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May 20, 2019

*Provided Electronically to: <https://oehha.ca.gov/comments> and
Monet.Vela@OEHHA.ca.gov*

Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Public Comments on Proposed Title 27, Section 28500 Rulemaking

To Whom It May Concern:

I am writing on behalf of the National Confectioners Association (NCA) and its members with respect to the Office of Environmental Health Hazard Assessment's (OEHHA's) 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).

Summary. NCA requests that OEHHA revise its proposed Section 25800 regulation to:

- 1) Set a higher "naturally occurring" lead level for Mexican Candy that is more reflective of all available data and better accounts for the upper end of the range of natural variation in the lead levels in Mexican Candy and associated lead-bearing ingredients, particularly those used to compose the unique flavor profiles emphasized by Mexico-based manufacturers;
- 2) Avoid discrimination against Mexican manufacturers and ingredient processors to the extent they have demonstrated compliance with the California Attorney General's good manufacturing and supply chain requirements, by establishing a "naturally occurring" lead level that is based on the upper end of the range of the data measuring lead in their products/ingredients, not just data measuring lead in products/ingredients sourced from California;

3) To help account for inherent variability, follow the Attorney General's prior expert panel-recommended approach in specifying that the measurement of the lead level in Mexican Candy may be calculated for purposes of demonstrating compliance with the Section 28500 "naturally occurring" standard as an average rather than as a single sample maximum; and

4) Adopt a multi-year, phase-in/step-down compliance schedule to allow relevant confectionary companies, especially those based in Mexico, to be educated on and plan and manage the transition from the interim "naturally occurring" level to that adopted in 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.¹ 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 proposal does not reflect the full range of data the agency examined and does not reflect data concerning several of the key ingredients used to make Mexican Candy.** The technical support document upon which the proposed rule is predicated indicates that the lead level in washed and dried Guajillo chili ranged as high in the agency's limited study as 0.054 ppm, yet

¹ *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

OEHHA ignores this information and erroneously assumes that the chili ingredient used in Mexican Candy can always be sourced at <0.010 ppm. Flavors of different types of chili are not interchangeable so even if other types of chili, such as Anaheim, appear to be available on a consistent basis at <0.010 ppm, the same is not the case for Guajillo and Chilaca chili, which are used by Mexican manufacturers to create a key Mexican Candy flavor profile.

OEHHA also does not take into account its own study data on chili powder made from pre-washed and dried chilis that are used for Mexican Candy. The technical support document indicates that even recently measured levels in chili powder made from pre-washed and dried chilis ranged as high as 0.107 ppm, indicating substantial inherent variation in the concentration of lead in these chili powder batches. Indeed, even this broader range is not fully indicative. Analysis of chili powder made from a Guajillo/Chilaca chili blend by the largest suppliers of this key ingredient in Mexico – companies that have been certified as meeting the good manufacturing practices requirements specified by the California Attorney General in the *Alpro Alimento* consent judgment – indicate that, even in relatively recent years, mean lead levels of this key ingredient are annually on the order of 0.08-0.1 ppm and that the levels from individual samples can range as high as 0.3-0.5 ppm (see Attachments). As it is a critical ingredient for Mexican manufacturers, the data on Guajillo/Chilaca chili powder needs to be accounted for in establishing the final Section 28500 “naturally occurring” level.

Likewise OEHHA’s consideration of data on sugar is incomplete and fails to account for the difference between types of sugars, including “estandar” sugar which, like Guajillo/Chilaca chili powder, is needed by candy manufacturers in Mexico to create the unique flavor profiles of their products. As a practical matter, the use of estandar and other sugars that can be sourced in Mexico is also necessary as a result of trade restrictions on imported sugar imposed by the Mexican government. While OEHHA found that mean levels of lead in highly refined sugar available in California averaged 0.003 ppm, the average for estandar and other sugars sourced in Mexico is on the order of 0.010-.0.020 ppm and ranges as high as 0.030-0.050 ppm (see Attachments). As the sugar that can be sourced in Mexico is often a significant proportion of the ingredients comprising Mexican Candy, the data characterizing it must also be accounted for in establishing the final Section 28500 “naturally occurring” level.

2. **OEHHA’s proposal for Section 28500 discriminates against manufacturers in Mexico who have met the California Attorney General’s manufacturing and supply chain requirements.** OEHHA also ignores recent data discussed in the technical support document demonstrating that almost 8% of Mexican Candy

manufactured in Mexico in compliance with the good manufacturing and supply chain requirements imposed by the Attorney General through the *Alpro Alimento* consent judgment present lead levels in excess of the agency's proposed 0.020 ppm Section 28500 regulatory level. The Initial Statement of Reasons goes to lengths to emphasize that the proposed rule will not burden *California* candy manufacturers because their recent data indicate an ability to consistently meet the 0.020 ppm level, but it fails to consider the discriminatory burden the proposed rule is likely to impose on Mexican manufacturers. In fact, data from one of the largest manufacturers in Mexico that is a party to and has continuously addressed the requirements of the *Alpro Alimento* consent judgment suggests that approximately 10% of products it tested in recent years would be found at or in excess of the 0.020 ppm level, with the upper end of the range of results extending to 0.060 ppm (see Attachment). The agency's approach therefore raises serious concerns for Mexican manufacturers, including under the dormant Commerce Clause of the U.S. Constitution which prohibits California from adopting discriminatory regulations to favor in-state producers over out-of-state competitors. At a minimum, OEHHA's failure to account for the upper end of the range of data reflecting Mexican Candy made in compliance with the *Alpro Alimento* consent judgment's requirements represents a significant gap in the agency's analysis.

3. **OEHHA should set the "naturally occurring" regulatory level based on an average subject to an outlier limitation.** Based on the recommendation of an expert panel assembled by the California Attorney General, the *Alpro Alimento* consent judgment allows for compliance with its Proposition 65-related lead standard (which concurrently served as the interim standard for purposes of Health and Safety Code Section 110552) to be determined based on an average of the measured lead levels detected in multiple samples of a representative product obtained within a 6 month period once ongoing compliance was first established based on quarterly production periods. To further account for inherent variability, the judgment establishes an "outlier limitation" for single sample maximums at 150% of the compliance level. (See *Alpro Alimento* consent judgment at Section 3.1.6.) OEHHA should follow the approach recommended by the multi-disciplinary expert panel the Attorney General relied on and conform its Section 28500 proposed rule accordingly.
4. **OEHHA should facilitate compliance, particularly by Mexican manufacturers, by phasing in its final approach through a series of step-downs over a period of several years.** The interim Health and Safety Code Section 110552 rule has been in effect since 2006 and has become institutionalized as a reference point by candy manufacturers and ingredient

suppliers in Mexico. In addition to adjusting its proposed Section 28500 standard in response to the issues described above, OEHHA needs to recognize that a significant amount of time and effort will be needed to re-educate the Mexican manufacturing and ingredient processor community on a very significant change in their California-imposed Mexican Candy compliance requirements. (Indeed, it took the Attorney General, the Environmental Health Coalition, and NCA several years of collective effort to educate the bulk of Mexican manufacturers on, and bring them under and into compliance with, the *Alpro Alimento* consent judgment.)

For example, to help re-orient the Mexican manufactures to significantly more stringent requirements than they have faced from California over the past decade and facilitate a transition that does not result in a significant percentage of their products being found in non-compliance if test results reflect the upper end of the range of natural variation due to key flavor profile ingredients, OEHHA might initially implement a 50% reduction from the interim level and its associated outlier limitation, resulting in the standard being set at 0.050 ppm as an average and 0.075 as a single sample maximum for the remainder of this year and 2020. The agency could then, in a second step, implement, as of 2021, a 60% reduction from the current level, resulting in the standard being set at 0.040 ppm as an average and 0.060 ppm as the single sample maximum. A 70% reduction from the current level could then be implemented in a third and last step effective at the end of 2022, under which a final standard of 0.030 ppm as an average and 0.045 ppm as the single sample maximum may, by then, be more feasibly complied with for those that use Guajillo/Chilaca chili and estandar sugar in their candy.

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, including those which address lead. 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 shares the California Legislature's stated goal of reducing lead in Mexican Candy as much as possible so that any lead present reflects what is naturally occurring, establishment of a reduced level by OEHHA must account for and not ignore the full range of available data, including data from confectioners and ingredient processors in Mexico. In addition, natural variation weighs heavily in favor of features like regulating compliance based on an average of multiple samples and with a higher "outlier" limitation. Finally, a multi-year, phased in approach to lowering the compliance levels is necessary to allow the full range of suppliers and confectioners, especially those in Mexico, to become educated and adjust their management of ingredient supply chains and quality control practices accordingly.

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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 black ink, appearing to read "Debra Miller". The signature is fluid and cursive, with the first name "Debra" being more prominent than the last name "Miller".

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