

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

MARCH 2019

Summary

Health and Safety Code section 110552¹ 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 2019)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). 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

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

² Hereafter referred to as “Technical Support Document”.

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 powder³
- Tamarind
- Food-grade salt
- Sugar
- Food-grade silicon dioxide
- Food-grade titanium dioxide

Chocolate candies are not within the scope of the 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 plausibly considered to be naturally occurring consistent with section 110552.

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:

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.

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 ppm⁴ and 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.

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.” The current default level was determined by the California Attorney General as part of a 2006 consent judgment in *People v. Alpro Alimento Proteinicos* (Los Angeles County Superior Court Case #BC318207 and related cases).

California Candy Manufacturers

Most manufacturers of candies containing chili and/or tamarind are located outside of California, with many located in Mexico. To ascertain the scale of potentially impacted California manufacturers, OEHHA identified approximately 200 candy manufacturers within the state from public databases, industry publications, and trade organizations (e.g., The National Confectioners Association)⁵, and then reviewed available information on products and product lines for over 100 of these candy manufacturers, including all major companies that are based in California or operate manufacturing facilities in the state⁶. Fewer than ten California candy manufacturers evaluated by OEHHA currently produce any candies containing chili and/or tamarind. Further, these few California manufacturers are likely in compliance with the proposed naturally occurring level, based on recent past performance of these types of candies in monitoring studies conducted by CDPH⁷ and an evaluation of recent data for similar candies provided by manufacturers in Mexico⁸.

None of the identified California manufacturers of candies flavored with chili and/or tamarind have had a product with lead detected by CDPH in at least the last five years⁹. 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 these were manufactured outside of the United States and imported to California. Based on these data and trends in detectable levels of lead in candy, which were more common in earlier years of the CDPH monitoring program, it is reasonable

⁵ Shumow, Laura. 2017. Written comments submitted on behalf of the National Confectioners Association in response to the Center for Environmental 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 OEHHA was unable to evaluate many of the smaller California candy manufacturers identified because limited public information was available. Many small 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. 27-29.

⁹ CDPH. 2018. Lead in Candy Testing Data. Available at www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx.

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 procedures¹⁰. 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 content¹¹. 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 as California manufacturers appear to be able to meet this level. 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 nine different manufacturers in Mexico for sale into California between 2012 and 2017¹². Fewer than 8% of these Mexican candies sold in California would have exceeded the proposed level of 0.02 ppm, and no candy was reported to contain more than 0.03 ppm. Given that the vast majority of Mexican candies flavored with chili and/or tamarind are already in compliance, 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 Californian and Mexican manufacturers offered for sale in

¹⁰ Technical Support Document, pp. 5-14.

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.

¹² Technical Support Document, pp. 27-29.

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 those 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 92.3% would have been in compliance with the proposed level.

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 because there are very few California manufacturers that produce the type of candies covered by this proposed regulation and the volume of sales is low compared to other candies sold in California. As discussed above, OEHHA was able to evaluate the types of candies made by over 100 of the approximately 200 candy manufacturers based in California, and fewer than ten companies currently produce any candies containing natural chili and/or tamarind.

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*. Citations to documents relied on for establishing this standard are provided in the technical support document. Copies of these documents 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 workshop¹³ 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 California¹⁴. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

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

No reasonable alternatives to this proposed amendment have been proposed to OEHHA. 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. The 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. Continuing with the current default level would allow candies to be sold in California that contain lead levels that can be feasibly reduced.

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

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

13 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.

14 CDPH. 2018. Lead in Candy Testing Data. Available at www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx

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 exist and none are anticipated to be noncompliant with the proposed standard. Further, of those candies produced by Mexican manufacturers that were tested between 2012 and 2017 for compliance with the current standard of 0.10 ppm, less than 8 percent of the candies exceeded the proposed level of 0.02 ppm, and none contained more than 0.03 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.