



August 17, 2020

***Provided Electronically to: <https://oehha.ca.gov/comments> and  
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1001 I Street  
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**Re: Public Comments on Proposed Title 27, Section 28500 Rulemaking**

These comments are submitted on behalf of the National Confectioners Association (NCA) and its members with respect to the Office of Environmental Health Hazard Assessment's (OEHHA's) renewed request for public comment on OEHHA's proposal to adopt a 0.020 part per million (ppm) standard under Section 25800 of Title 27 of the California Code of Regulations as the "naturally occurring" lead level in non-chocolate candy containing chili or tamarind (Mexican Candy).

NCA submitted comments on OEHHA's prior, parallel proposal on May 20, 2019, which are incorporated herein with their prior attachments by reference.<sup>1</sup> OEHHA's new Initial Statement of Reasons (ISOR) and technical support document reference NCA's prior comments, but appear to ignore their substance and cast aside the underlying data that was submitted to substantiate them. In light of its cooperation with the agency on other matters, 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.

**Summary.** NCA again requests that OEHHA revise its proposed Section 25800 regulation. Specifically, OEHHA should:

1) Set a substantially higher "naturally occurring" lead level for Mexican Candy that is more reflective of what the industry has shown it can and cannot achieve based on the most recent production data available and which accounts for the use of commercially-sourced

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<sup>1</sup> We would be happy to resubmit these in electronic or hard copy again if you so request.

ingredients presenting the unique flavor profiles characteristic of Mexican Candy (such as Guajillo and Chilaca chilies and estandar sugar);

2) Set the Section 25800 level as an average to be applied to each Mexican Candy product line based on a specified minimum number of samples to be collected and analyzed on a specified periodic (e.g., annual, semi-annual) basis and, if the agency believes it appropriate and necessary, as subject to a not-to-exceed maximum reflecting at least two standard deviations from that mean; and

3) Set the effective date of the new Section 25800 level out by at least one year following its publication as a final rule.

**Background.** The NCA is the not-for-profit trade association of the confectionery industry. NCA represents more than 250 companies that manufacture chocolate, confectionery, gum and mints in the United States and another 250 companies that supply those manufacturers. The majority of our members are small and medium-sized companies. The confectionery industry includes hundreds of small, family-owned businesses that pass on candy-making expertise from generation to generation. Nearly 200 confectionery manufacturers are based in and/or have facilities and operations in California. For every job that is created in confectionary, another seven are supported in related industries.

On behalf of its members who make or distribute Mexican Candy, NCA was involved in the development and passage of the legislation that resulted in Health and Safety Code Section 110552, the U.S. Food and Drug Administration's (FDA's) concurrent adoption of a lead guideline for candy frequently consumed by children, and the California Attorney General's (Cal-AG's) efforts to implement the *Alpro Alimento* consent judgment.<sup>2</sup> NCA also coordinated with its counterpart trade association in Mexico with regard to the adoption of the Section 110552 legislation and the negotiation and implementation of the *Alpro Alimento* consent judgment and has worked with it to provide outreach and education on lead issues and good manufacturing practices to a broad cross-section of Mexico-based confection manufacturers.

### ***Specific Comments.***

- 1. OEHHA's renewed proposal is based on limited and/or irrelevant data and does not reflect data better characterizing actual Mexican-style candy production and the key commercially-sourced ingredients used to make it.**

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<sup>2</sup> *People et al. v. Alpro Alimento Proteinicos, et al.*, Los Angeles Superior Court No. BC 318207, consent judgment approved and entered on August 3, 2006 and available at [https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/People\\_v\\_Alpro\\_Alimentos\\_Proteinicos.pdf](https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/People_v_Alpro_Alimentos_Proteinicos.pdf)

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.

Indeed, 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.<sup>3</sup>

OEHHA's reliance on its additive ingredient approach instead of direct data on the full range of finished Mexican candy products available to consumers also misses the mark by brushing aside key data.<sup>4</sup> For example, 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

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<sup>3</sup> 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.

<sup>4</sup> 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. But here, OEHHA appears to be doing just that – it simply asserts that its data is somehow superior to that submitted by industry due solely to the analytic methodology used; however, 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.

Attorney General-certified chili powder processors in Mexico, in favor of reliance on data from non-commercially prepared chilies.

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. 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.

OEHHA's reliance on the results of its own testing on chilies is therefore misplaced and inappropriate for a naturally occurring determination based on lowest level feasible criteria. 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.

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.

**2. OEHHA is incorrect that setting the Section 25800 level based on an average is just an enforcement issue to be addressed by others in the future.**

In addition to casting aside the industry's data, 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>.<sup>5</sup>

**3. 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

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<sup>5</sup> 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/cmr/notice-proposed-rulemaking-adoption-section-25505-exposures-listed-chemicals>

interim level established by the Attorney General in the *Alpro Alimento* consent judgment and adjust their sourcing, quality control and testing programs accordingly.<sup>6</sup> 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.<sup>7</sup> 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.

**Conclusion:** California consumers have and continue to enjoy a wide variety of NCA members' confectionary products, including Mexican Candy, all of which comply fully with FDA and California food safety requirements and guidelines. These products do not contain lead at levels that would render them adulterated or toxic based on exposure analyses conducted by both the federal and state governments. 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. In addition, 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.

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<sup>6</sup> For the reasons stated above, OEHHA's assumption that virtually all Mexican-style candies already can consistently meet its proposed 0.02 ppm lead level is erroneous.

<sup>7</sup> 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.

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We very much appreciate the opportunity to offer our views and comments on this issue. Please do not hesitate to contact me if NCA can help provide further information that would be helpful to OEHHA with regard to these issues.

Sincerely yours,

A handwritten signature in cursive script that reads "Debra Miller".

Debra Miller  
Senior Vice President, Scientific & Regulatory Affairs  
National Confectioners Association