

**Final Statement of Reasons
Title 27, California Code of Regulations**

**Proposed Adoption of New Chapter and Section
Chapter 3: Naturally Occurring Lead in Candy
Section 28500: Naturally Occurring Levels of Lead in Candy**

August 2021



**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

Table of Contents

General Information 3

 Summary 3

 Process and Timeline 3

 OEHHA's Conclusions 5

Update of Initial Statement of Reasons 5

Modification of Text of Proposed Regulation 15-day Comment Period 5

Peer Review 5

Summary and Response to Peer Review Comments 6

Public Comments Received During the Initial Public Comment Period 11

Summary and Response to Public Comments Received During the Initial Public Comment Period 12

 Section I. Scope of Regulation and Legal Issues 12

 Section II. Scientific Issues with the Basis for the Proposed Naturally Occurring Level of Lead in Candy Flavored with Chili and/or Tamarind 14

General Issues 14

Ingredient-Specific Issues 21

Finished Product Issues 27

 Section III. Proposed Naturally Occurring Level of Lead in Candy Flavored with Chili and/or Tamarind 28

Proposed Level Too High 28

Proposed Level Too Low 29

Proposed Level Supported 32

 Section IV. Implementation of Regulation 32

 Section V. Other Issues 34

Summary and Response to Comments Received During the Proposed Modification of Regulation Text 15-day Comment Period 34

Alternatives Determination 36

Local Mandate Determination 36

General Information

Summary

This is the Final Statement of Reasons (FSOR) for the adoption of 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 regulation establishes a “naturally occurring level” of lead in candies flavored with chili and/or tamarind, as required by Health and Safety Code section 110552¹. This naturally occurring level of lead in candies flavored with chili and/or tamarind was determined by 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 (OAG). The level is based on a scientific analysis described in the OEHHA document *Naturally Occurring Lead in Certain Candies. Candies Flavored with Chili and/or Tamarind* (OEHHA 2020)².

Briefly, in determining the naturally occurring level for lead in candies flavored with chili and/or tamarind, OEHHA developed an ingredient-based approach to estimate the sum of naturally occurring lead in candy containing chili and tamarind. This approach was based on an evaluation of the level of naturally occurring lead plausibly contributed by a given ingredient, consistent with Section 110552, and the amounts of each such ingredient typically present in these candies. The ingredients identified as potential contributors to naturally occurring lead in candies flavored with chili and/or tamarind were as follows: chili peppers and chili powder³, tamarind, food-grade salt, food-grade sugar, food-grade silicon dioxide, and food-grade titanium dioxide. Note that chocolate candies are not within the scope of the regulation.

This document lays out the process and timeline followed in the development of this regulation and summarizes and responds to scientific peer review and public comments received.

Process and Timeline

OEHHA initially proposed a naturally occurring level of lead in these candies on March 15, 2019 but was unable to complete the proposed rulemaking within the one-year statutory timeframe. While the proposed level has not changed, OEHHA incorporated

¹ Hereafter referred to as “Section 110552” or “the Statute”.

² Hereafter referred to as “Technical Support Document” or “TSD”.

³ “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.

additional information received during the comment period for the 2019 proposed rulemaking into the 2020 version of the proposed rulemaking.

This review is reflected in the Technical Support Document and the Initial Statement of Reasons (ISOR) for the current rulemaking. For example, the 2020 ISOR states:

"The purpose of this regulation is to establish a naturally occurring level of lead in candies containing chili and tamarind, as required by section 110552(c)(3). OEHHA initially proposed a naturally occurring level of lead in these candies on March 15, 2019 (hereafter, "the 2019 proposed rulemaking"), but was unable to complete the proposed rulemaking within the one-year statutory timeframe. While the proposed level has not changed, OEHHA has incorporated additional information received during the comment period for the 2019 proposed rulemaking into this Initial Statement of Reasons and the attached technical support document. " [ISOR, pages 1-2]

The ISOR further states under reasonable alternatives:

"Multiple commenters on the 2019 proposed rulemaking stated that the proposed naturally occurring level is too low. In some cases, these commenters submitted data that they believe supports adopting a higher naturally occurring level. To the extent this data is relevant to this proposed rulemaking, it is addressed in the updated Technical Support Document. One commenter, NCA, stated that OEHHA's approach does not sufficiently account for inherent variability and recommended that OEHHA set the naturally occurring regulatory level based on an average subject to an outlier limitation, such as the allowance of single sample maximums at 150% of the compliance level in the 2006 Alpro Alimento consent judgment. After reviewing the relevant comments and data received on the 2019 rulemaking proposal, OEHHA has determined that the submitted information and data do not support changing the previously proposed naturally occurring level of 0.02 ppm." [ISOR, page 8]

"Commenters on the 2019 proposed rulemaking also made recommendations on how the regulatory level should be implemented and enforced. For example, NCA suggested a phased-in approach through a series of step-down levels over a period of several years and that compliance should be based on the average of multiple candy samples. NCA's suggested approach of setting the "naturally occurring" regulatory level based on an average subject to an outlier limitation is also more appropriately viewed as a recommendation on compliance approaches. To the extent these recommendations address enforcement of the regulatory level, they are outside the scope of this rulemaking and OEHHA's authority under the Statute. Under Section 110552, subsection (e), CDPH is

responsible for ensuring that candy is not adulterated, including implementation and enforcement activities related to lead in candy. This includes establishing sampling and testing procedures in consultation with the Office of the Attorney General, testing samples of candy, adopting regulations necessary for enforcement, and evaluating the regulatory process.” [ISOR, page 9]

OEHHA published the most recent Notice of Proposed Rulemaking and ISOR for this action on June 19, 2020. Four written comments were received during the 60-day public comment period, which closed on August 18, 2020. OEHHA also received written comments from three peer reviewers.

OEHHA’s Conclusions

OEHHA has carefully read and considered the peer reviewers’ comments and the public comments received on this proposed rulemaking and the prior rulemaking. Taking into account all the relevant comments, OEHHA’s conclusion regarding the naturally occurring level of lead in candies flavored with chili and/or tamarind has not changed: The naturally occurring level of lead in candies flavored with chili and/or tamarind is 0.02 parts per million. However, OEHHA agrees that a delayed effective date would allow CDPH and the Attorney General’s Office time to address any testing, regulatory or enforcement issues. Therefore, OEHHA has requested that the Office of Administrative Law delay the effective date of the regulation for one year from the date of adoption of the regulation.

Update of Initial Statement of Reasons

There are no updates to the information contained in the Initial Statement of Reasons, and no new documents were relied upon or added to the rulemaking file.

Modification of Text of Proposed Regulation 15-day Comment Period

In the Notice of Modification of Text published on July 23, 2021, OEHHA proposed an amendment to the proposed regulation for lead in candy. OEHHA modified the proposed language in the table to add “(excluding chocolates)” after the phrase “Candies flavored with chili and/or tamarind”, to provide clarity that this regulation applies to all candies flavored with chili and/or tamarind, but not to chocolate candies.

Peer Review

To comply with Health and Safety Code section 57004, OEHHA in August 2020 provided the technical support document (TSD) for this regulation and the ISOR to three

subject-matter experts for peer review. The peer reviewers, who each submitted comments, were:

- Bruce Fowler, Ph.D., Rollins School of Public Health, Emory University
- Pertti J. Hakkinen, Ph.D., F-SRA, National Center for Biotechnology Information, National Institutes of Health
- Jerome Nriagu, Ph.D., D.Sc., Environmental Health Sciences, School of Public Health, University of Michigan

Summary and Response to Peer Review Comments

Comment 1 (Drs. Fowler, Hakkinen, and Nriagu): Peer reviewers state support for the proposed regulatory level and the approach to determining naturally-occurring lead in candies flavored with chili and/or tamarind.

Dr. Fowler supports the selected value for lead in candies flavored with chili and/or tamarind of 0.02 ppm “based upon the best currently available sound science”, describing the proposed regulation as an “important public health effort”. Dr. Fowler stated that his overall opinion is that OEHHA’s conclusions “represent reasonable and sound approaches to providing solid public health guidance on lead in candies based on the best available science”. He indicated that his opinion was based “in part on NAS/NRC vetted information regarding lead toxicity risks for sensitive populations”, but that this information “coupled with application of modern analytical methods which incorporate the best available technologies and practices should provide a sound scientific basis for regulatory decision making”.

Dr. Hakkinen stated that, after reviewing the information provided, “OEHHA developed a well thought-out ingredient-based approach to estimate the level of naturally occurring lead in candies flavored with chili and/or tamarind.” Further, he stated that “OEHHA’s approach to estimate the level of naturally occurring lead in candies flavored with chili and/or tamarind (as presented on pages 1 to 2 of the Naturally Occurring Lead in Certain Candies: Candies Flavored with Chili and/or Tamarind technical support document) is based upon sound scientific knowledge, methods, and practices”. Dr. Hakkinen noted that OEHHA also “did more than an adequate job of describing how policy reasons led to a selection of a single value for the naturally occurring concentration of lead in all sugar-based, salt-based, and tamarind-based candies flavored with chili and/or tamarind”, further stating that the TSD “very well” explained “why OEHHA selected a single value, rather than a range, to facilitate straightforward decisions about compliance as well as enforcement actions on the part of the lead agency (CDPH)”. Dr. Hakkinen concluded that “OEHHA selected a single value for lead

in candies flavored with chili and/or tamarind that is based upon sound scientific knowledge, methods, and practices”.

Dr. Nriagu stated that the naturally occurring lead levels presented in the TSD to derive a value for naturally occurring lead in candies flavored with chili and/or tamarind are “practical values based on the professional opinion of leading experts in the field. The numbers represent a balancing of current scientific knowledge, the available data, relevancy to the candy manufacturers, and the need to protect public health (which is not specifically addressed in the report)”. He further noted that OEHHA “should be applauded for the commonsense approach that has been used in deriving the values for naturally occurring lead in candy ingredients”.

Response: OEHHA acknowledges these comments.

Comment 2 (Drs. Fowler, Hakkinen, and Nriagu): The peer reviewers agree with OEHHA’s use of a limit of detection for estimation of values for naturally-occurring lead in specified ingredients (chili peppers and chili powder, salt, and sugar).

Dr. Fowler stated that it was his opinion that

“OEHHA accurately selected values for naturally occurring lead in chili peppers and chili powder, salt and sugar that were based on current limits of detection from analyses of these ingredients. The limits of detection approach is appropriate, in my opinion, since children are a major population at risk for low-level lead toxicity as documented in the NAS/NRC report noted above. The overall public health goal for CDC lead is to reduce lead exposures as much as possible. Clearly using the limit of detection approach for candies flavored with chili and tamarind is consistent with this goal.”

Dr. Hakkinen stated his agreement

“with OEHHA’s approach of establishing a naturally occurring level for lead. That is, absent any data or study design details supporting an alternate approach to identify a naturally occurring level, OEHHA assumed that the detection limits for lead in these ingredients represent the naturally occurring levels for these ingredients.”

Dr. Hakkinen also stated that, after reviewing the information provided, he agreed that “OEHHA accurately selected values for naturally occurring lead in chili peppers and chili powder, salt, and sugar that were based on limits of detection from analyses of these ingredients”. Dr. Hakkinen further agreed with OEHHA that “even though there was some noteworthy variation in lead concentrations in these ingredients across sources and types, there are available sources of each ingredient with undetectable

concentrations of lead.” Finally, Dr. Hakkinen concurred that there is “some uncertainty in such estimates since it is not clear how far below the limit of detection the naturally occurring levels may be,” and stated his agreement with “OEHHA’s conclusion (as was discussed in the respective analyses) that the use of detection limits for lead from the analyses of these ingredients is reasonable and is supported by the data available for each ingredient”.

In considering the use of a limit of detection approach for estimating the naturally occurring level of lead in chili pepper / chili powder, Dr. Nriagu noted that, though the proposed naturally occurring level is based on a detection limit of 0.01 ppm, the detection limit for high resolution ICP-MS “has been lowered to <0.2 parts per billion (ppb)”. This raise the question for the reviewer as to what is the “lowest level currently feasible” for lead in chili peppers and chili powder. Dr. Nriagu also acknowledged that the ability to detect lead in plant material is dependent on sample digestion volume and the instrumentation used and suggested that it “would be a good idea to include the specific analytical procedure and the instrumental model on which the detection limit of 0.01 ppm is based”. Dr. Nriagu described the proposed level of 0.01 ppm as “more of a practical value than a true threshold of naturally occurring lead level”. Dr. Nriagu noted that “recent data from growing a plant (dandelion) in a lead-free laboratory (Odigie et al., 2019) and the natural depuration mechanisms point to the fact that the level of naturally occurring lead in chili pepper fruits and seeds should be well below this value”. In considering the use of a limit of detection approach for estimating the naturally occurring level of lead in salt, Dr. Nriagu stated that “the lowest concentration detectable (0.02 ppm) in salt samples from a candy manufacturer was selected even though lower concentrations were reported by the US FDA” (US Food and Drug Administration), a selection that was “driven more by practical considerations and professional judgement”. In considering the use of a limit of detection approach for estimating the naturally occurring level of lead in sugar, Dr. Nriagu observed that, “as in other instances, none of the available data provide the type of information needed to distinguish between naturally occurring and anthropogenic lead in the sugar samples”. Dr. Nriagu stated that the lowest levels of lead from samples from the US FDA market basket surveys were “considered to be reflective of the naturally occurring value” and the detection limit for these samples “was assumed to be naturally occurring level for lead in sugar and was justified by the fact that the data provided by the candy manufacturers also contained many values that were less tha[n] the 0.003 p[p]m”.

Response: OEHHA acknowledges these comments. OEHHA notes that the TSD describes in some detail the methods used in its study of lead in chili peppers, describing the study design, sampling strategy, sample preparation, and the analytical laboratory methods and instrumentation used (i.e., inductively-coupled plasma mass spectrometry, or ICP-MS) (see pages 4 – 10 of the TSD).

Comment 3 (Drs. Fowler, Hakkinen, and Nriagu): Peer reviewers agree with the use of a value one standard deviation above the mean for estimation of the naturally occurring level of lead in tamarind.

Dr. Fowler stated that, in his opinion, the “value of one standard deviation above the mean is a reasonable and scientifically sound approach”.

Dr. Hakkinen noted that the information presented in the TSD indicated that tamarind with lead concentration below the value selected (0.02 ppm, one standard deviation above the sample mean) “appear to be readily available”. Dr Hakkinen stated that he thought “quite a bit about how OEHHA determined that adding one standard deviation to the mean lead level observed in the data provided would be appropriate to accommodate natural variation in lead levels given the limitations in the sample set”, noting that one standard deviation would only account for about 68% of the values if this was an approximately normal data set, before agreeing that it is “reasonable” that the value of 0.02 ppm (one standard deviation above the sample mean) “can be used to represent naturally occurring lead in tamarind, especially since the information presented indicates that tamarind with lead concentrations below 0.02 ppm appear to be readily available”. Dr. Hakkinen further commented that, as noted in the TSD, “while there can be some degree of variation in levels of lead in tamarind pulp, over one quarter of the samples contained less than 0.01 ppm lead”. Dr. Hakkinen concluded that, thus, “tamarind pulp with low concentrations of lead is available for use in candy”.

Dr. Nriagu noted that the value of 0.02 ppm was selected based on “just 22 samples of tamarind pulp obtained from local suppliers in Mexico”; he observed that in order to make the pulp, the tamarind had to “be removed from the shell, then heated, preservatives added and the mixture ground – the grinding and preservatives entail some risks of lead contamination.” As such, Dr. Nriagu noted “there is no data for ascertaining the naturally occurring lead in tamarind” and stated that the “selection criteria in this case seems to be based on professional judgement rather than on the ‘lowest level currently feasible’.”

Response: OEHHA acknowledges these comments.

Comment 4 (Drs. Fowler, Hakkinen, Nriagu): Two peer reviewers agree with the use of a maximum allowable level specified by a manufacturer for estimation of the naturally occurring level of lead in food-grade silicon dioxide, and one does not.

Dr. Fowler stated his opinion that OEHHA “accurately used a sound basis” for selecting the value for naturally-occurring lead in food-grade silicon dioxide as specified by the authors.

Dr. Hakkinen noted that OEHHA's analysis (presented on pages 24 to 25 of the TSD) "supported use of a major manufacturer's standard for purity with respect to levels of lead in its food-grade silicon dioxide products as the value for naturally occurring lead" and that lead content in these food-grade silicon dioxide products reported to be less than 0.05 ppm indicates "food-grade silicon dioxide with total lead content at or less than 0.05 ppm is readily available". Dr. Hakkinen then stated his agreement with OEHHA's conclusion that "it is reasonable to assume that lead occurs naturally in food-grade silicon dioxide at levels no greater than 0.05 ppm".

Dr. Nriagu disagreed with the use of the maximum allowable level specified by a manufacturer for selection of a value for naturally-occurring lead in food-grade silicon dioxide and indicated that there is no evidence for naturally-occurring lead in food-grade silicon dioxide. Dr. Nriagu observed that all food-grade silicon dioxide used in candies is "produced by chemical reactions, rather than derived directly from naturally occurring substances, such as diatomaceous earth", and stated that "such synthetic material should contain no naturally occurring lead". Dr. Nriagu asserted that any lead "introduced into such product from raw materials used in its production is more of a "human-introduced" contaminant or an impurity," and stated that OEHHA's "claim that "Based on available information, lead is assumed to occur naturally in the silicon dioxide at levels no greater than 0.05 ppm" seems to be misleading".

Response: OEHHA acknowledges that two of three expert reviewers agreed with the approach utilized by OEHHA for estimation of the naturally occurring level of lead in food-grade silicon dioxide, while the third contends that no lead present may be considered naturally-occurring given that silicon dioxide is a synthetic substance. Considering these comments as a whole, along with the very limited data available on levels of lead in food-grade silicon dioxide, OEHHA concludes that naturally occurring lead should not be present in food-grade silicon dioxide at levels greater than 0.05 ppm. No changes to the proposed regulation were made based on these comments.

Comment 5 (Drs. Fowler, Hakkinen, Nriagu): Two peer reviewers agree with the use of the midpoint of a range of values provided by a candy manufacturer for estimation of the naturally occurring level of lead in food-grade titanium dioxide, and one does not.

Dr. Fowler stated his belief that OEHHA's selection of a value that is the midpoint of a range of values provided by a major candy "is a reasonable and scientifically sound approach".

Dr. Hakkinen noted that OEHHA's analysis (presented on pages 26 to 27 of the TSD) "supported use of the range of lead (<1 to 4 ppm) reported by a major candy manufacturer in ingredient-quality titanium dioxide used in their candies as a basis for selecting a value for naturally occurring lead" and stated his agreement with OEHHA's

conclusion 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”.

Dr. Nriagu disagreed with the use of the midpoint of a range of values provided by a candy manufacturer for selection of a value for naturally-occurring lead in food-grade titanium dioxide. Dr. Nriagu noted that food-grade titanium dioxide used in candies is “also synthetically prepared” and stated that his comments on silicon dioxide, summarized in Comment 4 above, “equally apply to titanium dioxide”.

Response: OEHHA acknowledges that two of three expert peer reviewers agreed with the approach utilized by OEHHA for estimation of the naturally occurring level of lead in food-grade titanium dioxide, while the third contends that no lead present may be considered naturally-occurring given that titanium dioxide is a synthetic substance. Considering these comments as a whole, along with the limited data available on levels of lead in food-grade titanium dioxide, OEHHA concludes that levels of lead at the midpoint of a range of values provided by a candy manufacturer, 2.5 ppm and lower, is a reasonable estimation of the naturally-occurring level in food-grade titanium dioxide used for candies. No changes to the proposed regulation were made based on these comments.

Comment 6 (Dr. Fowler): Dr. Fowler offered additional comments “which are outside the peer-reviewer’s charge but may be of value in refining an overall public health risk assessment of this problem area even if pursued in the future”. Specifically, Dr. Fowler noted that excipients and coloring agents may also contribute to the final lead content of candies, stating that “it is important to have this information for assessing the overall lead risk of the final candy product”.

Response: OEHHA acknowledges this comment. OEHHA also notes that to date, such excipients and coloring agents have not been identified as contributors of *naturally occurring* lead to candy.

Public Comments Received During the Initial Public Comment Period

Four written public comments were received during the comment period ending on August 18, 2020. Individuals submitting comments along with their affiliations are shown in Table 1. Also shown in Table 1 are the designations by which the submission will be referenced in the summary of and responses to comments.

Some written comments submitted during the regulatory process included observations that do not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. In addition, some commenters

offered their interpretation of the proposed action, which does not constitute an objection or recommendation directed at changing the proposed action or the procedures followed in this rulemaking process. OEHHA is not required under the Administrative Procedure Act (APA) to respond to such remarks in the rulemaking and therefore is not providing responses to all of these comments in this FSOR. However, the absence of responses to such comments should not be construed to mean that OEHHA in any way agrees with them.

Table 1. Written public comments received during the comment period

Designation	Organization Commenters
CEH	Center for Environmental Health (CEH), submitted by Caroline Cox
DDLRL	Dulces De La Rosa (DDLRL) member companies ¹ submitted by Victor Zavala
EHC	Environmental Health Coalition (EHC), submitted by Leticia Ayala
NCA	The National Confectioners Association (NCA), submitted by Debra Miller

¹ Member companies are noted in the signature block as: Distribuidora de la Rosa S.A. de C.V. / Chupaletas S.A. de C.V. / Caramelos de la Rosa S.A. de C.V. Mazapan de la Ros S.A. de C.V.

Summary and Response to Public Comments Received During the Initial Public Comment Period

A summary of the comments received during the public comment period that are relevant to this rulemaking is provided below, along with OEHHA's responses to those comments. Some commenters made the same or similar comments.

One commenter, NCA, included in its 2020 submission comments previously provided to OEHHA during the 2019 proposed rulemaking. As discussed at some length above under General Information and the subheading "Process and Timeline", OEHHA incorporated the information received during the comment period for the 2019 proposed rulemaking into the current rulemaking's Initial Statement of Reasons and TSD.

Section I. Scope of Regulation and Legal Issues

Comment 7 (DDLRL): This commenter perceived bias in the scope of the proposed regulation, claiming that that it targets certain candy manufacturers and candy products (candies containing chili and tamarind) that are usually found in Mexican traditional candies and confections, and therefore demonstrates "discrimination and/or ethnic bias against some manufacturers and /or California consumers". [Dulces De La Rosa, page 2]

Response: Section 110552 requires OEHHA to establish naturally occurring levels of lead only in certain types of candy, not in other foods, and subsection (c)(2) of the Statute defines the types of candy covered by the Statute as “any confectionary intended for individual consumption that contains chili, tamarind, or any other ingredient identified as posing a health risk in regulations adopted by the office or department”.

Further, subsection (c)(3) requires OEHHA to first determine naturally occurring levels of lead in candy containing chili and tamarind, with additional direction that OEHHA determine naturally occurring levels of lead in candy containing other ingredients upon request by CDPH or the OAG, or, in the absence of such a request, when OEHHA determines that the presence of lead in candy containing other ingredients may pose a health risk.

This regulation establishes a naturally occurring level of lead for candy flavored with chili and/or tamarind, in keeping with Section 110552(c)(3). OEHHA does not restrict applicability of this regulation to candies produced by Mexican manufacturers or to ‘Mexican-style’ candies. Chili and tamarind ingredients are both found in a variety of candies, and this is recognized by OEHHA. See, for example, the discussion on page 16 of the TSD, which indicates that tamarind pulp and paste “are popular ingredients in many candies, including a variety of Mexican-style and Asian-style candies.”

No changes to the proposed regulation were made based on this comment.

Comment 8 (DDLRL): This commenter questioned why the proposed regulation is focused on candy flavored with chili and/or tamarind given that other agricultural commodities contain lead, and that other foods contain chili and/or tamarind and can contribute to intake of lead.

- “**Other agricultural food products**, with larger daily consumption are not considered (like figs, strawberries, almonds, cocoa, nuts, juices, etc.) If the reason for the proposed limit is to protect California residents, other foods that are consumed more frequently and in larger amounts should be considered as higher risk than candies.” (emphasis in original) [Dulces De La Rosa, page 2]
- “**Other food products that contain tamarind and/or chili** and sold in the US marketplace including but not limited to California are not included in the scope of this proposal (i.e., Thai, Chinese, Hindi foods, etc.)” (emphasis in original) [Dulces De La Rosa, page 2]

Response: As discussed in some detail in the response to Comment 7 above, Section 110552 only applies to naturally occurring levels of lead in candy only, and not other foods or agricultural products. The lead content of other foods is regulated under

different laws. Thus, consideration of the levels of lead, including naturally occurring lead, in foodstuff other than candy is outside the scope of this rulemaking.

No changes to the proposed regulation were made based on this comment.

Comment 9 (DDLRL): This commenter asserted that OEHHA must consider the economic impact of the proposed regulation and that OEHHA's regulation should address economic considerations for out-of-state manufacturers. DDLRL supports its contention of alleged differential treatment by stating that most of the candies flavored with chili and tamarind are manufactured in Mexico and imported to California, and that the TSD itself mentions "Most manufacturers of candies containing chili and/or tamarind are located outside of California, with many located in Mexico."

- "It provides a "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter. The discrimination may be explicit on the face of the law or contained within the law's effect or purpose." [Zenith/Kremer Waste Sys. v. Western Lake Superior Sanitary Dist., 572 N.W.2d 300 (Minn. 1997)]. [Dulces De La Rosa, page 2]

Response: OEHHA does not agree that there is a differential effect on businesses who manufacture candies containing chili and tamarind and sell them in California. The level of lead established in the regulation applies equally to any candies in this category. In adopting this level, OEHHA is complying with the Statute.

Section II. Scientific Issues with the Basis for the Proposed Naturally Occurring Level of Lead in Candy Flavored with Chili and/or Tamarind

General Issues

Comment 10 (NCA): This commenter disagrees with the approach utilized by OEHHA, which identified a single value for a maximum concentration of naturally occurring lead in candies flavored with chili and/or tamarind, rather than an average value or values.

- "...OEHHA rejects the industry's suggestion that it establish the Section 25800 level as an average given that there is inherent variability in the lead content of both finished products and their key ingredients, as demonstrated by the data in the record. The updated ISOR summarily dismisses such an approach as "a recommendation on compliance" and then seeks to shift responsibility to CDPH and the Attorney General to address it in the context of their enforcement policies and procedures. But defining what compliance is and how it should be measured is precisely the task the Legislature assigned to OEHHA in the first instance by directing it to set the Section 25800 level as a replacement for the interim level

established by the Attorney General. Where underlying conditions are subject to anticipated inherent variation and the primary risk to be managed is associated with chronic exposure scenarios, regulatory agencies commonly define compliance levels by use of an average. For example, air quality standards for lead are set on the basis of 30-day or 3-month average levels. <https://ww2.arb.ca.gov/resources/lead-and-health>. Occupational protection are also defined by their implementing agencies based on a time weighted average.

<https://www.cdc.gov/niosh/topics/lead/limits.html#:~:text=The%20NIOSH%20Recommended%20Exposure%20Limit,over%20an%208%2Dhour%20period>. And in the context of food regulation for contaminants, FDA commonly also uses averages to set defect action levels. <https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook>.” (emphasis in original) [NCA, pages 4 - 5]

- “We note that OEHHA itself has recently proposed regulatory safe harbor levels for acrylamide in certain foods on the basis of its assessment of the lowest level currently feasible which are expressed as averages. <https://oehha.ca.gov/proposition-65/crn/notice-proposed-rulemaking-adoption-section-25505-exposures-listed-chemicals>.” [NCA, page 5]
- “...given precedents by a variety of other regulators and the role it was specifically assigned by the Legislature, OEHHA should not pass on to potential enforcers or courts the job of setting a standard that acknowledges and accommodates natural variation in key ingredients and resulting products and which provides a reasonable amount of time for manufacturers to be held accountable to a standard which represents a substantial reduction from that on which their quality control programs have been based for more than a decade.” [NCA, page 6]

Response: The Statute directs OEHHA to set a *naturally occurring* level for lead in candy flavored with chili and/or tamarind. Moreover, Section 110552, 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.”

Thus, the Statute explicitly excludes from the definition of “naturally occurring” a number of possible sources of lead which can contribute to variability in the lead content of finished candy products. The Statute further requires that natural chemical contaminants in candy be reduced to the “lowest level currently feasible.” Relying on the definition in the Statute, OEHHA has set a maximum level of *naturally occurring* lead in candy containing chili and tamarind, rather than a level to be applied as an average value to candies tested over some specified period of time. While the commenter argues that the level of naturally occurring lead in candy should be based on averages (e.g., across time), citing examples of other regulatory levels for contaminants in either air and food set on the basis of averages, OEHHA disagrees, and notes that none of the cited examples establish “naturally occurring” levels of contaminants in air or food. Furthermore, the controlling language in the statutes under which the cited example regulatory levels were proposed or promulgated are each unique, and differ significantly from that of Section 110552 as they address entirely different scenarios.

As explained in the TSD, OEHHA used an ingredient-based approach to set the maximum level of naturally occurring lead in candy containing chili and tamarind, based on estimates of the levels of naturally occurring lead plausibly contributed by each of those ingredients (i.e., chili peppers and chili powder, tamarind, food-grade salt, sugar, food-grade silicon dioxide, and food-grade titanium dioxide). One peer reviewer, Dr. Hakkinen, specifically commented that the TSD “very well” explained why OEHHA “selected a single value, rather than a range, to facilitate straightforward decisions about compliance as well as enforcement actions on the part of the lead agency (CDPH)”. Dr. Hakkinen further concluded that “OEHHA selected a single value for lead in candies flavored with chili and/or tamarind that is based upon sound scientific knowledge, methods, and practices”.

Under subsection (e) of the Statute, CDPH is responsible for ensuring that candy is not adulterated, including implementation and enforcement activities. This includes establishing appropriate sampling and testing procedures in consultation with the Office of the Attorney General, testing samples of candy, adopting regulations necessary for enforcement, and evaluating the regulatory process. OEHHA is not authorized by the Statute to take these actions.

No changes to the proposed regulation were made based on this comment.

Comment 11 (NCA): This commenter asserted that OEHHA’s ingredient approach “misses the mark by brushing aside key data”. NCA claims that, while OEHHA references data and information provided by NCA in the prior comment period on the 2019 ISOR and TSD, OEHHA “appear[s] to ignore their substance and cast aside the underlying data that was submitted to substantiate them”. NCA “is particularly disappointed that OEHHA has never reached out to discuss its prior comments or data

submission or to seek further information from us, our members, or our colleagues in the confectionary industry in Mexico.”

NCA further asserted that “the California Administrative Procedures Act does not allow OEHHA to arbitrarily or capriciously cast aside data that has been presented to it in favor of its own in order to reach a conclusion it already proposed”. NCA noted that OEHHA appears to be doing so in asserting that “its data is somehow superior to that submitted by industry due solely to the analytic methodology used”. NCA also stated that “the industry’s data, much of which comes from CIATEJ, a lab that whose quality has been carefully reviewed and certified as adequate by the California Attorney General and his auditor, is based on fundamentally the same methodology (ICP/MS) and employs same 0.01 ppm detection limit”.

Response: OEHHA disagrees that the calculations it used are arbitrary and capricious or otherwise do not comport with the APA. OEHHA did not cast aside the data provided by the commenter. As stated on page 8 of the ISOR, to the extent data provided by commenters on the 2019 proposed rulemaking are relevant to this proposed rulemaking, they have been addressed by OEHHA in the updated TSD. OEHHA considered all relevant data provided by stakeholders and commenters, including NCA and its individual member companies, in the development of the updated TSD for this proposed regulation, as well as data available from other sources. This multi-year process initiated in 2006 included reviews of data available from the scientific literature, CDPH, and US FDA, as well as multiple outreach efforts to candy manufacturers and other stakeholders, including a formal data request period and public workshops held in 2008. In addition, OEHHA conducted its own study of lead in fresh and dried chili peppers, described in detail in the TSD. Since 2017, OEHHA has updated its review of data available from the scientific literature, CDPH, and US FDA, and obtained additional data and information from industry and governmental stakeholders in the course of a public hearing and public comment period held in 2017, and subsequent meetings with multiple stakeholders.

As discussed in the TSD, OEHHA evaluated the body of available data and information and gave careful consideration to salient factors relevant to the informativeness of the data for purposes of estimating the naturally occurring level of lead in candies flavored with chili and/or tamarind. This included evaluating the underlying study designs employed, the appropriateness of the materials sampled for determining naturally occurring levels of lead in candy (or candy ingredients), the analytical methods and instrumentation used to measure lead content, and the achievable limits of detection and/or quantification of those analytical methods and instrumentation.

When the data available on lead content for a given ingredient did not provide the type of information necessary to distinguish between naturally occurring and anthropogenic

sources of lead in that ingredient, a level of lead plausibly considered to be naturally occurring was determined, consistent with Section 110552, which states that “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.”

Peer review comments received by OEHHA as part of this regulatory process, as summarized in Comment 1, unanimously support the ingredient-based approach utilized by OEHHA. Two reviewers, Drs. Fowler and Hakkinen, respectively, describe the approach taken by OEHHA as being “reasonable and sound” and “well thought-out”, and the third, Dr. Nriagu, noted that the approach balanced “current scientific knowledge, the available data, relevancy to the candy manufacturers, and the need to protect public health”.

No changes to the proposed regulation were made based on this comment.

Comment 12 (DDL, NCA): These two commenters stated that there are general limitations in the data on individual candy ingredients that OEHHA considered. These purported limitations include a failure to adequately account for feasibility in evaluation of data and a reliance on limited data, such as from samples that do not reflect “the full range of products” and flavor profiles of candies flavored with chili and/or tamarind. For example:

- “While NCA agrees that lead in Mexican Candy should be reduced as much as feasible and that recent data support a lowering of the longstanding interim level, OEHHA needs to better account for feasibility based on real world input of what is commercially achievable, including for manufacturers in Mexico, rather than on limited market survey data and its own constructed assessments that do not reflect commercial production or all ingredients needed to make the full range of these products with the particular flavor profiles that consumers want and expect.” [NCA, page 6]
- “The Technical Support Document does not provide a satisfactory **Statistical approach**, showing only some results of some tests to determine and support the selection of arbitrary adopted levels for the main raw materials listed (Chili peppers and chili powder, Tamarind, Food-grade salt, Sugar, Food-grade silicon dioxide and Food-grade titanium dioxide).” (emphasis in original) [Dulces De La Rosa, page 1]

Response: OEHHA identified relevant data and information for all six ingredients that are anticipated to contribute naturally occurring lead to candies flavored with chili and/or tamarind. In this process, as discussed in the response to comment 11 above, OEHHA evaluated available data resulting from a multi-year process initiated in 2006, that included reviews of data available from the scientific literature, CDPH, and US FDA, as

well as multiple outreach efforts to candy manufacturers and other stakeholders. Data and information reviewed include “real world input” provided by NCA manufacturers and others.

OEHHA adhered to the statutory definition of “naturally occurring” in its ingredient-based approach to estimate the sum of naturally occurring lead in candy containing chili and tamarind, as discussed on pages 1-2 of the TSD. In keeping with the Statute, OEHHA can only consider lead in candy to be naturally occurring “to the extent that it is not avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible”. As appropriate, OEHHA did take feasibility into consideration in determining the level of naturally occurring lead plausibly contributed by a given ingredient. For example, “market survey data” such as the US FDA Total Diet Study, along with supporting data from candy manufacturers, form the basis for an estimated naturally occurring level of lead for one ingredient, sugar. As discussed in the TSD on pages 22-23, lead was not detected in TSD market basket sugar samples between 2014 and 2017. Data on ingredient lead levels provided by NCA, a third party auditor of candy manufacturers (the HACCP Registrar), as well as one Mexican candy manufacturer, indicated availability of sugar with lead content at or below the level based on the US FDA Total Diet Study limit of detection (0.003 ppm). In keeping with the definition in Section 110552, sourcing ingredients with lower lead content, or altering manufacturing procedures to reduce or remove lead content, would be consistent with good manufacturing or procurement practices. Lead that is avoidable by such practices cannot, under this Statute, be considered “naturally occurring”.

OEHHA considered data that reflect naturally occurring levels of lead for all ingredients, including those in which a particular type or variety may be used to contribute a specific flavor profile in the production of candy flavored with chili and/or tamarind. Relevant data are presented in the TSD on pages 2-16 for chili peppers (e.g., Chilaca, Guajillo) as well as pages 22-23 for sugar (e.g., estandar [standard] sugar, powdered sugar). While there may be variation in total lead content, OEHHA is not aware of information or data to support a differing naturally occurring level of lead for such varieties of ingredients. This is consistent with the understanding expressed by the peer reviewers, whose comments, summarized in comment 2 above, unanimously support the ingredient-based approach utilized by OEHHA. Two peer reviewers, Drs. Fowler and Hakkinen, explicitly stated their opinion that “OEHHA accurately selected values for naturally occurring lead” in sugar. The third reviewer, Dr. Nriagu, stated that none of the available data provide the type of information needed to distinguish between naturally occurring and anthropogenic lead in the sugar samples, but noted that OEHHA justified the use of a limit of detection by the fact that “data provided by the candy manufacturers also contained many values that were less than the 0.003 ppm”. As regards naturally occurring lead in chili peppers, two peer reviewers, Drs. Fowler and Hakkinen, explicitly

stated their opinion that “OEHHA accurately selected values for naturally occurring lead in chili peppers and chili powder”. The third reviewer, Dr. Nriagu, concluded that recent studies of a model plant grown in a lead-free laboratory, taken together with known plant depuration mechanisms “point to the fact that the level of naturally occurring lead in chili pepper fruits and seeds should be well below” what he referred to as the “practical value” derived by OEHHA. Dr. Hakkinen also agreed with OEHHA that “even though there was some noteworthy variation in lead concentrations in these ingredients across sources and types, there are available sources of each ingredient with undetectable concentrations of lead.”

In response to the comment from DDLR regarding “arbitrary adopted levels for the main raw materials listed”, OEHHA has not proposed to adopt levels for naturally occurring lead in any individual ingredients used in candies flavored with chili and/or tamarind. As noted on pages 2-3 of the ISOR, for each substance identified as a potential contributor of naturally occurring lead in candies flavored with chili or tamarind, OEHHA “determined a level of lead that is considered naturally occurring consistent with section 110552 and used these levels to determine the proposed regulatory level of naturally occurring lead in candies flavored with chili and/or tamarind”. Regulation of lead levels, including naturally occurring lead, in raw materials or in foodstuff other than candy is “outside the scope of the Statute and this regulatory action” (ISOR, page 9); this statement was responding to similar comments received on the 2019 proposed rulemaking.

As regards the comment that OEHHA has not provided a “satisfactory” statistical approach in estimating levels of naturally occurring lead in ingredients in these candies, peer review comments received by OEHHA as part of this regulatory process supported the use of limits of detection in estimating levels of naturally-occurring lead in chili peppers and chili powder, salt, and sugar (see comment 2), and the use of a value one standard deviation above the mean for estimation of the naturally occurring level of lead in tamarind (see comment 3). In addition, two of three peer reviewers agreed with OEHHA’s use of a maximum allowable level specified by a manufacturer for estimation of the naturally occurring level of lead in food-grade silicon dioxide (see comment 4). The third reviewer, Dr. Nriagu, stated his opinion that there is no evidence for naturally-occurring lead in food-grade silicon dioxide, and concluded that “such synthetic material should contain no naturally occurring lead”. Similarly, two of three peer reviewers agreed with OEHHA’s use of the midpoint of a range of values provided by a candy manufacturer for estimation of the naturally occurring level of lead in food-grade titanium dioxide, with Dr. Nriagu noting that food-grade titanium dioxide used in candies is “also synthetically prepared” and stating that his comments on silicon dioxide, “equally apply to titanium dioxide” (see comment 5).

No changes to the proposed regulation were made based on this comment.

Ingredient-Specific Issues

Comment 13 (DDL, NCA): These commenters asserted that OEHHA did not consider variation in lead across the varieties of chili peppers that are used as ingredients in candies flavored with chili and/or tamarind. Commenters identified multiple varieties (e.g., Ancho, Arbol, Chilaca, Guajillo) that should be considered in this context, given that different chili peppers and chili pepper blends are used to create specific flavor profiles for use in candy. NCA noted that OEHHA disregarded more relevant data on commercial ingredients. For example:

- “The chili powder data industry submitted is considerably more robust than that on which OEHHA relies – it includes thousands of data points spanning almost a decade showing the lead levels in chili peppers post-washing. That those levels have come down somewhat since 2007-08 due to improved sourcing and washing procedures does not make the entire dataset, especially the more recent part of it, irrelevant or allow OEHHA to just look to its own limited data that does not reflect the commercial conditions faced by Mexican Candy manufacturers.” [NCA, page 3]
- “...OEHHA’s conclusions about the level of lead in chili powder casts aside industry-submitted commercial ingredient data, including from Frudest, one of the largest California Attorney General-certified chili powder processors in Mexico, in favor of reliance on data from non-commercially prepared chilies.” [NCA, pages 3 - 4]
- “While recognizing that even its own data on washed Guajillo and Chilaca chilies (let alone the industry-provided data) presents average lead levels that are above 0.01 ppm with individual samples testing well above this level, OEHHA’s analysis leaves this behind and relies instead on its observations that lead levels in fresh and dried Anaheim chilies and fresh sweet green peppers are non-detectable.” [NCA, page 4]
- “But as OEHHA itself admits in the technical support document, flavors of different types of chilies are not interchangeable so even if other types of chili appear to be available on a consistent basis at <0.010 ppm, the same is not the case for Guajillo and Chilaca chilies, which are the types used by Mexican manufacturers and necessary to create the unique flavor profiles presented in their products.” [NCA, page 4]
- “The **kind of chilis** mentioned to determine the “Lead Naturally Occurring Level” on the Technical Support Document are varieties of the *longum* group of the species *Capsicum annuum* (*C. annuum* L.), Anaheim Chili and Guajillo Chili. The latter being one of the many chilis varieties used in candies and confections, but not the only variety. Anaheim chili is not a common chili kind found on traditional candies. Perhaps Chili Ancho and Chili de Arbol are more commonly used.” (emphasis in original) [Dulces De La Rosa, page 2]

- “The Technical Support Document refers to chili crops from California and Mexico, without specifying an exact Geographical location, and without considering that the levels of lead the soil may vary from location to location.” [Dulces De La Rosa, page 2]

Response: In determining a level of lead in chili peppers and chili powder plausibly considered to be naturally occurring, consistent with the definition in Section 110552, OEHHA considered data on lead content in chili peppers and chili powder from a number of sources. This includes data submitted by chili powder producers and candy manufacturers, data and information available from the Office of the Attorney General, other governmental sources, the published literature, and data from an OEHHA study of fresh and dried chili peppers. These data and other information reviewed by OEHHA in making this determination, including a 2006 opinion from the US FDA that freshly grown raw chili peppers are not likely to contain significant levels of lead, are discussed in more detail in the TSD (pages 2 – 16).

In considering available data on lead in chili peppers and chili powder, OEHHA focused on data most relevant to determining the level of lead that occurs naturally in chili peppers, and thus, in chili powder. As discussed on pages 2-4 of the TSD, OEHHA identified potential pathways by which lead could become associated with the fruiting part of a chili pepper plant prior to harvest (e.g., root uptake from soil), and reviewed studies investigating the potential for chili pepper plants to take up lead from soil and for lead to be transported to the edible fruit. Several of these studies were conducted with chili pepper plants belonging to the *longum* group of the species *Capsicum annuum*. The *longum* group (*C. annuum* L) includes several varieties (cultivars) of chili peppers (e.g., Anaheim, Ancho, Arbol, Chilaca, Guajillo). These include varieties cited by the commenters as being used in candies either alone or in combination to create specific flavor profiles. The results of these uptake studies, discussed on pages 3 – 4 of the TSD, indicate that, while uptake and transport of lead from soil to the edible fruit (i.e., the “chili pepper”) 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, regardless of geographic origin. As noted in Comment 2 above, one peer reviewer concluded that recent studies of a model plant grown in a lead-free laboratory, taken together with known plant depuration mechanisms “point to the fact that the level of naturally occurring lead in chili pepper fruits and seeds should be well below” what he referred to as the “practical value” derived by OEHHA (i.e., 0.01 ppm).

Lead that is present in chili pepper and chili powder as a result of contamination is not naturally occurring, nor is any lead considered naturally occurring under Section 110552 if it is “avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible”. Lead contamination of chili peppers and chili powder

may occur, for example, as the chili is harvested, transported, dried, and/or processed into chili powder. The occurrence of such lead contamination has been confirmed by various studies that have investigated the impact of washing of fresh and dried chili peppers, including studies reported to OEHHA by candy manufacturers as well as the study conducted by OEHHA. The findings of these studies, discussed on pages 3 – 13 of the TSD, indicate that washing the chili peppers prior to further processing can significantly reduce the level of lead in dried whole chili peppers and in chili powder made from the washed and dried peppers.

As discussed in the TSD, no lead was detected in any fresh chili peppers from the OEHHA study of chili peppers grown in California and Mexico, and analyzed either as unwashed or washed fresh or oven-dried peppers (Parts A-C of the OEHHA study). This indicated that the naturally occurring level of lead in these chili peppers was lower than the study's limit of detection (0.01 ppm). Part D of the OEHHA study analyzed samples of two different brands of Guajillo peppers from Mexico that were purchased as pre-dried peppers; these samples were analyzed either as unwashed or "washed" (i.e., rehydrated, washed, rinsed, and oven-dried) peppers. While some lead was detected in both unwashed 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 limit of detection. That at least some lead could be removed by washing indicates surface contamination of these peppers with lead, rather than incorporation of lead in the tissue of the chili pepper, and suggests that lead levels can be reduced with improvements to agricultural and/or manufacturing practices related to the harvesting and handling of these peppers before, during and after the drying process.

Data on levels of lead in chili powder reviewed in the TSD indicate that the total lead content in chili powder, including any naturally occurring lead, is generally very low. For example, as discussed on page 12 of the TSD, mean total lead in three of six batches of chili powder, analyzed by a qualified laboratory under the *People v. Alpro Alimentos Proteinicos* settlement, fell within a factor of two of the limit of detection in the OEHHA chili pepper study, i.e., 0.01 ppm.

The data provided by a chili powder processor, Frudest, on lead concentrations measured in chili powder produced using chili peppers that were sun-dried with or without industrial washing (discussed on page 13 of the TSD) provide additional confirmation that lead present in chili powder can be reduced by washing the chili peppers prior to processing, which indicates surface contamination of peppers with lead rather than incorporation of lead in the tissue of the chili pepper. However, the summary data provided by Frudest represent an unspecified number of samples for which no information on harvesting and handling practices were provided, and thus these data are not informative as to the natural occurrence of lead in chili peppers and

chili powder. As noted in the response to Comment 12, all three peer reviewers supported OEHHA's evaluation of the available data and literature relevant to the natural occurrence of lead in chili peppers, and supported the selection of 0.01 ppm as the estimated naturally occurring level of lead in chili powder.

No changes to the proposed regulation were made based on this comment.

Comment 14 (NCA): This commenter stated that the chili peppers used in the OEHHA study do not represent the majority of chili peppers used in chili powder. NCA further asserted that OEHHA did not sufficiently consider the results of Part D of the OEHHA study, in which pre-dried chili peppers were rehydrated, washed to remove superficial lead, and oven-dried prior to grinding into chili powder for analysis. NCA also asserted that the practices used in the study (e.g., washing and oven drying) are not representative of those used by the industry.

- “While recognizing that even its own data on washed Guajillo and Chilaca chilies (let alone the industry-provided data) presents average lead levels that are above 0.01 ppm with individual samples testing well above this level, OEHHA’s analysis leaves this behind and relies instead on its observations that lead levels in fresh and dried Anaheim chilies and fresh sweet green peppers are non-detectable.” [NCA, page 4]
- “For example, in Part D of its studies, the data OEHHA developed on Guajillo and Chilaca chilies reflects time-consuming preparation of rehydrated and detergent washed peppers under laboratory conditions instead of under good manufacturing practices for preparing and washing the same types of peppers in a commercial environment. Instead of basing its analysis on data on the wrong chilies or that which is artificially low due to its unrealistic preparation of Guajillo and Chilaca chilies under laboratory versus commercial conditions, OEHHA should utilize the washed chili powder data in its possession that was previously submitted by Frudest and other companies.” [NCA, page 4]

Response: OEHHA disagrees with the commenter’s criticism of the use of Anaheim chili peppers in Parts A-C of the OEHHA study as being “the wrong chilies”. As discussed in the TSD, and explained in some detail in the response to Comment 13 above, the Anaheim chili pepper belongs to the *longum* group of the species *C. annuum* (*C. annuum* L), as do the Ancho, Arbol, Chilaca, and Guajillo chili pepper varieties. Studies from the published scientific literature indicate that, for pepper plants of multiple species, including the species *C. annuum* and the groups *C. annuum* L (e.g., Anaheim, Ancho, Arbol, Chilaca, Guajillo) and *C. annuum* G (e.g., sweet green peppers), the uptake and transport of lead from soil to the edible fruit (i.e., the “pepper”) is not expected to result in detectable levels of lead in peppers when plants are grown in soil without significant lead contamination. Data on lead uptake by one type of pepper plant in the *C. annuum* L group should thus be considered representative of lead uptake by

other types of pepper plants in that group. As such, data on lead content in Anaheim chili peppers is applicable to Ancho, Arbol, Chilaca and Guajillo chili peppers. No lead was detected in any fresh chili peppers from the OEHHA study of Anaheim chili peppers grown in California and Mexico, when analyzed either as unwashed or washed fresh or oven-dried peppers (Parts A-C of the OEHHA study). Moreover, one peer reviewer (see Comment 2) concluded from his knowledge of the scientific literature on lead uptake that the level of naturally occurring lead in chili pepper fruits and seeds should be well below 0.01 ppm, the limit of detection in the OEHHA study.

The commenter has misinterpreted the purpose of Part D of the OEHHA study, which was to measure lead content in pre-dried Guajillo peppers (sampled from two different brands) obtained from a Northern California market and grown in Mexico, and to investigate the effect of washing on lead content in those pre-dried peppers. As the commenter noted, some lead was detected in both unwashed pre-dried Guajillo peppers from Mexico and washed pre-dried Guajillo peppers from Mexico. However, as discussed in response to comment 13 above, washing did reduce the amount of lead present across both brands tested, to an extent in one brand just above the limit of detection (0.01 ppm). Thus, the finding from Part D of the OEHHA study that at least some lead could be removed by washing indicates surface contamination of these peppers with lead, rather than incorporation of lead in the tissue of the chili pepper. These findings also indicate that lead levels can be reduced in these peppers with improvements to agricultural and/or manufacturing practices related to the harvesting and handling of the peppers before, during and after the drying process.

Finally, OEHHA disagrees with the implication by the commenter that the finding from Part D of the OEHHA study, namely that lead content in dried chili peppers can be lowered by reducing surface contamination of chili peppers with lead, is not applicable to commercial production, since the study employed different washing procedures than are practical under commercial conditions. OEHHA is not suggesting that washing dried chili peppers is either the best or the only method for reducing lead contamination in dried chili peppers. As noted above, improvements to agricultural and/or manufacturing practices at various points throughout the chili pepper growing, harvesting, handling, and drying processes can reduce surface lead contamination of dried chili peppers.

No changes to the proposed regulation were made based on this comment.

Comment 15 (NCA): This commenter stated that OEHHA did not sufficiently consider the available data on sugar, particularly the “industry’s data on commercially sourced ingredients in Mexico”, and that OEHHA failed to account for the difference between types of sugars, including “estandar” sugar, which contribute to the flavor profile of certain candy products. NCA concluded that OEHHA’s naturally occurring level of lead

in sugar of 0.003 ppm is “unrealistically low in comparison to the industry-provided data that was previously submitted on estandar sugar which is considerably higher”.

- “OEHHA’s consideration of data on sugar and its contribution to finished product lead levels is similarly flawed and biases the agency’s analysis of what lead levels are actually commercially feasible for Mexican Candy manufacturers. It again casts aside the industry’s data on commercially-sourced ingredients in Mexico and fails to account for the difference between estandar sugar and the more heavily processed sugar that is the subject of FDA’s total dietary study results. But estandar sugar is the type needed by candy manufacturers in Mexico to create the unique flavor profiles of their products and, as a practical matter due to trade restrictions on imported sugar, the type that is available to candy manufacturers in Mexico. OEHHA’s conclusion that the naturally occurring lead level in sugar is only 0.003 ppm is unrealistically low in comparison to the industry-provided data that was previously submitted on estandar sugar which is considerably higher (mean of approximately 0.013 ppm) and, as with the use of data on the wrong kind of chilies, it inappropriately taints the agency’s further analysis.” [NCA, pages 4 – 5]

Response: In determining a level of lead in sugar plausibly considered to be naturally occurring, consistent with the definition in Section 110552, OEHHA considered data from a number of sources. This included data on the lead content of estandar and other types of sugar submitted by four candy manufacturers operating in Mexico (Dulces Vero, Mars Inc., The Hershey Company, and Zumbapica), NCA, and the HACCP Registrar, and data available from the US FDA Total Diet Study. The data available on levels of lead in sugar, discussed in the TSD on pages 22-23, do not provide the type of information necessary to distinguish between naturally occurring and anthropogenic sources of lead. However, data from the candy manufacturers, NCA, the HACCP Registrar and the US FDA all indicate the availability of sugar with undetectable or low concentrations of lead. OEHHA therefore used 0.003 ppm, the detection limit for lead in sugar from the most recent US FDA Total Diet Study analyses, as the estimate of the naturally occurring level of lead in sugar.

As discussed in the TSD and noted in the response to comment 12 above, the use of the detection limit for lead in sugar (0.003 ppm) from the recent US FDA Total Diet Study analyses, in which lead was not detected in samples collected between 2014 and 2017, is supported by data from the candy manufacturers, NCA and the HACCP Registrar. Data on lead levels in samples of sugar provided by the Mexican candy manufacturer Zumbapica, the NCA, and the HACCP Registrar indicate availability of sugar with lead content at or below the US FDA Total Diet Study limit of detection (0.003 ppm). While there may be variation in total lead content across different types of sugar (e.g., estandar, powdered sugar), OEHHA is not aware of information or data to

support a different naturally occurring level of lead for such varieties of sugar. In keeping with the definition in Section 110552, sourcing ingredients with lower lead content, or altering manufacturing procedures to reduce or remove lead content, would be consistent with good manufacturing or procurement practices. Lead that is avoidable by such practices cannot be considered “naturally occurring” under this Statute.

Peer review comments received by OEHHA as part of this regulatory process, as summarized in Comment 2 in the previous section, support the approach utilized by OEHHA to estimate naturally occurring lead contributed by sugar. One reviewer, Dr. Nriagu, stated that none of the available data provide the type of information needed to distinguish between naturally occurring and anthropogenic lead in the sugar samples, but noted that OEHHA justified the use of a limit of detection by the fact that “data provided by the candy manufacturers also contained many values that were less than the 0.003 p[p]m”.

No changes to the proposed regulation were made based on this comment.

Finished Product Issues

Comment 16 (NCA): This commenter stated that “OEHHA is erroneous in concluding that its proposed 0.02 ppm level is already being met with negligible exceptions”. Some candies within the scope of the proposed regulation produced by manufacturers have lead content that exceeds the proposed naturally occurring lead limit of 0.02 ppm. For example:

- “OEHHA’s new ISOR indicates that the agency believes its proposed 0.02 ppm naturally occurring level is achievable based largely on California Department of Public Health (CDPH) surveillance data finding only a handful of detections over the past few years. But the vast majority of CDPH’s 2017-18 data does not reflect Mexican-style (chili- or tamarind-flavored) candy or come close to assessing the full range of Mexican candy products available in the California market. Moreover, even when using the limited data set that OEHHA’s technical support documents describes as coming from the HACCP auditor, the ISOR acknowledges that approximately 1 out of 8 Mexican-produced chili/tamarind candies do not meet the proposed 0.02 ppm level.” [NCA, page 3]
- “...data on the more relevant range of finished products previously submitted by Mexican candy manufacturers (either through NCA or directly) underscores the point that OEHHA is erroneous in concluding that its proposed 0.02 ppm level is already being met with negligible exceptions. It instead shows that numerous samples from recent years, made by companies which comply with the good manufacturing and supply chain management practices specified in the Alpro Alimento consent judgment, present lead levels from 0.02 to 0.06 ppm. Hence, there is significant

disparity between the finished product data OEHHA plans to rely on and that in the prior record (now re-incorporated by reference) which better characterizes the fuller scope and range of the Mexican Candy products at issue.” [NCA, page 3]

- “...OEHHA’s assumption that virtually all Mexican-style candies already can consistently meet its proposed 0.02 ppm lead level is erroneous.” [NCA, page 6]

Response: First, the results referenced by this commenter are not specific to naturally occurring lead, as defined under Section 110552, but rather reflect total lead content in the candy tested. Further, OEHHA has not used the term “negligible” in either the ISOR or TSD to describe the results of recent lead analyses of candies flavored with chili and/or tamarind provided by NCA and the HACCP Registrar, in which a small proportion of candy products had total lead content greater than 0.02 ppm. OEHHA acknowledged in both the ISOR (pages 4 – 6) and the TSD (pages 31 – 33) that, while a majority of candies within the scope of the proposed regulation produced by manufacturers under current manufacturing conditions have *total* lead content that does not exceed the proposed naturally occurring lead level of 0.02 ppm, there are some candies that do exceed that level. For example, the TSD discussed the summary testing information for “Company X” provided by NCA, finding that lead content was at or below 0.02 ppm for approximately 94% of the candy tested in 2017 and 2018. The TSD also discussed data provided by the HACCP Registrar, in which a small proportion (approximately 1 in 8) of candy products flavored with chili and/or tamarind and produced under current manufacturing conditions have total lead content that exceeds 0.02 ppm. OEHHA acknowledges this, stating on page 33 of the TSD that “...for most of the candies tested, concentrations of lead are lower than 0.02 ppm, while historically levels have measured much higher.”

That a majority of candy products flavored with chili and/or tamarind have total lead content that is no greater than the proposed level for naturally occurring lead in such candy indicates that ingredients contributing minimal naturally occurring lead are available to the manufacturers of these candy products. Some changes to sourcing or production processes may be necessary to bring down the lead levels for those products that exceed the naturally-occurring level as is contemplated by the Statute.

No changes to the proposed regulation were made based on this comment.

Section III. Proposed Naturally Occurring Level of Lead in Candy Flavored with Chili and/or Tamarind

Proposed Level Too High

Comment 17 (CEH): CEH stated that “a naturally occurring level of 10 parts per billion (ppb), in addition to being more health protective than the proposed 20 ppb [0.02 ppm],

is a feasible and justifiable naturally occurring level.” The commenter asserts that a “level higher than 10 ppb is not appropriate”. CEH commented that many available data sets include values mostly below the level of quantitation for lead analysis, which it described as “challenging” for estimation of naturally occurring lead. CEH noted that in “data compiled by the Attorney General’s office, over 80% of the tested candies were contaminated with less than 10 ppb lead”. CEH asserted that this is “clear evidence that through good agricultural, manufacturing, and procurement practices, lead contamination less than 10 ppb is feasible”.

Response: OEHHA estimates that the naturally occurring level of lead in candies flavored with chili and/or tamarind is 0.02 ppm, using the ingredient-based approach described in the TSD. Briefly, OEHHA identified ingredients in these candies that may be potential contributors of naturally occurring lead, and determined for each of these ingredients a level of lead plausibly considered to be naturally occurring, consistent with Section 110552. Based on the amounts of each such ingredient typically present in various formulations and types of candies containing chili and tamarind (i.e., sugar-based, salt-based, tamarind-based), OEHHA estimated the level of naturally occurring lead in these candies to be 0.02 ppm. As indicated in Comments 1 and 2, scientific peer reviewers of the TSD support the proposed regulatory level of 0.02 ppm, as well as OEHHA’s approach to determining naturally-occurring lead in candies flavored with chili and/or tamarind, including use of limits of detection when the data available includes measures below limits of quantification/detection.

As to the commenter’s statement that “over 80% of the tested candies were contaminated with less than 10 ppb lead”, OEHHA does not have data or information supporting that level. The candy data provided to OEHHA through the Office of the Attorney General discussed on pages 32-33 of the TSD indicate that more than 86% of the 195 tested samples of candy flavored with chili and/or tamarind had levels of lead at or below 20 ppb (0.02 ppm), and 75.9% had levels of lead at or below 10 ppb (0.01 ppm) (See Figure 3 of the TSD). OEHHA also evaluated another set of recent candy data, provided by NCA, for which approximately 94% of the samples contained lead at or below 0.02 ppm, as discussed on pages 31-32 of the TSD. As OEHHA concluded on page 33 of the TSD, “in summary, for most of the candies tested, concentrations of lead are lower than 0.020 ppm, while historically levels have measured much higher”. While these candy data support the proposed level of 0.02 ppm for naturally occurring lead in candies flavored with chili and/or tamarind, these data were not used in the derivation of that level.

No changes to the proposed regulation were made based on this comment.

Proposed Level Too Low

Comment 18 (NCA, DDLR): These commenters asserted that the naturally occurring level of lead in candy proposed by OEHHA is too low to be achieved. NCA emphasized that a substantially higher level would be more reflective of what “industry has shown it can and cannot achieve” and “accounts for the use of commercially-sourced ingredients presenting the unique flavor profiles characteristic of Mexican Candy (such as Guajillo and Chilaca chilies and estandar sugar)”. DDLR noted that limits of detection at many laboratories, including laboratories currently certified by the State of California for compliance under existing settlements are “not as low as required”. DDLR also noted that the current CDPH adulterated candy program detection limit is 0.05 ppm for compliance. DDLR then proposed that the naturally occurring level instead be initially reduced to 0.05 ppm from the current default level of 0.1 ppm.

- “While NCA agrees that lead in Mexican Candy should be reduced as much as feasible and that recent data support a lowering of the longstanding interim level, OEHHA needs to better account for feasibility based on real world input of what is commercially achievable, including for manufacturers in Mexico, rather than on limited market survey data and its own constructed assessments that do not reflect commercial production or all ingredients needed to make the full range of these products with the particular flavor profiles that consumers want and expect.” [NCA, page 6]
- “The **Limits of Detection** for the accredited labs to show compliance to the default limit determined by the California Attorney General as part of a 2006 consent judgment in *People vs Alpro Alimentos Proteicos* (Los Angeles County Superior Court Case #BC318207 and related cases) are not as low as required to establish Statistical Process Control and set control limits for the manufacturing process or raw material lead content trends and performance. Provided data only conveys when a product is out of specification. (i.e. CIATEJ, with a detection limit of 0.02ppm). The data shown on <https://www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx> indicates for most of the results ND (i.e. Food and Drug Laboratory with a No Detection level of 0.05ppm).” (emphasis in original) [Dulces De La Rosa, pages 1 - 2]
- “Dulces de la Rosa companies would like to propose that the Lead “Naturally Occurring Level” be initially reduced from the existing default level of 0.1 ppm down to 0.05ppm, and after a period of 2 years (which should provide enough data on the real Lead Natural Occurring Level) meet again with this Office to review if the “Lead Naturally Occurring Level” can be reduced even further. It will also provide sometime to educate our agricultural partners and quality control teams to continue with HACCP and Good Manufacturing practices.” [Dulces De La Rosa, page 2]

Response: OEHHA acknowledges these comments, but notes that neither commenter specifically addressed *naturally occurring* lead. As noted on page 2 of the TSD, and as discussed in the responses to Comments 10 through 15, under this Statute OEHHA can only consider lead in candy to be naturally occurring "...to the extent that it is not avoidable by good agricultural, manufacturing, and procurement practices, or by other practices currently feasible". The Statute goes on to specify that 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."

OEHHA acknowledges that laboratories may have different limits of detection, even those using the same type of instrumentation (e.g., inductively coupled plasma mass spectrometry [ICP-MS]). However, OEHHA did not consider a level lower than limits of detection in available data sets. Indeed, data and information provided to OEHHA by candy manufacturers, NCA, and the HACCP Registrar indicates that there are many laboratories already operating at lower limits of detection or quantification for lead in the analyses of both finished candies, and ingredients (e.g., sugar, chili peppers and chili powder). One of the peer reviewers, Dr. Nriagu, also commented on recent improvements in analytical techniques for the measurement of lead, stating that, in comparison to some of the reported studies, "the detection limit for high resolution ICP-MS has been lowered to <0.2 parts per billion (ppb)".

No changes to the proposed regulation were made based on this comment.

Comment 19 (NCA): This commenter stated that the purpose of the legislation codified at Section 110552 was to protect health, and that there are either no health concerns associated with candy containing lead levels higher than OEHHA's proposed naturally occurring level of 0.02 ppm, or that OEHHA has not provided evidence of health benefits resulting from the proposed naturally occurring level. For example:

- "The expressed purpose of that legislation was to empower the Department of Public Health to prevent the sale in California of adulterated candy that could pose an actual health risk."
- "The actual health impacts of the proposed level of 0.02 as compared to a level of 0.05 ppm have not been demonstrated."

Response: This comment asks OEHHA to take actions that are beyond the scope of the proposed regulation. Section 110552 does not require OEHHA to provide evidence of a health risk when establishing a naturally occurring lead level for candy flavored with chili and/or tamarind. Subsection (c)(3) explicitly directs OEHHA to determine naturally occurring levels of lead in candy containing chili and tamarind, with additional direction

that OEHHA determine naturally occurring levels of lead in candy containing other ingredients upon request by CDPH or the AG, or, in the absence of such a request, when OEHHA determines that the presence of the ingredient in candy may pose a health risk.

No changes to the proposed regulation were made based on this comment.

Proposed Level Supported

Comment 20 (EHC): EHC indicated their support for the proposed 0.02 ppm standard “as it will be achievable by most candy manufacturers”. EHC also stated that protecting public health, especially that of children, is a priority, and noted that lead poisoning, a “preventable environmental disease” is “the number one environmental health threat to children under 6 years-old”, and that “the CDC has affirmed there is no safe blood lead level in children”. EHC emphasized that “ALL children deserve protection from this preventable and shameful source of lead” and OEHHA is urged to “take immediate steps towards adopting and implementing this new naturally occurring lead in candy 0.02 ppm standard”.

Response: OEHHA acknowledges the commenter’s support for the proposed regulation. No changes to the proposed regulation were made based on this comment.

Section IV. Implementation of Regulation

Comment 21 (DDL, NCA): These two commenters expressed concerns about implementation of the regulation and offered recommendations for implementation and enforcement of the proposed regulation.

- “There is no mention or even consideration of **the Time required to the enforcement** of these limits, and the impact to the retailers, distributors and manufacturers. Some if not most of the products exhibit a long shelf life (i.e., in the range of 24 months), meaning that a candy produced today would be within the expiration date in about two years, and perfectly suitable to be sold and consumed. Moreover, we are in the mi[d]st of a worldwide pandemic that has severed our ability to respond as quickly as all would want”. (emphasis in original) [Dulces De La Rosa, page 2]
- “Dulces de la Rosa companies would like to propose that the Lead "Naturally Occurring Level" be initially reduced from the existing default level of 0.1 ppm down to 0.05ppm, and after a period of 2 years (which should provide enough data on the real Lead Natural Occurring Level) meet again with this Office to review if the "Lead Naturally Occurring Level" can be reduced even further.” [Dulces De La Rosa, page 2]

- “Set the effective date of the new Section 25800 level out by at least one year following its publication as a final rule.” [NCA, page 2]
- **“If OEHHA is not going to phase in its final Section 25800 level through a series of step-downs over time, it should provide for an effective date that is at least one year from publication of a final rule.** The updated ISOR recognizes but then ignores or dismisses as yet another “enforcement issue,” NCA’s prior suggestion that the final Section 25800 level be phased in over a series of years to allow manufacturers to transition from the interim level established by the Attorney General in the *Alpro Alimento* consent judgment and adjust their sourcing, quality control and testing programs accordingly. Such a managed transition would allow companies to remain in compliance rather than leave them at the mercy of a prosecutor’s potential exercise of enforcement discretion or the class actions bar. If OEHHA will not adopt a step down approach, then, at a minimum, it should avoid throwing Mexican companies immediately into a non-compliance position and facilitate the change to the Section 25800 level by providing for an effective date that is at least one year following publication of the final rule. As was the case when the *Alpro Alimento* consent judgment was finalized and entered by the court, the state government, and non-profits, including NCA, could then use the intervening year to educate Mexican manufacturers and help them adjust operations and export product lines to address the newly required level.” (emphasis in original) [NCA, pages 5 - 6]
- “It is not uncommon for compliance dates to be set a year or more downstream of effective dates. Indeed, such an approach was incorporated into the *Alpro Alimento* consent judgment, Proposition 65 provides for a full year between a new listing and the onset of its associated warning requirement, and FDA commonly provides several years for regulated companies to address its implementation of enhanced requirements under the Food Safety and Modernization Act. Indeed, OEHHA’s discretion to not establish any final Section 25800 level in the absence of a new appropriation from the Legislature necessarily allows it to establish one that has an effective compliance date downstream of publication of a final rule.” [NCA, page 6]

Response: As noted by NCA, under subsection (e) of the Statute, CDPH is responsible for ensuring that candy is not adulterated, including implementation and enforcement activities. As discussed in the response to Comment 10 above, this includes determination of appropriate sampling and testing procedures in consultation with the Office of the Attorney General, testing samples of candy, adopting regulations necessary for enforcement, evaluating the regulatory process, and establishing appropriate timeframes for all such activities. OEHHA agrees that a delayed effective date would allow CDPH and the Attorney General’s Office to address any testing, regulatory or enforcement issues. Therefore, OEHHA has requested a delayed effective date of one year from the date of adoption of the regulation.

No changes to the proposed regulation were made based on this comment.

Section V. Other Issues

Comment 22 (EHC): OEHHA should review results of candy product lead testing three years after adoption of the naturally occurring standard to ensure that candy manufacturers “continue to do their best in getting the lead out and maintaining themselves well below the 0.01 ppm level”. EHC referenced best practices such as use of non-lead-based inks in candy wrappers and washing of chili peppers that have been demonstrated to reduce levels of lead, then stated that they “hope that the new naturally occurring standard will continue to promote these best practices and thus continue to motivate others in the food industry to do the same”. EHC indicated concern that lead levels may increase in some products with a “higher allowable standard of 0.02 ppm”, as there are candy manufacturers currently achieving total lead levels below 0.01 ppm.

Response: OEHHA agrees that reviewing the results of candy product lead testing, routinely conducted by CDPH, is a reasonable way to monitor compliance and determine if lead levels are increasing or decreasing. OEHHA acknowledges the rest of the comment.

No changes to the proposed regulation were made based on this comment.

Summary and Response to Comments Received During the Proposed Modification of Regulation Text 15-day Comment Period

OEHHA received seven comments in response to the proposed modification. The following organizations and individuals submitted written comments on the proposed amendment during the July 23, 2021, to August 6, 2021, comment period.

Center for Environmental Health (CEH)

Clean Earth 4 Kids (KIDS)

John Bottorff (Bottorff)

National Confectioners Association (NCA)

Steve Sander (Sander)

Suzanne Hume (Hume)

Sydney (Sydney)

Comment 23 (CEH, KIDS, Bottorff, NCA): These four commenters support the regulation.

Response: OEHHA acknowledges the support for the regulation. No further response is required.

Comment 24 (NCA): NCA supports the proposed amendment to the regulation, adding that the intent not to include chocolate candies was in the original proposal, but the amendment adds clarity to the regulation text.

Response: OEHHA acknowledges the comment. No further response is required.

Comment 25 (CEH): CEH states that the naturally occurring level currently used (100 parts per billion) is outdated and should be reduced and that a naturally occurring level of 10 parts per billion (ppb) is a feasible and justifiable level. CEH adds that 10 ppb would be a much more protective level than the proposed 20 ppb, especially for candies that are consumed by developing children who are particularly vulnerable to the toxic effects of lead. They add the way to achieve these levels includes good agricultural, manufacturing, and procurement practices. CEH also explained that California's lead in candy law requires the naturally occurring lead level to be reviewed every three to five years. CEH stated that this is overdue.

Response: The comments are beyond the scope of the amendment to the proposed regulation that clarified the exclusion of chocolates. No change was made to the proposed regulation based on these comments.

Comment 26 (NCA): NCA states that the proposed 0.02 ppm naturally occurring lead level that is still reflected in the currently proposed Modification is improperly derived and does not reflect an accurate assessment of the lowest level currently feasible.

Response: The comments are beyond the scope of the amendment to the proposed regulation. No change was made to the proposed regulation based on this comment.

Comment 27 (Hume, Sander, Sydney): Three commenters stated that the regulation does not go far enough and should include chocolate candies as well. The commenters pointed out that lead crosses the placental barrier and can damage the nervous system of a developing baby. One of the commenters also wanted to include chocolate and other foods and other toxic heavy metals like arsenic, cadmium, chromium, and mercury.

Response: Chocolate-based candies are not within the scope of the current proposed regulation. The regulation is specific to candy made with chili and tamarind as required by Health and Safety Code section 110552(c)(3). 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 these candies. [ISOR, page 2]

No change was made to the proposed regulation based on these comments.

Alternatives Determination

In accordance with Government Code section 11346.9(a)(7), OEHHA has considered available alternatives, including those presented by commenters such as NCA, to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed. OEHHA has also considered whether an alternative existed that would be as effective as, and less burdensome to, affected private persons than the proposed action. OEHHA has determined that no alternative considered would be more effective, or as effective and less burdensome to affected private persons, than the proposed action, including those offered by the commenters. Further, OEHHA considered the alternative of taking no action, but finds that taking no action is inconsistent with the statutory requirements. Therefore, OEHHA has determined that no alternative considered would be more cost-effective, or as effective in implementing the statutory policy or other provision of law.

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. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.