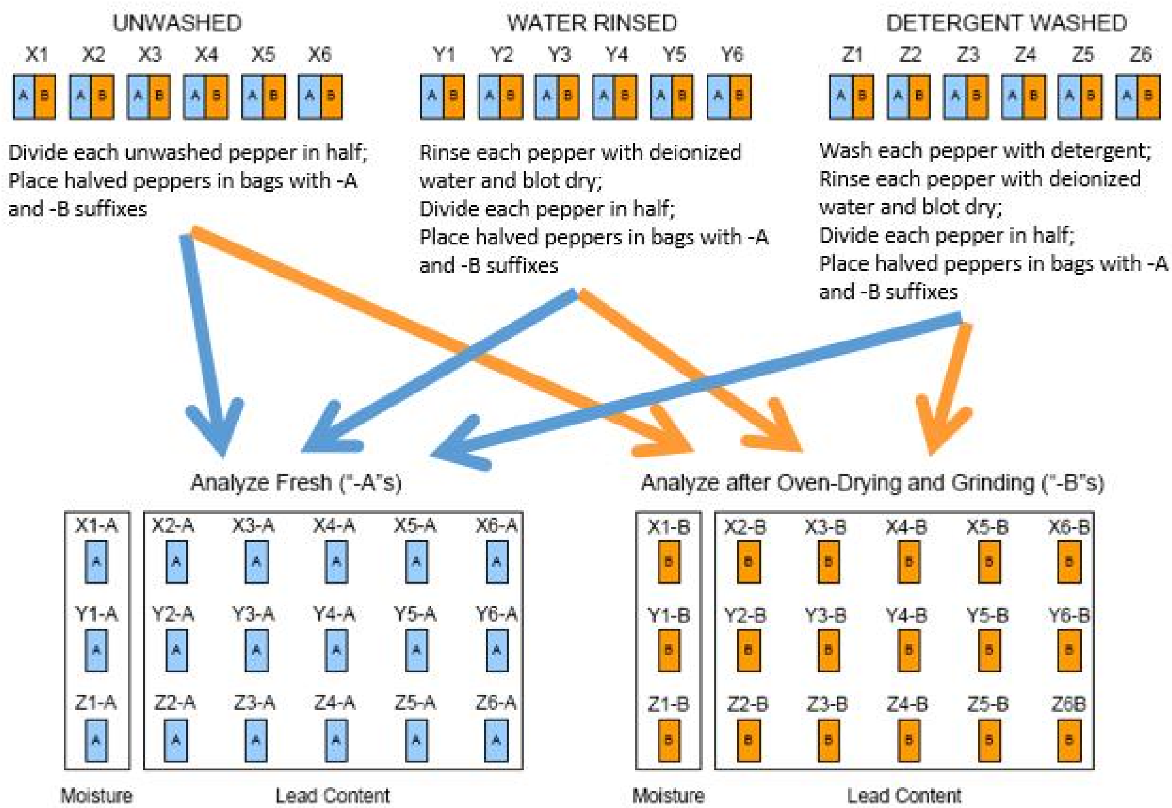

Table 3. Lead Levels in Anaheim Peppers from Part C of the OEHHA Study

Type and Treatment	Sample Origin	No. Samples	Lead (ppm)	Sampling Dates
Unwashed peppers	Mexico	5*	ND**,#	Nov. 2007
Rinsed peppers	Mexico	5*	ND**,#	Nov. 2007
Mild detergent-washed and rinsed peppers	Mexico	5*	ND**,#	Nov. 2007
Unwashed, oven-dried peppers	Mexico	5*	ND**,##	Nov. 2007
Rinsed and oven-dried peppers	Mexico	5*	ND**,##	Nov. 2007
Mild detergent-washed, rinsed, and oven-dried peppers	Mexico	5*	ND**,##	Nov. 2007

* Composite samples, eight chili pepper halves per sample
** Not detected, LOD = 0.01 ppm.
# Wet weight
Dry weight

Part D of the OEHHA study was conducted in stages in October 2007 and January 2008. The goal of Part D was to determine lead content in commercially available pre-dried guajillo peppers.

i. Part D of the OEHHA Study: Samples

Pre-dried guajillo pepper samples from two brands were obtained from a Northern California market, with a total of 48 pre-dried guajillo pepper samples from Brand 1 and 40 pre-dried guajillo pepper samples from Brand 2. Four pre-dried chili peppers (>100 g) from each respective brand were combined to create composite samples for analysis. There were 12 composite samples from Brand 1 and 10 composite samples from Brand 2.

ii. Part D of the OEHHA Study: Sample Treatment and Analysis

Two composite samples from each brand were designated for moisture content analysis and the remaining 18 composite samples were split into two treatment groups. In the first treatment group (n = 10), composite samples were ground into powder prior to analysis. In the second treatment group (n = 8), composite samples were rehydrated by being soaked in water for five minutes, rinsed with water containing mild detergent, subsequently rinsed with deionized water, re-dried overnight in an oven, and then ground into powder prior to analysis.

iii. Part D of the OEHHA Study: Results

Lead was detected in all composite samples of pre-dried guajillo peppers from Mexico without further treatment, with mean lead levels, by brand, of 0.047 ppm for Brand 1 and 0.050 ppm for Brand 2, with an overall range from 0.025 to 0.072 ppm, as shown in Table 4. Rehydration and rinsing of pre-dried guajillo pepper samples, then re-drying, prior to analysis reduced the lead levels, with mean lead levels, by brand, of 0.014 for Brand 1 and 0.043 for Brand 2, with an overall range from 0.011 to 0.054 ppm. The reduction of lead was statistically significant in Brand 1 ($p = 0.008$), though not in Brand 2 ($p = 0.28$).

Table 4. Lead Levels in Pre-dried Guajillo Peppers from Part D of the OEHHA Study

Type and Treatment		Sample Origin	No. Samples	mean Lead## ± SD (ppm)	range Lead## (ppm)	Sampling Dates
Brand 1	Unwashed	Mexico	6*	0.047 ± 0.014	0.025 – 0.072	Oct. 2007 & Jan. 2008
	Rehydrated, mild detergent-washed, rinsed, and oven-dried	Mexico	4*	0.014 ± 0.003	0.011 – 0.0174	Jan. 2008
Brand 2	Unwashed	Mexico	4*	0.050 ± 0.009	0.0387 – 0.059	Jan. 2008
	Rehydrated, mild detergent-washed, rinsed, and oven-dried	Mexico	4*	0.043 ± 0.007	0.0367 – 0.0541	Jan. 2008

Dry weight

* Composite samples, four chili peppers per sample

Summary of the OEHHA Study Findings

In the OEHHA study, no detectable levels of lead were found in fresh Anaheim chili peppers grown in California and Mexico, with and without treatments including washing and oven-drying. Further, while pre-dried Guajillo chili peppers from Mexico were determined to have detectable levels of lead, the lead present was reduced by washing. Lead removed from the surface by washing is not incorporated into the tissue of the chili pepper, which, in contrast, may occur following uptake and distribution of lead from soil.

II. Additional Information on Lead in Chili Powder, Chili Peppers, and Sweet Green Peppers

In addition to the OEHHA study, data were provided to OEHHA on lead concentrations in chili powder and/or chili peppers used to make chili powder by several entities: multiple candy manufacturers (e.g., The Hershey Company, Mars Inc., Caramelos Don Picoso, and Zumbapica), a chili/chili powder manufacturer (Frudest), an industry trade organization (National Confectioners Association (NCA)), a third party auditor of candy manufacturers (the HACCP Registrar), and the Office of the Attorney General. Data provided by these entities consisted of either summary data (e.g., average lead concentrations and concentration ranges), or data sets reporting lead concentrations for individual samples. OEHHA also identified data that are available from the US Food and Drug Administration (US FDA) on lead concentrations in a related subgroup of *C. annuum* peppers, namely sweet green peppers.

Data from candy manufacturers

Data recently provided by or on behalf of candy manufacturers can be summarized as follows:

- Caramelos Don Picoso provided OEHHA with an average range for lead content in “chili used for powder” of 0.08 to 0.1 ppm (Menéndez, 2019). No study details or individual sampling data were provided.
- Zumbapica provided OEHHA with an average lead concentration (0.064 ppm) in Guajillo chili powder samples analyzed by ICP/MS between 2011 and 2019, with a limit of detection of 0.005 ppm (Jonguitud, 2019). No individual sampling data were provided.
- The NCA provided OEHHA with data from two anonymous candy manufacturers (Miller, 2019):
    - The dataset from “Company X” comprised lead levels in various chili powders from at least four suppliers between 2012 and 2019 that were analyzed by ICP/MS (Miller, 2019). The average level of lead in these chili powders (which include arbol chili powder and chilaca/guajillo chili powder blends) was 0.094 ppm, with an annual average range of 0.070 to 0.108 ppm (Miller, 2019).
    - The dataset from “Company Y” consisted of line graphs representing a range of lead concentrations (approximately 0 to 0.26 ppm) in chili pepper samples from three suppliers between 2017 and 2019 that were analyzed by ICP/MS; the maximum lead concentrations in samples from one supplier were approximately 0.1 ppm less than those in samples from the other two suppliers (Miller, 2019).

- The third-party auditor, the HACCP Registrar, provided a scatterplot representing a range of lead concentrations (approximately 0.017 to 0.31 ppm, with most samples falling below 0.1 ppm) measured in four categories[7] of chili and chili powder samples from an unknown number of their certified manufacturers between 2010 and 2018[8] (Pineda, 2019). No further details regarding sample origin or analytical methodology were provided.
- Levels of lead in six batches of chili powder from analyses conducted in 2016-2017 by the Centro de Investigación y Asistencia en Tecnología y Diseño del Estado de Jalisco (CIATEJ) on behalf of various candy manufacturers[9,10] were reported to be 0.018, 0.018, 0.020, 0.029, 0.049, and 0.107 ppm. The mean level for these six samples was 0.04 ppm, with a standard deviation of 0.035 ppm. Information on the origin and handling of the chili peppers and the processing methods utilized to make the respective batches of chili powder was not available.

These recent data submitted by, or on behalf of, candy manufacturers reflect levels of lead in chili powder, and in chili peppers used to make chili powder, that are considerably lower than the levels in data submitted to OEHHA in 2008 by candy manufacturers:

- The Hershey Company provided data from a 2004 study that demonstrated a broad range of lead levels in chili powders originating in Mexico, and indicated that higher levels of lead are present in chili powder made from unwashed, as compared to washed, chili peppers (Mastrorocco, 2008):
  - For chili powder made from washed chili peppers, the mean lead concentration was 0.241 ppm (dry weight; range 0.023 to 1.14 ppm, n = 225).
  - For chili powder made from unwashed chili peppers the mean was 0.938 ppm lead (dry weight; range 0.049 to 2.21 ppm, n = 109).
- The range of lead concentrations reported by The Hershey Company for chili powders made from washed chili peppers analyzed between 2007 and 2008 was 0.028 ppm to 0.893 ppm (n = 324) (Mastrorocco 2008).

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[7] Categories (in Spanish) translate to Arbol chili, Guajillo chili, chili powder, and export chili.
[8] Data have been collected through the HACCP Registrar certification program surveillance plan, which includes a number of candy manufacturers in compliance with Office of the Attorney General requirements included in the consent judgment in *People v. Alpro Alimento Proteinicos, et al.*, Los Angeles County Superior Court case #BC318207 (August 3, 2006).
[9] Data and other information from Wil Sumner, Sumner Analytical Services, received by OEHHA on January 29, 2018, through the Office of the Attorney General.
[10] CIATEJ is one of the qualified laboratories used to monitor compliance with the settlement in *People v. Alpro Alimento Proteinicos, et al.*, Los Angeles County Superior Court case #BC318207 (August 3, 2006). CIATEJ has demonstrated proficiency in conducting lead analysis (ICP/MS) on chili-containing products based on "current satisfactory performance in the Food Analysis Performance Scheme program ('FAPAS') administered by Central Science Laboratory, York, UK".

- Mars Inc. reported a range of lead concentrations in accepted lots of chili powder made from washed chili peppers of 0.050 ppm to 0.375 ppm (n = "200+") in 2008 (Ahn, 2008).

Data from chili powder processor

OEHHA has also been provided data and information from a chili powder processor, Frudest. Frudest stated that the average lead in the chili used for powder ranged from 0.110 to 0.150 ppm and provided two sets of data to OEHHA (Castaño, 2019):

- Levels of lead in samples of ground chili pepper commercially produced from industrial washed and sun dried "Grade B" chili peppers that were analyzed by CIATEJ, presumably by ICP/MS - mean lead concentration was 0.113 ppm (range 0.046 to 0.804 ppm, n = 368).
- A summary dataset reflecting levels of lead in chili powder produced from sun drying washed chili peppers (range: 0.09 to 0.331 ppm) and unwashed chili peppers (range: 0.15 to 0.571 ppm).

Data on fresh chili from US FDA

OEHHA reviewed US FDA measurements of lead in sweet green peppers, which belong to a related, but different subgroup of *C. annuum* (*grossum*) peppers than those used to make chili powder. These US FDA data are part of the ongoing US FDA Total Diet Study (TDS), also known as the Market Basket Study (US FDA 2007; US FDA 2017; US FDA 2020). The most recent TDS data for lead in sweet green peppers are for 15 samples of raw sweet green peppers collected in the first four years of the current market basket study, i.e., 2014 through 2017 (US FDA 2020). These samples were analyzed for lead content using a multi-element ICP/MS method, for which the limit of detection was 0.003 ppm. Lead was not detectable in any of the 15 samples. For years 2006 to 2013, 32 sweet green peppers samples were analyzed by graphite furnace atomic absorption spectroscopy (GFAAS), with a LOD of 0.007 ppm (US FDA 2017). Lead was not detected in 31 of 32 samples; lead was detected in one sample at the LOD of 0.007 ppm. These results indicate that lead is generally not present at measurable concentrations in sweet green peppers commercially available in the US.

<u>Estimation of Naturally Occurring Lead in Chili Peppers and Chili Powder</u>

According to HSC Section 110552, the "naturally occurring level" of lead is defined as naturally occurring only to the extent that the level is "not avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible".

The OEHHA study did not detect lead (LOD = 0.01 ppm) in samples of:

- Anaheim chili peppers obtained directly from agricultural fields in Southern California (washed)
- Anaheim chili peppers grown in California purchased from Northern California markets (washed)

- Anaheim chili peppers grown in Mexico and purchased from Northern California markets (unwashed and washed)
- Anaheim chili peppers grown in Mexico and purchased from Northern California markets (unwashed and washed) that were subsequently oven dried

Thus, lead could not be found in a type of chili pepper used to make chili powder to flavor candies, whether the chili peppers came from Mexico or California. The chili peppers purchased at the market were subject to potential post-harvest contamination, such as from handling and shipping. Nonetheless, no detectable level of lead was found in any of the market samples, nor from the samples obtained by OEHHA directly from an agricultural field in Southern California.

The OEHHA study results are in agreement with a US FDA (2006) opinion that freshly grown raw chili peppers are not likely to contain significant levels of lead. These results are also in agreement with US FDA (2017, 2020) TDS results for sweet green peppers, a *C. annuum G*. variety related to the C. *annuum L.* chili pepper varieties used in the manufacture of candies flavored with chili.

The results of the OEHHA study also demonstrate that oven drying fresh chili peppers from California and Mexico does not increase lead above the limit of detection. Drying the chili peppers concentrates non-water components of the pepper, which would include any lead that may have been present, but no lead was detected in any of the dried chili peppers. At an average moisture content of 4.09% in the oven-dried chili peppers, lead in the corresponding fresh, undried chili peppers would be expected to fall below 0.001 ppm, given an average moisture content of 92% in fresh pepper measured in the OEHHA study. It follows that if chili powder were made from these dried chili peppers, the naturally occurring level in the powder would also be at or below the LOD of 0.01 ppm.

The oven-dried chili peppers in the OEHHA study have lower levels of lead than chili powders tested in 2016 and 2017 used in candy manufacturing in Mexico[11]. However, it is notable that the levels of lead in chili powders from Mexico tested in 2016 and 2017 are considerably lower than the levels reported by candy manufacturers for 2007 and 2008 samples of chili powder from Mexico made from both washed and unwashed chili peppers, as discussed in detail above. The lower levels in the most recent samples of chili powder from Mexico likely reflect measures that have been put in place to reduce lead in chili powder used to make candy. Moreover, these data indicate that the higher levels reported in 2008 reflect lead contamination, rather than the presence of lead that is naturally occurring, as defined under HSC section 110552.

Also, from the OEHHA study, rehydration and washing of the Guajillo chili peppers from Mexico significantly reduced levels in one of the brands tested, by approximately a

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[11] Data and other information from Wil Sumner, Sumner Analytical Services, received by OEHHA on January 29, 2018, through the Office of the Attorney General.

factor of three – from a mean of 0.047 ppm to a mean of 0.014 ppm, indicating that some of the lead present may be due to surface contamination.

The OEHHA study, which used the best available analytical method, provides the most reliable data to establish a naturally occurring level for lead in chili peppers and in chili powder, given its analysis of chili peppers of relevant variety and, in the case of those sampled directly from an agricultural field, known origin and handling. Lead was not detected in any of the fresh Anaheim chili peppers originating in California or Mexico, in specimens obtained directly from a California agricultural field, as well as specimens obtained from a variety of markets. Similarly, no lead was detected in any of the oven-dried samples of Anaheim chili peppers that were ground prior to analysis. While some lead was detected in both unwashed pre-dried Guajillo peppers from Mexico and washed pre-dried Guajillo peppers from Mexico, washing did reduce the amount of lead present across both brands tested, to an extent in one brand just above the LOD. Half of the recent batches of chili powder from Mexico provided to the Office of the Attorney General fall within a factor of two of the detection limit.

Thus, 0.01 ppm, which is the detection limit for lead in both fresh and dried chili peppers from the OEHHA study, will be used for estimation of the naturally occurring level of lead in chili powder.

<u>Contribution of Naturally Occurring Lead by Chili Peppers and Chili Powder in Candy Flavored with Chili and/or Tamarind</u>

OEHHA has assumed, based on communications with manufacturers (Ahn 2008; Mastrorocco 2008), that a typical sugar-based candy flavored with chili is comprised of as much as 15% chili powder. Therefore, the concentration of naturally occurring lead contributed by chili pepper, in the form of chili powder, in such a candy would be 0.0015 ppm (= 0.01 × 15%). Formulations for tamarind-based candies flavored with chili vary, but a typical product may contain as much as 17.5% chili powder. Therefore, the concentration of naturally occurring lead contributed by chili peppers and chili powder in such a tamarind-based candy would be 0.0018 ppm (= 0.01 × 17.5%). Formulations for salt-based candies flavored with chili vary, but a typical product may contain as much as 30% chili powder (Ahn 2008; Mastrorocco 2008). Therefore, the concentration of naturally occurring lead contributed by chili peppers and chili powder in a typical salt-based candy would be 0.003 ppm (= 0.01 × 30%), as in Table 5 below.

One candy manufacturer, Dulcera Chaca Chaca, has indicated that there could be candies with more than 90% chili content (Torres 2019). Although no further information or data were provided to OEHHA regarding such a candy formulation, the contribution of naturally occurring lead by chili powder in a “chili-based candy” with 90% chili content would be 0.009 ppm (= 0.01 × 90%).

Table 5. Contribution of Naturally Occurring Lead by Chili Powder in Formulations of Candy Flavored with Chili and/or Tamarind

Naturally Occurring Lead in Chili Powder (ppm)	Estimated Amount of Chili Powder in Candy Formulations (%)	Naturally Occurring Lead Contributed by Chili Powder (ppm)
0.01	0 – 30	0 – 0.003

2. Tamarind

Tamarind is the fruit of the leguminous tamarind tree (*Tamarindus indica*). Removal of the outer pod yields a tamarind pulp; both this pulp and a paste made by further processing to remove seeds and fibers are popular ingredients in many candies, including a variety of Mexican-style and Asian-style candies. In such candies, tamarind may be the sole flavoring ingredient or be present in some combination with other flavors, including chili powder. The US FDA has previously reported that some tamarind candies contain high levels of lead (US FDA 2006). Tamarind candies may be contaminated by processing, by use of tamarind pulp that has been stored in ceramic glazed pottery that can leach lead, and by packaging of the candy in wrappers that can leach lead (Lynch et al. 2000; Meyer et al. 2008; Diaz-Ruiz et al. 2016). Further, the uptake of lead in the soil by the roots of the tamarind tree is a pathway by which lead may be introduced into tamarind pulp. When the lead in the soil is naturally occurring, the lead in the pulp introduced in this way can be considered naturally occurring.

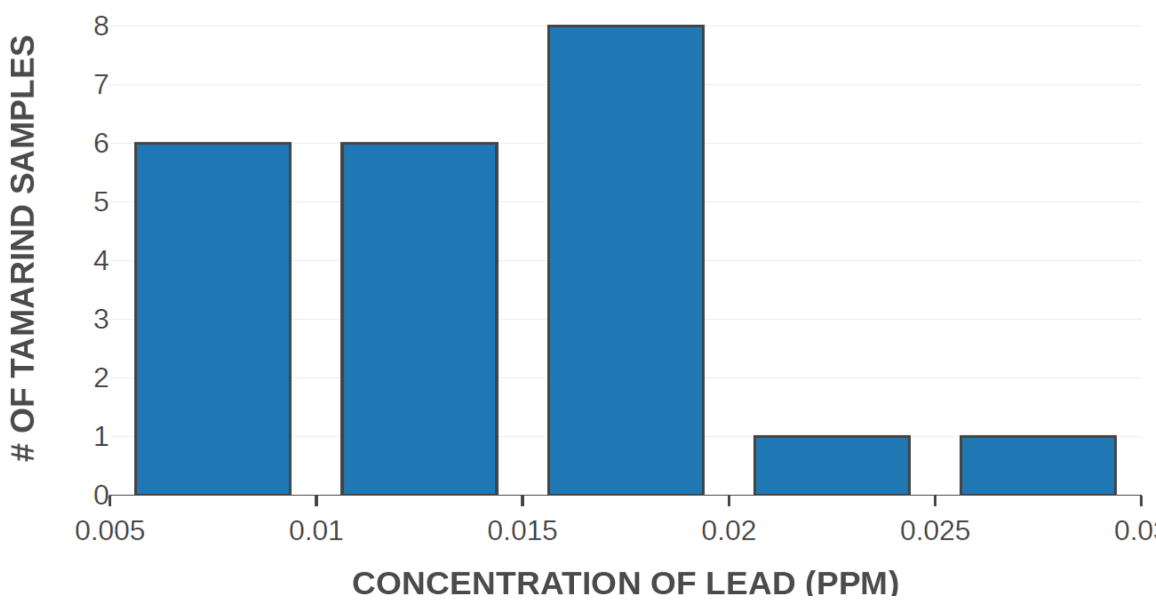
Three categories of tamarind-containing candies are considered in establishing naturally occurring levels: sugar-based candies in which tamarind provides flavor, tamarind pulp candies covered with a chili powder coating, and tamarind paste itself. Information submitted by Mars Inc. and The Hershey Company, indicates that certain sugar-based candies may contain up to 5% tamarind (Ahn 2008; Mastrorocco 2008). However, no data are available regarding the variation in amount of tamarind as an ingredient in these sugar-based candies. For the purpose of estimating the level of naturally occurring lead in sugar-based candies flavored with tamarind, it is assumed that these candies are formulated with 5% tamarind. Tamarind pulp candies are assumed to contain up to 80% tamarind pulp with some amount of chili powder. The third type of tamarind candy is tamarind paste; these candies are assumed to be comprised of 100% tamarind paste. Historically they have been packaged in ceramic glazed pottery, some with high lead content.

Naturally Occurring Lead in Tamarind: Relevant Data

One set of data, provided by Mars Inc., is available regarding lead in tamarind pulp[12].

The Mars Inc. data set consists of 22 samples of tamarind obtained from local suppliers in Mexico. All 22 samples were collected over a period of approximately one year and stored cold until analysis by ICP/MS. In preparation for analysis of lead content, each tamarind sample was processed to create a tamarind pulp, which involved the removal of shell and seeds, application of a heating process, addition of preservatives, and grinding the remaining material. The range of lead in the tamarind pulp samples was 0.006 to 0.028 ppm, and the distribution of lead in these samples is shown in Figure 2. The mean lead level in this data set was 0.014 ppm with a standard deviation of 0.005 ppm.

Figure 2: Concentration of Lead in Mars Inc. Tamarind Samples



Estimation of Naturally Occurring Lead in Tamarind

The very limited data available on levels of lead in tamarind do not provide the type of information necessary to distinguish between naturally occurring and anthropogenic (i.e., lead introduced in tamarind by human activity) sources of lead.

The available data from Mars Inc. indicate that, though there can be some degree of variation in levels of lead in tamarind pulp, tamarind pulp with low concentrations of lead (< 0.01 ppm) are available for use in candy. Over half the Mars Inc. samples fall into

[12] Data from Tim Ahn, Mars Inc., received by OEHHA on April 24, 2007.

the range of 0.006 to 0.015 ppm[13], with one quarter containing lead below 0.01 ppm. The information provided does not include sample origin. No other data relevant to determination of a naturally occurring level of lead in tamarind have been identified.

The concentration of lead reported for the Mars Inc. tamarind samples are considerably lower than concentrations of lead in processed tamarind candy reported previously, which is consistent with the data from earlier analyses that indicate wrappers may have contributed substantial lead to tamarind candies. Lynch et al. (2000) analyzed lead levels in two tamarind candy products, with 20 samples each per product. Mean lead level in one product was 0.42 ppm, with a range 0.15-1.17. The wrappers for these candies had high levels of lead, with a mean of 20,176 ppm. The mean lead level for the second candy product was 0.85 ppm, with a range 0.36-3.61 ppm, while the mean level in the candy wrappers was 662 ppm.

For the purpose of establishing a naturally occurring level of lead, and absent any data or study design details supporting an alternate approach to identify a naturally occurring level, 0.02, one standard deviation above the mean lead level in tamarind from the Mars Inc. data set, is assumed to represent the naturally occurring level of lead in tamarind pulp. As 20 of the 22 samples tested had lead concentrations below this level, this indicates that tamarind with lead concentrations below 0.02 ppm were readily available at the time of this study.

<u>Contribution of Naturally Occurring Lead by Tamarind in Candy Flavored with Chili and/or Tamarind</u>

In terms of sugar-based tamarind candy, it is assumed that a typical candy is comprised of 5% tamarind (Ahn 2008; Mastrorocco 2008). Therefore, the total amount of naturally occurring lead contributed by tamarind in such a candy would be 0.001 ppm (= 0.02 × 5%). Product formulations for tamarind pulp candies are not available, but it is assumed that 80% tamarind paste might be used for this type of product in combination with some chili powder. Therefore, the total amount of naturally occurring lead contributed by tamarind is 0.016 ppm (= 0.02 × 80%). Similarly, there is no specific formulation available for tamarind paste packaged in ceramic pottery. It is assumed here that 100% tamarind paste is used for this type of product, thus the total amount of naturally occurring lead contributed would be 0.020 ppm (= 0.02 × 100%), as in Table 6 below.

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[13] The Mars Inc. tamarind data set was evaluated for outliers, the presence of which may indicate contaminated samples. Outliers were defined using the interquartile range (IQR = 75th minus 25th percentiles), with data that fall outside the range of the 1st quartile less 1.5 × IQR and the 3rd quartile plus 1.5 × IQR classified as outliers. Using this approach, which does not require an assumption regarding the nature of the distribution of the data, no samples in this data set were classified as outliers.

Table 6. Contribution of Naturally Occurring Lead by Tamarind in Formulations of Candy Flavored with Chili and/or Tamarind

Naturally Occurring Lead in Tamarind (ppm)	Estimated Amount of Tamarind in Candy Formulations (%)	Naturally Occurring Lead Contributed by Tamarind (ppm)
0.02	0 – 100	0 – 0.020

3. Food-Grade Salt

Food-grade salt, in this context referring to sodium chloride (NaCl), is a substantial fraction of salt-based candy flavored with chili and/or tamarind. Some products have been reported to contain more than 50% salt (Ahn 2008; Mastrorocco 2008). The US FDA has noted that salt may be a source of lead contamination in some of these candy products (US FDA 2006).

There are two types of salt that are generally used in food, sea salt (solar salt), produced by evaporation of sea water, and mined salt, produced by solution mining and subsequent thermal reduction of salt brine. A modern, properly operating solar salt plant can produce salt that is more than 99.7% NaCl (Salt Institute 2018). Lead in sea salt is assumed to come mainly from the sea water itself, as the production process presents few opportunities for lead contamination. In solution mining, a well is drilled into an underground salt deposit, then pressurized water is introduced to hydraulically fracture the bedded salt; the resulting brine is pumped to the surface and the brine is refined into salt through application of a refining process, such as a vacuum pan process (Salt Institute 2018). Rock salt mining, which is not typically a direct source of food-grade salt in the United States, extracts salt from naturally occurring solid rock deposits. This mined rock salt is then processed to remove impurities and screen the material to finer size fractions (USGS 2014).

Naturally Occurring Lead in Salt: Relevant Data

Data regarding the level of lead in salt are available from multiple sources. These include reported concentrations of lead in salt from the open literature (Amorim and Ferreira 2005; Proper et al. 2014), data obtained from a 1994 survey of lead content in samples of sea salt and mined salt (Satin 2008), and data provided by five candy manufacturers (Mars Inc., The Hershey Company, Dulces Anahuac, Dulces Vero, and Zumbapica) and by a third-party auditor of candy manufacturers, the HACCP Registrar.

Mars Inc. provided a data set containing 22 individual measurements of lead in salt to OEHHA in 2007[14], and in a subsequent workshop presentation indicated that 0.030 ppm was the maximum allowable concentration of lead in salt for their candies. Mars Inc. indicated that sea salt meeting this specification was readily available in Mexico,

[14] Data from Tim Ahn, Mars Inc., received by OEHHA on April 24, 2007.

sourced from Yucatan marine brine. With regard to the data set provided to OEHHA, Mars Inc. obtained salt from two different vendors in Yucatan, Mexico. The samples were collected over a period of approximately 1½ years and analyzed for lead by ICP/MS. Additional information regarding the sampling and analysis protocol is not available. The concentration of lead in salt in the Mars Inc. data set ranged from 0.008 to 0.096 ppm. OEHHA evaluated the sample data for outliers[15]; three samples (with lead concentrations of 0.067, 0.072, and 0.096 ppm) were classified as outliers and excluded from analysis. The remaining nineteen samples of sea salt had reported lead levels ranging from 0.008 to 0.044 ppm with a mean lead level of 0.021 ppm and standard deviation of 0.009.

Dulces Anahuac provided data on lead in salts used as ingredients in candies flavored with chili and/or tamarind (Menéndez 2008). In this data set, three different laboratories were used over time, with the most recent testing conducted by CIATEJ in 2007. In the CIATEJ analyses for Dulces Anahuac, seven lots of ingredient-quality salt from five manufacturers each tested below the limit of detection of 0.02 ppm. Two lots of salt from a sixth manufacturer tested over the detection limit and were noted as having been rejected for use as an ingredient by Dulces Anahuac.

Dulces Vero provided OEHHA with a data summary including an average level of lead in salt of 0.036 ppm (range 0.015 to 0.469 ppm) determined from ingredients in its Picagomas candy product over a 2006 to 2007 period, although no information is available as to the sampling source, vendor, or analytical instrumentation (Ruiz 2008).

The Hershey Company provided OEHHA with a range of lead concentrations (0.02 ppm to 0.044 ppm, n = 262) in salt analyzed between 2007 and 2008 (Mastrorocco 2008). No information is available as to the sampling source, vendor, or analytical instrumentation.

Zumbapica provided OEHHA with an average lead concentration (0.054 ppm) in samples of salt sourced for candy ingredients that were analyzed by ICP/MS between 2015 and 2019 (Jonguitud, 2019). This average approximated the reported limit of detection of 0.05 ppm for salt. No individual sampling data were provided.

The HACCP Registrar provided a scatterplot representing a range of lead concentrations (≤ 0.001 ppm to approximately 0.25 ppm) measured in four categories[16] of salt samples between 2010 and 2018 [17] (Pineda, 2019). No further details regarding sample origin or analytical methodology were provided.

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[15] Outliers were defined using the interquartile range (IQR = 75th minus 25th percentiles), with samples that fall outside the range of the 1st quartile less 1.5 × IQR and the 3rd quartile plus 1.5 × IQR classified as outliers. This approach does not require an assumption regarding the nature of the distribution of the data (e.g., normal, lognormal).
[16] Categories (in Spanish) translate to salt, sea salt, Morton salt / Texas, refined salt.
[17] Data have been collected through the HACCP Registrar certification program surveillance plan, which includes a number of candy manufacturers in compliance with the settlement in *People v. Alpro Alimento Proteinicos, et al.*, Los Angeles County Superior Court case #BC318207 (August 3, 2006).

Estimation of Naturally Occurring Lead in Salt

The data available on levels of lead in salt, as reviewed above, do not provide the type of information necessary to distinguish between naturally occurring and anthropogenic (i.e., lead introduced in salt by human activity) sources of lead.

The data and information provided by five candy manufacturers collectively indicate that, though there can be some degree of variation in lead concentrations in salt, there are available sources of food-grade salt with low to undetectable (< 0.02 ppm) concentrations of lead. For example, the data provided by Dulces Anahuac reflecting multiple batches and variations and analyzed by a proficient laboratory (CIATEJ), indicate that low lead salt used as an ingredient in candies is available. This is supported by the more recent salt data provided by the HACCP Registrar, in which the lower end of the observed range of lead content in these samples was ≤ 0.001 ppm.

For the purpose of establishing a naturally occurring level for lead and absent any data or study design details supporting an alternate approach to identify a naturally occurring level, the limit of detection of 0.02 ppm from the CIATEJ analyses of the Dulces Anahuac salt samples is assumed to represent the naturally occurring level.

Contribution of Naturally Occurring Lead by Salt in Candy Flavored with Chili and/or Tamarind

OEHHA does not have specific information about the variation in percentage of salt as an ingredient in sugar- and salt- based candies. Manufacturers have advised OEHHA that a formulation of as much as 10% salt can be used in sugar-based candies (Ahn 2008; Mastrorocco 2008). Assuming that 10% salt is used for the formulation of a sugar-based candy flavored with chili and/or tamarind, the total amount of naturally occurring lead contributed from salt will be 0.002 ppm (= 0.02 × 10%). Assuming that 2% salt is used for the formulation of a tamarind-based candy flavored with chili, the total amount of naturally occurring lead contributed from salt will be 0.0004 ppm (= 0.02 × 2%). Manufacturers have advised OEHHA that a formulation of at least 50% salt, and as much as 60% salt, can be used in salt-based candies (Ahn 2008; Mastrorocco 2008). Assuming that 60% salt is used for the formulation of a salt-based candy flavored with chili and/or tamarind, the total amount of naturally occurring lead concentration contributed by salt will be 0.012 ppm (= 0.02 × 60%), as in Table 7 below.

Table 7. Contribution of Naturally Occurring Lead by Food-grade Salt in Formulations of Candy Flavored with Chili and/or Tamarind

Naturally Occurring Lead in Salt (ppm)	Estimated Amount of Salt in Candy Formulations (%)	Naturally Occurring Lead Contributed by Salt (ppm)
0.02	0 – 60	0 – 0.012

4. Sugar

Sugar is a principal ingredient of many candies flavored with chili or tamarind. Cane sugar is the predominant type used in such candies, although other types of sugar may be used. Data provided by candy manufacturers indicates that sugar may constitute at least 75% of the formulation in sugar-based candies (Ahn 2008; Mastrorocco 2008).

<u>Naturally Occurring Lead in Sugar: Relevant Data</u>

Data regarding the level of lead in sugar are available from multiple sources. Four candy manufacturers (Dulces Vero, Mars Inc., The Hershey Company, and Zumbapica) have provided data regarding the level of lead in sugar, as well as a confectionary industry trade organization (NCA), and the HACCP Registrar. Data are also available from the US FDA's TDS study. Dulces Vero provided OEHHA with a data summary of lead measurements obtained in 2006 and 2007 for ingredients in its Picagomas candy product that included an average level of lead in sugar of 0.008 ppm (range 0.003 to 0.048 ppm) (Ruiz 2008). However, no information is available as to the sampling source, vendor, or analytical instrumentation used to generate the data provided by Dulces Vero (Ruiz 2008). The range of lead in sugar reported in the Dulces Vero data summary is supported by data provided by the other three candy manufacturers.

Mars Inc. indicated that the level of lead in sugar is less than 0.05 ppm[18].

The Hershey Company provided OEHHA with a range of lead concentrations (0.005 ppm to 0.007 ppm, n = 11) in sugar analyzed between 2007 and 2008 (Mastrorocco 2008). No information was available as to the sampling source, vendor, or analytical instrumentation used to generate these data.

Zumbapica provided OEHHA with an average lead concentration (0.006 ppm) in samples of sugar sourced for candy ingredients that were analyzed by ICP/MS between 2015 and 2019 (Jonguitud, 2019). This average approximated the reported limit of detection of 0.005 ppm for sugar. No individual sampling data were provided.

NCA provided data from two anonymous candy manufacturers (Miller, 2019). The dataset from the first manufacturer, "Company X", comprised 32 measurements of lead (average 0.013 ppm; range 0.005 to 0.04 ppm) in "estandar" [standard] sugar samples from seven suppliers in 2014, 2017, and 2018. The NCA also provided line graphs representing a range of lead concentrations (≤ 0.001 to 0.05 ppm) in samples of powdered sugar and refined sugar from "Company Y" between 2017 and 2019.

The HACCP Registrar provided a scatterplot representing a range of lead concentrations (≤ 0.004 to approximately 0.38 ppm) measured in seven categories[19] of

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[18] Data and other information from Tim Ahn, Mars Inc., received by OEHHA on May 1, 2007.
[19] Categories (in Spanish) translate to sugar, confectioner's sugar, standard sugar, granulated sugar, powdered sugar, refined sugar, and sifted sugar.

sugar samples between 2010 and 2018 [20] (Pineda, 2019). No further details regarding sample origin or analytical methodology were provided.

The US FDA TDS is another source of data on lead in sugar. US FDA market basket surveys from 2014 to 2017, include 14 granulated white sugar samples (US FDA 2020). These sugar samples were evaluated for lead content using a multi-element ICP/MS method, for which the limit of detection was 0.003 ppm. Lead was not detectable in any of the 14 samples from the 2014 through 2017 reporting years.

The US FDA has additional data for levels of lead in sugar from older market basket surveys, and with higher detection limits. For years 2006 to 2013, the US FDA reported analysis of 32 granulated white sugar samples (US FDA 2017). These samples were analyzed by GFAAS, with a limit of detection of 0.02 ppm. Lead was not detectable in 31 of 32 samples; lead was detected in one sample at just above the detection level (0.022 ppm). For years 1991 to 2005, US FDA reported similar findings for 52 granulated white sugar samples analyzed by GFAAS, with a limit of detection of 0.01 ppm. Lead was not detected in 49 of the 52 samples, with three samples containing lead at the limit of detection (i.e., 0.01 ppm) (US FDA 2007).

Estimation of Naturally Occurring Lead in Sugar

The data available on levels of lead in sugar do not provide the type of information necessary to distinguish between naturally occurring and anthropogenic (i.e., lead introduced in sugar by human activity) sources of lead.

The data provided to OEHHA by four candy manufacturers, a trade association, and a third-party auditor, as well as the data obtained from the US FDA collectively indicate that, though there can be variation across sources, there are sources of sugar with undetectable or low concentrations of lead available. The most recent samples from the US FDA market basket survey were all below the 0.003 ppm detection limit and indicate the availability of low-lead sugar at that level. This is supported by the lower-end lead content, 0.003 ppm, of the data provided by Dulces Vero, the lower-end lead content, < 0.004 ppm, of the data provided by the HACCP Registrar, and the lower-end lead content, ≤ 0.001 ppm, of at least one form of sugar in the data provided by the NCA.

For the purpose of establishing a naturally occurring level for lead and absent any data or study design details supporting an alternate approach to identify a naturally occurring level, the naturally occurring level for lead in sugar is assumed to be 0.003 ppm, the detection limit for lead in sugar from the most recent US FDA analyses of sugar (US FDA 2020).

[20] Data have been collected through the HACCP Registrar certification program surveillance plan, which includes a number of candy manufacturers in compliance with the settlement in *People v. Alpro Alimento Proteinicos, et al.*, Los Angeles County Superior Court case #BC318207 (August 3, 2006).

Contribution of Naturally Occurring Lead by Sugar in Candy Flavored with Chili and/or Tamarind

There is no specific information available regarding the variation in relative amounts of sugar in sugar-based candies. Candy manufacturers have advised OEHHA that a formulation of at least 75% sugar can be used in sugar-based candy (Ahn 2008; Mastrorocco 2008). Assuming that as much as 80% sugar can be used for the recipes in sugar-based candies, the total amount of naturally occurring lead concentration contributed by sugar alone could be 0.0024 ppm (= 0.003 × 80%), as in Table 8 below.

Table 8. Contribution of Naturally Occurring Lead by Sugar in Formulations of Candy Flavored with Chili and/or Tamarind

Naturally Occurring Lead in Sugar (ppm)	Estimated Amount of Sugar in Candy Formulations (%)	Naturally Occurring Lead Contributed by Sugar (ppm)
0.003	0 – 80	0 – 0.0024

5. Food-Grade Silicon Dioxide

Food-grade silicon dioxide (SiO_2), also known as silica, is frequently added to dry chili powder as an anticaking agent. The maximum amount of silicon dioxide used in dry powders allowed by the US FDA is 2% (21 CFR §172.480).

All food-grade silicon dioxide used for anticaking purposes is amorphous (non-crystalline) silicon dioxide and is produced by chemical reactions, rather than derived directly from naturally occurring substances, such as diatomaceous earth. Precipitated silicon dioxide, fumed silicon dioxide, and silica gel are three types of amorphous silicon dioxide in common use as anticaking agents.

Lead has been identified in food-grade silicon dioxide. Lead in food-grade silicon dioxide may originate from raw materials used in production, such as silicon flour, and/or lead residues contributed by the manufacturing process.

Naturally Occurring Lead in Food-Grade Silicon Dioxide: Relevant Data

Data regarding the level of lead in food-grade silicon dioxide are available from multiple sources. Two candy manufacturers (Mars Inc. and Zumbapica) have provided data regarding the level of lead in food-grade silicon dioxide, as has the HACCP Registrar. Data are also available from manufacturers of food-grade silicon dioxide (J.M. Huber Corporation, Degussa, Inc., and Evonik Industries AG).

No studies characterizing the level of lead in food-grade silicon dioxide have been identified in the open scientific literature. Mars Inc. provided information to OEHHA that

1-2 ppm lead had been identified from tests of silicon dioxide[21]. Zumbapica reported a 3.94 ppm average lead content of food-grade silicon dioxide samples between 2015 and 2019, as determined by ICP/MS (Jonguitud, 2019). No individual sampling data were provided. The HACCP Registrar provided a scatterplot representing a range of lead concentrations (approximately 0.4 to 1.9 ppm) measured in silicon dioxide samples between 2010 and 2018 [22]; no further details regarding sample origin or analytical methodology were provided (Pineda, 2019). In 2007 and 2008 OEHHA also obtained information regarding lead levels in food-grade silicon dioxide from manufacturers producing food-grade silicon dioxide, including J.M. Huber Corporation and Degussa, Inc. Since this time, Evonik Industries AG, a large multinational distributor of specialty chemicals including food grade silicon dioxide, acquired Degussa, Inc. and the silica business unit from J.M. Huber Corporation. Evonik Industries AG now manufactures various grades of silicon dioxide, including food-grade Aerosil® 200 and Aerosil®380, in which lead content is reported to be less than 0.05 ppm, with purity "normally measured" by ICP/MS (Evonik Industries AG 2015).

Estimation of Naturally Occurring Lead in Food-Grade Silicon Dioxide

The very limited data available on levels of lead in food-grade silicon dioxide do not provide the type of information necessary to distinguish between naturally occurring and anthropogenic (i.e., lead introduced in food-grade silicon dioxide by human activity) sources of lead.

The Evonik Industries AG technical overview for Aerosil® fumed silica products, including food-grade silicon dioxide, indicates that food-grade silicon dioxide with total lead content at or less than 0.05 ppm is readily available. Based on available information, lead is assumed to occur naturally in the silicon dioxide at levels no greater than 0.05 ppm.

Contribution of Naturally Occurring Lead by Food-Grade Silicon Dioxide in Candy Flavored with Chili and/or Tamarind

As dry chili powder may constitute up to 15% or 30% of sugar- or salt- based candies, respectively, and the US FDA maximum of silicon dioxide in chili powder is 2%, it follows that the maximum amounts of silicon dioxide in sugar-based candies and salt-based candies with this formulation would be less than 0.3% and 0.6%, respectively. Assuming that the naturally occurring lead level in food-grade silicon dioxide is 0.05 ppm in a sugar-based candy made with 15% chili powder, the total naturally occurring lead concentration contributed by this ingredient would be 0.00015 ppm (= 0.05 × 0.3%). Assuming that the naturally occurring lead level in food-grade silicon dioxide is 0.05 ppm in a tamarind-based candy made with 17.5% chili powder, the total naturally

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[21] Data and other information from Tim Ahn, Mars Inc., received by OEHHA on May 1, 2007.
[22] Data have been collected through the HACCP Registrar certification program surveillance plan, which includes a number of candy manufacturers in compliance with the settlement in *People v. Alpro Alimento Proteinicos, et al.*, Los Angeles County Superior Court case #BC318207 (August 3, 2006).

occurring lead concentration contributed by this ingredient would be 0.0002 ppm (= 0.05 × 0.4%). Assuming that the naturally occurring lead level in food-grade silicon dioxide is 0.05 ppm in a salt-based candy made with 30% chili powder, the total naturally occurring lead concentration contributed by this ingredient would be 0.0003 ppm (= 0.05 × 0.6%), as in Table 9 below.

Table 9. Contribution of Naturally Occurring Lead by Food-grade Silicon Dioxide in Formulations of Candy Flavored with Chili and/or Tamarind

Naturally Occurring Lead in SiO_2 (ppm)	Estimated Amount of SiO_2 in Candy Formulations (%)	Naturally Occurring Lead Contributed by SiO_2 (ppm)
0.05	0 – 0.6	0 – 0.0003

6. Food-Grade Titanium Dioxide

Food-grade titanium dioxide (TiO_2) is a synthetically prepared substance commonly used as a color additive in candies at levels up to approximately 0.1%[23]. The maximum amount of titanium dioxide used in dry powders allowed by the US FDA is 1% by weight (21 CFR §73.575). Food-grade titanium dioxide in the US is manufactured by either a sulfate or chloride process (WHO 2004). Color additive regulations in the US for titanium dioxide do not specify a manufacturing process (21 CFR §73.575), and different manufacturing processes might result in product variation.
Lead in food-grade titanium dioxide may originate from raw materials used in production, and/or lead residues contributed by the manufacturing process.

<u>Naturally Occurring Lead in Food-Grade Titanium Dioxide: Relevant Data</u>

Data regarding the level of lead in food-grade titanium dioxide are available from two candy manufacturers – Mars Inc. and Zumbapica – and the HACCP Registrar. Data are also available from two studies in the literature. The US FDA specifies that titanium dioxide for food use must contain no more than 10 ppm lead (21 CFR §73.575).

Mars Inc. conducted testing on food-grade titanium dioxide used in its candy products and reported a range of lead content of less than 1 ppm to 4 ppm[24]. No individual sampling data were provided. Zumbapica reported a 3.94 ppm average lead content of food-grade titanium dioxide samples between 2015 and 2019, as determined by ICP/MS (Jonguitud, 2019). No other study details or individual sampling data were provided. The HACCP Registrar provided a scatterplot of lead concentrations measured in titanium dioxide samples[25] between 2010 and 2018, which were noted as

[23] Data and other information from Tim Ahn, Mars Inc., received by OEHHA on May 1, 2007.
[24] Data and other information from Tim Ahn, Mars Inc., received by OEHHA on May 1, 2007.
[25] Data have been collected through the HACCP Registrar certification program surveillance plan, which includes a number of candy manufacturers in compliance with the settlement in *People v. Alpro Alimento Proteinicos, et al.*, Los Angeles County Superior Court case #BC318207 (August 3, 2006).

"not trying to represent the naturally occurring level" (Pineda, 2019). The lead concentrations of these samples ranged from approximately 1.7 to 10 ppm. No further details regarding sample origin or analytical methodology were provided.

Two studies of impurities in food-grade titanium dioxide were also identified. The more recent study, conducted in the US, reported lead levels between 5 and 11 ppm in five acid-digested food-grade titanium dioxide samples imported to the US (Yang et al. 2014). In the second study, mean lead levels of 4.28 to 5.22 ppm were reported for one food-grade product from the Czech producer Precheza a.s. Přerov, using two different analytical methods ((Dočekal and Vojtková 2006).

Estimation of Naturally Occurring Lead in Food-Grade Titanium Dioxide

The limited data available on levels of lead in food-grade titanium dioxide do not provide the type of information necessary to distinguish between naturally occurring and anthropogenic (i.e., lead introduced in food-grade titanium dioxide by human activity) sources of lead.

The upper end of the range of lead levels reported by Mars Inc. for ingredient-quality titanium dioxide used in their candies, 4 ppm, indicates that the use of food-grade titanium dioxide with lead content of 4 ppm or more could be readily avoided by procurement practices. Further, the low end of the range of lead concentrations from Mars Inc. was less than 1 ppm. Thus, we conclude that levels of lead at the midpoint of this range, 2.5 ppm, and lower, is a reasonable estimation of the naturally occurring level in food-grade titanium dioxide used for candies.

Thus, for the purpose of establishing a naturally occurring level for lead, and absent data or study design details supporting an alternate approach to identify a naturally occurring level, the naturally occurring level for lead in titanium dioxide is assumed to be 2.5 ppm.

Contribution of Naturally Occurring Lead by Food-Grade Titanium Dioxide in Candy Flavored with Chili and/or Tamarind

Assuming that 0.1% titanium dioxide may be present in some types of candy, the total amount of naturally occurring lead concentration contributed from titanium dioxide would be 0.0025 ppm, as in Table 10 below (= 2.5 × 0.1%).

Table 10. Contribution of Naturally Occurring Lead by Food-Grade Titanium Dioxide in Formulations of Candy Flavored with Chili and/or Tamarind

Naturally occurring Lead in TiO_2 (ppm)	Estimated Amount of TiO_2 in Candy Formulations (%)	Naturally Occurring Lead Contributed by TiO_2 (ppm)
2.5	0 – 0.1	0 – 0.0025

ESTIMATION OF NATURALLY OCCURRING LEAD IN CANDIES

According to HSC Section 110552*,* the "naturally occurring level" of lead is defined as that level which is *"*not avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible*".* OEHHA's estimation of naturally occurring lead in candies approximates potential contributions of naturally occurring lead with respect to ingredients that OEHHA has determined may contain naturally occurring lead. For three of these ingredients few, if any, samples from at least one source had detectable levels of lead- chili peppers (and dried chili powder made from fresh chili peppers), sugar, and salt. Thus there is some degree of uncertainty in the estimate given it is not clear how far below the detection level the naturally occurring level may fall. Use of detection limits for lead from analyses of these ingredients may overstate the naturally occurring level.

There are also uncertainties regarding the relative percentages of ingredients in formulations/recipes of candies flavored with natural chili and/or tamarind. Formulations were determined for candies flavored with chili and/or tamarind, with ranges of key ingredients to reflect variation across different types of chili and tamarind candies (e.g., sugar-based, salt-based). A summary of the percentage ranges estimated for the different ingredients is given by candy type in Table 11.

Table 11. Estimated Percentages of Ingredients Which May Contribute Naturally Occurring Lead in Candies, by Type

	Estimated Ingredient Amounts in Candy Formulations (%)					
Type of Candy	**Chili Powder**	**Tamarind**	**Salt**	**Sugar**	**SiO_2**	**TiO_2**
Sugar-based candies flavored with chili and/or tamarind	0 – 15	0 – 5	0 – 10	75 – 80	0 – 0.3	0.1
Tamarind-based candies with/without chili	0 – 17.5	80 – 100	0 – 2	0 – 20	0 – 0.4	0 – 0.1
Salt-based candies flavored with chili	5 – 30	0	50 – 60	0 – 20	0.1 – 0.6	0.1
All candies flavored with chili and/or tamarind	0 – 30	0 – 100	0 – 60	0 – 80	0 – 0.6	0 – 0.1

For each of these ingredients, ranges of naturally occurring lead concentrations contributed by ingredient were calculated from the amount of the ingredient present and the concentration of naturally occurring lead estimated previously. Table 12 contains a summary of the estimated contribution of naturally occurring lead by ingredient.

Table 12. Estimated Contribution of Naturally Occurring Lead by Ingredient in Formulations of Candy Flavored with Chili and/or Tamarind

Ingredient	Naturally occurring Lead in Ingredient (ppm)	Estimated Amount of Ingredient in Candy Formulations (%)	Naturally Occurring Lead Contributed by Ingredient (ppm)
Chili powder	0.01	0 – 30	0 – 0.003
Tamarind	0.02	0 – 100	0 – 0.020
Salt	0.02	0 – 60	0 – 0.012
Sugar	0.003	0 – 80	0 – 0.0024
SiO_2	0.05	0 – 0.6	0 – 0.0003
TiO_2	2.5	0 – 0.1	0 – 0.0025

To estimate naturally occurring lead in candies flavored with chili and/or tamarind, OEHHA calculated the sum of lead concentrations contributed by varying amounts of ingredients that may contain naturally occurring lead across formulations for candy varieties as follows:

- For sugar-based candies flavored with chili and/or tamarind: 0-15% chili powder, 0-5% tamarind, 0-10% salt, 75-80% sugar, 0.1-0.3% silicon dioxide, and 0.1% titanium dioxide
- For tamarind-based candies with/without chili: 0-17.5% chili powder, 80-100% tamarind, 0-2% salt, 0-20% sugar, 0-0.4% silicon dioxide, and 0-0.1% titanium dioxide
- For salt-based candies flavored with chili: 5-30% chili powder, 50-60% salt, 0-20% sugar, 0.1-0.6% silicon dioxide and 0.1% titanium dioxide

OEHHA based its estimate of naturally occurring lead concentrations on the six ingredients discussed above. Table 13 presents examples of typical formulations for each candy type, showing the percentage of each ingredient in the selected formulations and, in the last column, the total concentration of naturally occurring lead in these candies. Also shown in the table in parentheses is the concentration of naturally occurring lead contributed by each ingredient in the selective formulations. For each candy type, the total concentration is calculated as the sum of each ingredient's contribution. The maximum concentration of naturally occurring lead in candies flavored with chili and/or tamarind is estimated to be 0.02 ppm (rounded to one significant figure) (Table 13). This value for the level of naturally occurring lead, 0.02 ppm, applies to all candies flavored with chili and/or tamarind, except chocolate candies which are outside the scope of the proposed regulation and this supporting analysis.

Table 13. Naturally Occurring Lead in Candy Flavored with Chili and/or Tamarind

	% Ingredient in Selected Candy Formulations (Naturally Occurring Lead Contributed by Ingredient (in ppm))						
Type of Candy	**Chili Powder**	**Tamarind**	**Salt**	**Sugar**	**SiO_2**	**TiO_2**	**Estimated Naturally Occurring Lead in the Candy (ppm)**
Sugar-based candies flavored with chili and/or tamarind	9.7% (0.00097)	5% (0.001)	5% (0.001)	80% (0.0024)	0.2% (0.0001)	0.1% (0.0025)	0.008
	14.6% (0.00146)	0% (0)	10% (0.002)	75% (0.00225)	0.3% (0.00015)	0.1% (0.0025)	0.008
Tamarind-based candies with/without chili	17.5% (0.00175)	80% (0.016)	2% (0.0004)	0% (0)	0.4% (0.0002)	0.1% (0.0025)	0.02
	0% (0)	100% (0.02)	0% (0)	0% (0)	0% (0)	0% (0)	0.02
Salt-based candies flavored with chili	20% (0.002)	0% (0)	60% (0.012)	19.5% (0.000585)	0.4% (0.0002)	0.1% (0.0025)	0.02
	30% (0.003)	0% (0)	60% (0.012)	9.3% (0.000279)	0.6% (0.0003)	0.1% (0.0025)	0.02

Comparison of Naturally Occurring Level to Recent Analyses of Lead Content in Candies Flavored with Chili and/or Tamarind

Results of recent lead analyses of candies flavored with chili and/or tamarind are available to OEHHA from an industry trade organization, the NCA, as well as a third-party auditor, the HACCP Registrar. The candies for which data on levels of lead are available include candies reflecting the three types of formulations shown in Table 13.

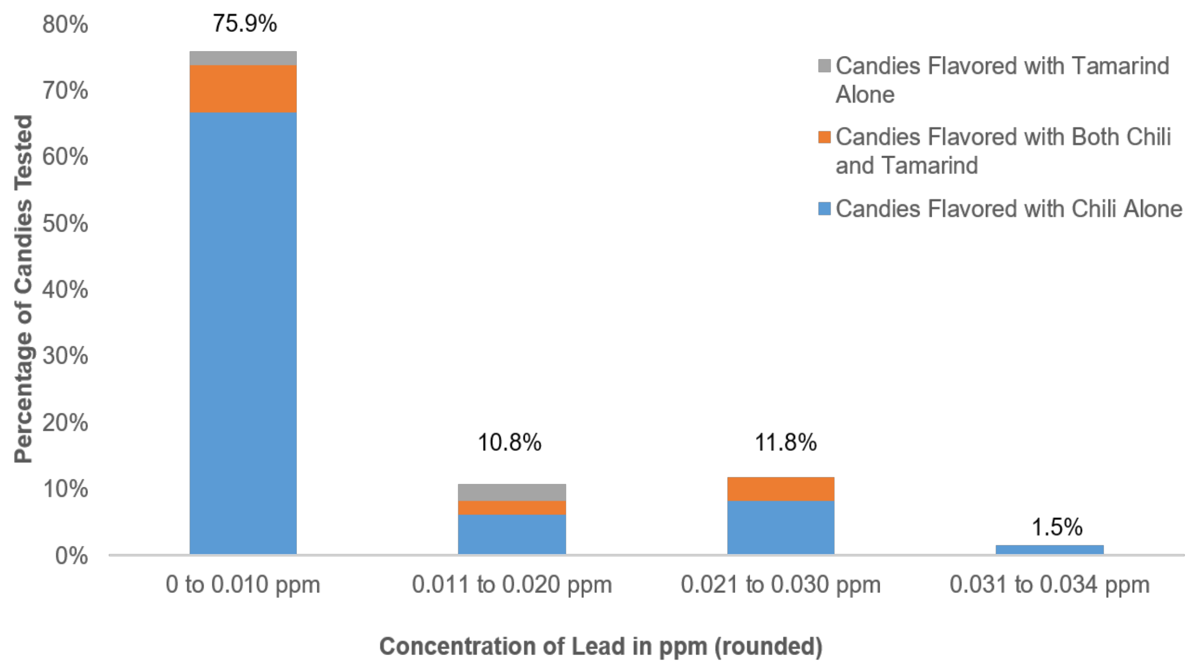
The NCA reported results of lead testing data for candy products from one anonymous manufacturer, “Company X”, described as one of the largest candy manufacturers in Mexico that has continually complied with the requirements of the *Alpro Alimento* consent judgement (Miller, 2019). The summary testing information provided by NCA indicates that approximately 90% of candy produced by “Company X” in 2017 and 2018 would be found to contain lead at levels below 0.02 ppm (Miller, 2019). NCA also provided individual data for the "approximately 10% of products" with lead levels ranging from 0.02 to 0.06 ppm (average 0.031 ppm; n = 59) (Miller, 2019). Almost half of these 59 samples (n = 26) contained 0.02 ppm lead. Thus, 94% of the approximately 590 samples in this dataset contained lead at or below 0.02 ppm.

The HACCP Registrar provided a scatterplot representing levels of lead[26] measured in 195 samples of candies flavored with natural chili and/or tamarind that were produced by nine manufacturers in Mexico between 2012 and 2017, similar to scatterplots provided by the HACCP Registrar for individual candy ingredients. The HACCP Registrar also provided scatterplots representing ranges of lead measured in other types of candies with formulations not anticipated to contribute naturally occurring lead (i.e., sugar candies without chili or tamarind, candies flavored with unspecified fruit, candies flavored with chili and unspecified fruit)[27]. OEHHA considered the scatterplot representing lead for the 195 relevant candy samples (i.e., candies flavored with chili, tamarind, and both chili and tamarind), and converted these data points to values using the GetData Graph Digitizer program.

In Figure 3 below, OEHHA illustrates the distribution of lead concentrations for these candies, in which the level of lead is rounded to two significant figures (e.g., 0.019 ppm). The concentration of lead measured in most of these samples (86%) was lower than 0.020 ppm; 87% of the candies tested contained lead content at or below 0.020 ppm. These candies with lead content at or below 0.020 ppm include all samples flavored with tamarind alone, 89% of samples flavored with chili alone, and 72% of samples flavored with both tamarind and chili. Of the 13% of tested candies containing lead content above 0.020 ppm, most contained less than 0.030 ppm lead, with only three samples (1.5% of all candies tested) found to contain lead between 0.030 and 0.034 ppm. Seven samples of candy flavored with both chili and tamarind exceeded 0.020 ppm lead content (none contained more than 0.022 ppm lead). 19 samples of candy flavored with chili alone exceeded 0.020 ppm lead content (none contained more than 0.034 ppm lead). No samples of candy flavored with tamarind alone contained more than 0.020 ppm lead.

[26] Data and other information from Mario Pineda, HACCP Registrar, first provided to OEHHA through the Office of the Attorney General on March 5, 2018.
[27] Data and other information from Mario Pineda, HACCP Registrar, first provided to OEHHA through the Office of the Attorney General on March 5, 2018.

Figure 3. Distribution of Lead Concentrations in Candies Tested 2012-2017[28]



In summary, for most of the candies tested, concentrations of lead are lower than 0.020 ppm, while historically levels have measured much higher. This further supports the proposed naturally occurring level of 0.02 ppm for naturally occurring lead in candies flavored with chili and/or tamarind.

[28] Data and other information from Mario Pineda, HACCP Registrar, first provided to OEHHA through the Office of the Attorney General on March 5, 2018.

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