INITIAL STATEMENT OF REASONS

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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

JUNE 2020

Summary

Health and Safety Code section 110552[1] requires the Office of Environmental Health Hazard Assessment (OEHHA), in consultation with the California Department of Public Health (CDPH) and the Office of the Attorney General (OAG), to determine the "naturally occurring level" of lead in candy containing chili and tamarind. Pursuant to this requirement, OEHHA is proposing to add Title 27 of the California Code of Regulations, Chapter 3: Naturally Occurring Lead in Candy, section 28500, Naturally Occurring Levels of Lead in Candy. The proposed regulation establishes a level for naturally occurring lead in candies flavored with chili and/or tamarind, based on a scientific approach summarized in this document and discussed in detail in the attached scientific analysis titled *Naturally Occurring Lead in Certain Candies. Candies Flavored with Chili and/or Tamarind* (OEHHA 2020)[2].

Purpose and Background of Proposed Regulation

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.

[1] Hereafter referred to as "section 110552" or "the Statute".
[2] Hereafter referred to as "Technical Support Document".

The attached technical support document lays out the detailed scientific approach and analysis supporting the proposed regulatory level. A summary of the approach is provided below.

Approach for establishing the naturally occurring level of lead in candies containing chili or tamarind

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. The approach is as follows:

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

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

- Chili peppers and chili powder[3]
- Tamarind
- Food-grade salt
- Sugar
- Food-grade silicon dioxide
- Food-grade titanium dioxide

Chocolate-based candies are not within the scope of the current proposed regulation.

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

[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.

used these levels to determine the proposed regulatory level of naturally occurring lead in candies flavored with chili and/or tamarind.

As required by the statute, the proposed regulatory level was determined in consultation with CDPH and OAG.

Proposed Regulatory Standard

OEHHA is proposing to add the following new chapter and section to Title 27 of the California Code of Regulations:

CHAPTER 3. NATURALLY OCCURRING LEAD IN CANDY

§ 28500. Naturally Occurring Levels of Lead in Candy

For purposes of Health and Safety Code section 110552(c)(3), the following levels of lead in candy are deemed by the Office of Environmental Health Hazard Assessment to be naturally occurring:

Type of Candy	Naturally-Occurring Level (parts per million)
Candies flavored with chili and/or tamarind	0.02 ppm

Details on the basis for the proposed level are provided in the attached Technical Support Document.

Necessity

The proposed regulation is necessary to set a standard for naturally occurring levels of lead in candies containing chili and tamarind as required by Health and Safety Code section 110552(c)(3).

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

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

Creation or elimination of jobs within the State of California

The proposed regulation would establish a new naturally occurring level for lead in candies containing chili and/or tamarind. The existing default level is 0.10 ppm, which was determined by the California Attorney General as part of a 2006 consent judgment in a Proposition 65 enforcement action, *People v. Alpro Alimento Proteinicos* (Los Angeles County Superior Court Case #BC318207 and

related cases)[4]. The proposed naturally occurring level is 0.02 ppm. This regulatory action will not significantly impact the creation or elimination of jobs within the State of California.

California Candy Manufacturers

Most manufacturers of candies containing chili and/or tamarind are located outside of California, with many located in Mexico. OEHHA used information available from public databases, industry publications, and trade organizations (e.g., The National Confectioners Association (NCA))[5] to identify candy companies in California that produce candies containing chili and/or tamarind[6]. OEHHA identified fewer than ten California candy manufacturers that currently produce any candies containing chili and/or tamarind. These California manufacturers are likely already in compliance with the proposed naturally occurring level, based on recent past performance of these types of candies in monitoring studies conducted by CDPH[7] and an evaluation of recent data for similar candies provided by manufacturers in Mexico[8].

None of the identified California manufacturers of candies flavored with chili and/or tamarind have had a product with detectable lead reported by CDPH in at least the last six years[9]. Further, lead was detected in only seven individual candy samples of the more than 1,000 samples of any candies or related products tested by CDPH since January 2015. Of these seven samples with lead detected by CDPH, only two potentially contained chili and/or tamarind, and

[4] Pursuant to section 110552(c)(3), until OEHHA adopts regulations determining the naturally occurring level of lead in candy, "the Attorney General's written determination, if any, including any determination set forth in a consent judgment entered into by the Attorney General…shall be binding for purposes of this section."
[5] Shumow, Laura. 2017. Written comments submitted on behalf of the National Confectioners Association in response to the Center for Environemtnal Health petition for rulemaking determining the "naturally occurring" level of lead in candy containing chili and tamarind, p. 2. Submitted by Laura Shumow, Vice President, Scientific and Regulatory Affairs, NCA, July 19, 2017.
[6] Limited public information is available on many smaller California candy manufacturers, since many of these smaller manufacturers are independent operations with limited to no advertising, social media, or internet presence, and some appear to operate only as contract manufacturers or on a seasonal basis.
[7] CDPH. 2018. Lead in Candy Testing Data. Available at www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx.
[8] Technical Support Document, pp. 31-33.
[9] CDPH. 2018. Lead in Candy Testing Data. Available atFwww.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx.

these were manufactured outside of the United States and imported to California. Based on these data and trends showing that detectable levels of lead in candy were more common in earlier years of the CDPH monitoring program, it is reasonable to expect that California manufacturers are already sourcing ingredients of high quality, low lead concentration and would therefore not be significantly impacted by the proposed level.

For any manufacturer that might be impacted, OEHHA believes this proposed naturally occurring level is achievable with minimal cost to the manufacturer by following good agricultural, manufacturing, and procurement practices, or by other currently feasible practices. For example, the lead in chili powder can be significantly reduced by washing the chili peppers before processing and employing simple and relatively low-cost drying procedures[10]. As of 2008, there was an approximately $1.60 (USD) per kilogram cost difference for Mexican candy manufacturers to purchase higher grade chili peppers to produce chili powder with less lead content[11]. This would be the equivalent of an increase in cost ranging from fractions of a cent per candy to no more than three cents per candy for a typical sugar-based product containing chili flavor.

California Candy Retailers

California retailers are not likely to incur additional costs or face difficulty in obtaining candy products containing chili and/or tamarind that meet the proposed lead level of 0.02 ppm, because as discussed above based on CDPH surveillance data California manufacturers do not have detectable levels of lead in their products. Similarly, CDPH surveillance data indicate most imported candies flavored with chili and/or tamarind produced by Mexican manufacturers do not have detectable levels of lead. Thus the proposed level will not result in any significant economic impact on California businesses including the creation or elimination of jobs in California.

OEHHA has reviewed test results for levels of lead present in candies containing chili and/or tamarind that were produced by multiple manufacturers in Mexico. Data from testing of candies produced by nine different manufacturers between 2012 and 2017 for sale into California indicate that 87% of the tested candies had lead concentrations at or below 0.020 ppm. Further,only three candies were

[10] Technical Support Document, pp.4-13.
[11] Sumner, Wil. 2008. CA OEHHA Mexican Candy Workshop. Slide Presentation by Wil Sumner, Sumner Analytical Services, Consultant to the California Attorney General's Office. Los Angeles, CA: March 6, 2008. Workshop Transcript, 56-57.

reported to contain more than 0.030 ppm lead, and no candy was reported to contain more than 0.034 ppm lead[12]. Additional data from testing conducted between 2017 and 2018 of candies containing chili and/or tamarind produced by one of the largest candy manufacturers in Mexico that is a party to the *Alpro Alimento* consent judgement[13] indicate that 94% of these candies had lead concentrations at or below 0.02 ppm. Given that the vast majority of Mexican candies flavored with chili and/or tamarind are already in compliance with the proposed level of 0.02 ppm, and that Mexico is a leading producer of such candies, most importers, distributors or retailers of these candies in California are already sourcing compliant candies from Mexican manufacturers. Further, as the majority of candies flavored with chili and/or tamarind manufactured by both California and Mexican manufacturers offered for sale in California are already compliant with the proposed regulation, California retailers of these candies are unlikely to be significantly impacted.

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

For the reasons noted above, this proposed regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California because very few California manufacturers exist, and none are anticipated to be unable to comply with the proposed standard. Further, of candies produced by Mexican manufacturers that were tested between 2012 and 2017 for compliance with the current standard of 0.10 ppm, none of the candies exceeded that level, and approximately 87% to 94% would be compliant with the proposed level of 0.02 ppm.

Expansion of businesses currently doing business within the State of California

This regulatory action will not impact the expansion of businesses within the State of California. There are very few California manufacturers that produce the type of candies covered by this proposed regulation. Over the past several years CDPH has not reported any detectable lead in chili or tamarind containing candy products produced by California manufacturers[14]. As discussed above, data

[12] Technical Support Document, pp. 31-33.
[13] Technical Support Document, pp. 31-32.
[14] CDPH. 2018. Lead in Candy Testing Data. Available at www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx.

from testing of candies produced in Mexico by nine different manufacturers offered for sale in California indicate that 87% of the tested candies had lead concentrations at or below 0.020 ppm. Further, only three candies were reported to contain more than 0.030 ppm lead, and no candy was reported to contain more than 0.034 ppm lead[15].

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

The proposed regulation would establish a naturally occurring level of lead in candies containing chili and tamarind for the purpose of enforcing other provisions of the law related to the sale or distribution of adulterated candy within California. The proposed regulation will therefore benefit the health and welfare of California residents by setting a science-based naturally occurring level that will be used to ensure that candy sold or distributed in California is not adulterated with lead.

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

The scientific basis for the naturally occurring level of lead in candy containing chili and tamarind is outlined in the technical support document included with this Initial Statement of Reasons and titled *Naturally Occurring Lead in Certain Candies. Candies Flavored with Chili and/or Tamarind* (OEHHA 2020). Citations to documents and other materials relied on for establishing this standard are provided in the technical support document. Copies of these documents and other materials will be included in the regulatory record for this action, and are available from OEHHA upon request. In considering the potential impact of the proposed regulation, OEHHA also reviewed materials presented by an industry consultant during a 2008 public workshop[16] and the results of analyses conducted by CDPH as part of the CDPH Food and Drug Branch monitoring and enforcement activities to prevent the sale of adulterated candy in California[17]. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

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[15] Technical Support Document, pp. 31-33.
[16] Sumner, Wil. 2008. Lead in Mexican Candy: Report Summary of the audits and investigation by Wil Sumner, SA Services. Slide Presentation by Wil Sumner, Sumner Analytical Services. Los Angeles, California: March 6, 2008.
[17] CDPH. 2018. Lead in Candy Testing Data. Available at www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx

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

Health and Safety Code section 110552 requires OEHHA to determine the naturally occurring level of lead in candy containing chili and tamarind and publish that level in regulation. Pursuant to this mandate, OEHHA developed an ingredient-based approach to estimate the sum of naturally occurring lead in candy containing chili and tamarind, which is described above and, in more detail, in the OEHHA 2020 Technical Support Document.

One alternative to the proposed naturally occurring level is to continue with the current default level that was determined by the Attorney General as part of a consent judgment in 2006. However, continuing with the current default level would allow candies to be sold in California that contain lead levels that can be feasibly reduced.

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.

Some commenters on the 2019 proposed rulemaking recommended different lead level limits for specific ingredients in candies containing chili and tamarind based on an apparent misunderstanding that OEHHA's proposed regulation was setting naturally occurring levels for individual ingredients in candy rather than the candy as a whole. For example, one commenter, Frudest, recommended a level of lead in chili powder between 0.120 and 0.180 ppm. However, OEHHA is not establishing naturally occurring lead levels for individual candy ingredients through this regulatory proposal, nor is such an approach authorized by the statute. As discussed above, this regulation establishes the naturally occurring level of lead for candy flavored with chili and/or tamarind, in accordance with

Section 110552, subsections (c)(2) and (c)(3). Regulation of lead levels, including naturally occurring lead, in raw materials or foodstuff other than candy is outside the scope of the statute and this regulatory action.

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. The 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.

One commenter on the 2019 proposed rulemaking, the Center for Environmental Health (CEH), suggested the proposed level is too high. CEH commented that many of the available data sets considered by OEHHA include lead values that are mostly below the level of quantitation and that, in the compiled product data evaluated, over 80% of the tested candies were contaminated with less than 10 parts per billion (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". Therefore, CEH concludes that a "level higher than 10 ppb is not appropriate". The naturally occurring level of lead in candies flavored with chili and/or tamarind proposed by OEHHA, 0.02 ppm or 20 ppb, was not determined from the available data on lead levels in candy products. Rather, the naturally occurring level is based on OEHHA's evaluation of the level of naturally occurring lead that could reasonably be contributed by the following ingredients typically present in these candies: chili peppers and chili powder, tamarind, food-grade salt, sugar, food-grad silicon dioxide, and food-grade titanium dioxide, as described in the 2020 Technical Support Document.

For all these reasons, OEHHA has determined that there is no alternative to the proposed regulation that is less burdensome and equally effective in achieving

the purposes of the regulation in a manner that ensures full compliance with the authorizing statute.

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

For the reasons discussed above, OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulation establishes a naturally occurring level for lead in candy containing chili and tamarind. For the reasons noted above, this proposed regulatory action will not have a significant adverse economic impact on businesses within the State of California because very few California manufacturers of these candy products exist, and none are anticipated to be noncompliant with the proposed standard. Further, of candies produced recently by Mexican manufacturers that were tested for lead content between 2012 and 2018, approximately 87% to 94% would be compliant with the proposed level of 0.02 ppm. Additionally, OEHHA has determined the proposed level is achievable by following good agricultural, manufacturing, and procurement practices, or by other currently feasible practices for California businesses that would not pose significant costs on these businesses.

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

OEHHA has determined that the proposed regulation does not duplicate and will not conflict with federal regulations. Although the FDA has published a guidance document concerning lead levels in candies frequently consumed by children, there are no current federal regulations for naturally occurring levels of lead in candies flavored with chili and/or tamarind.