



1101 30th Street NW, Suite 200
Washington, DC 20007
(202) 534-1440 | www.CandyUSA.com

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

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

Re: Proposition 65 Rulemaking: Public Comments on Proposed Title 27, Section 25505

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) request for public comments on OEHHA's proposal to add a new Section 25505 to the Proposition 65 implementing regulations concerning exposures to listed chemicals in cooked or heat processed foods. NCA appreciates and generally supports OEHHA's proposed rule, but requests several clarifications and refinements, as discussed below. NCA also supports and joins in the comments of the coalition led by the California Chamber of Commerce and Consumer Brands Association relative to this rulemaking.

Background and Basis for NCA's Comments and Requests. 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 NCA's 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. Confectionery companies employ more than 6,000 people in the state directly with manufacturing jobs, with over 2,100 additional related jobs for brokers and nearly 14,000 related jobs in the retail sector.

Notable cocoa bean processors and chocolate companies with major operations or headquarters in California include Barry Callebaut USA, Blommer Chocolate, Guittard, Lindt-Ghirardelli, and See's, among others. Annual shipments of cocoa and chocolate from

California are valued at more than \$1.8 billion. Numerous clinical trials and meta-analyses have shown associations between cocoa and dark chocolate intake and cardiovascular health, and a 2016 review shows that cocoa antioxidants may also have chemopreventive effects on retarding the development of colon cancer. (See Appendix A.) The roasting process for cocoa beans is also critical to assure public health because it eliminates microbiological contamination—in addition to maximizing flavor/palatability, roasting is a validated process to mitigate Salmonella contamination in cocoa beans and kills mold and other pathogenic bacteria, such as Listeria, E. Coli, and Staphylococcus. In addition, roasting cocoa beans is essential in meeting the needs of consumers – it is what creates the characteristic “chocolate taste.” Likewise, cooking and other heat processing is essential to creating the taste profiles of numerous other confections and confectionary coatings, including caramels and toffees, among others.

Chocolate and other confection companies have previously been confronted with a significant number of Proposition 65 bounty hunter claims concerning acrylamide in cocoa, chocolate and, recently, other confectionary treats.¹ While some plaintiffs have not gone forward, a number of 60-day notices have resulted in litigation against confectionary companies. As of this date, at least six of the filed cases have resulted in consent judgments. These settlements constitute a sufficient basis for OEHHA to establish a subsection (d) safe harbor level for confections as part of this rulemaking based on the same rationale it has applied to other foods for which it has proposed such safe harbor levels.²

Several of these consent judgments apply a 225 part per billion (ppb) warning threshold/reformulation standard (to be determined as an average) to all “chocolate almond products” regardless of whether the almonds are in whole, sliced, or in further processed form. Two of the consent judgments also apply the same 225 ppb level beyond chocolate almond products to also include almonds with non-chocolate confectionary coatings (as well as to almonds with non-confectionary coatings).

<https://oag.ca.gov/system/files/prop65/settlements/2019-01271S8756.pdf>;
<https://oag.ca.gov/system/files/prop65/settlements/2019-01941S8557.pdf>. In addition, two further consent judgments have extended the same 225 ppb threshold to confections composed of chocolate and walnuts and to chocolate confections with other inclusions that undergo cooking or heat processing, including peanuts in various forms, wafers, and toasted

¹ See e.g., <https://oag.ca.gov/system/files/prop65/notices/2020-02505.pdf>;
<https://oag.ca.gov/system/files/prop65/notices/2020-01915.pdf>

² Several of the consent judgments in question are relatively recent, only began receiving court approvals this summer, and have yet to be posted in their approved form on the Attorney General’s website such that OEHHA may not have been aware of them at the time it was formulating its proposed rule; however, based on the rationale presented in the ISOR, they now serve as appropriate justification for NCA’s requests.

rice. See <https://oag.ca.gov/system/files/prop65/settlements/2019-01243S8783.pdf>; <https://oag.ca.gov/system/files/prop65/settlements/2019-01312S8459.pdf>.³

NCA's Comments and Requests.

1. NCA appreciates and generally supports OEHHA's proposed rule and believes it is well within the agency's authority to adopt in furthering the purposes of Proposition 65 and the intent of the voters that adopted it.

2. NCA would appreciate OEHHA clarifying in a final statement of reasons that:

(a) a showing of the "lowest level currently feasible" in future proceedings is to be based on the totality of evidence concerning a wide variety of factors and determined on a case-by-case basis given the nature and characteristics of the particular food product and business involved, including its relative size and role in the chain of commerce,

(b) the ppb numbers being proposed for acrylamide in specified types of foods in subsection (d) of the proposed regulation are safe harbor levels and businesses therefore will have the option to rely on them or to make an evidentiary showing to establish the lowest level currently feasible applicable to them given their specific food product and commercial situation.

3. With respect to the proposed 225 ppb safe harbor level for acrylamide in almonds, including chocolate-covered almonds, NCA requests that OEHHA clarify that it applies to all chocolate confections containing almonds as an inclusion, including in forms other than whole nuts (i.e., to "chocolate almond products" as several of the prior consent judgments specify). Since several of the recent consent judgments do so, NCA further requests that OEHHA expand this safe harbor category to include almonds covered with confectionary coatings other than chocolate that also undergo cooking or heat processing, such as caramel or toffee.

4. As several of the consent judgments recently approved by the Alameda County Superior Court extend the 225 ppb average acrylamide level beyond chocolate almond products,⁴

³ NCA notes that a further consent judgment has employed a higher, 280 ppb, acrylamide threshold to a chocolate-covered graham cracker confection made by a candy company. <https://oag.ca.gov/system/files/prop65/settlements/2019-01423S8499.pdf>.

⁴ See <https://publicrecords.alameda.courts.ca.gov/PRS/Case/CaseDetails/UkcyMDA2NDcxNQ%3d%3d>;

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NCA requests that OEHHA adopt an additional subsection (d) safe harbor level for chocolate containing inclusions other than almonds that have undergone cooking or heat processing (such as walnuts, peanuts, raisins, wafers, caramel, toffee, toasted rice, etc.).

* * * * *

NCA very much appreciates the opportunity to offer its views and comments on this much needed proposed rule. Please do not hesitate to contact me if we can help provide further information that would be helpful.

Sincerely yours,

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

Appendix A

1. Maria A. Martin, Luis Goya, and Sonia Ramos. "Potential for Preventative Effects of Cocoa and Cocoa Polyphenols in Cancer, *Food and Chemical Toxicology*, Vol. 56, pp. 336-351 (Jun. 2013). <https://www.sciencedirect.com/science/article/pii/S0278691513001294?via%3Dihub> (Cocoa prevents chronic inflammation and oxidative damage affecting carcinogenesis. Cocoa increases serum antioxidant status and apoptosis of cancer cells. Moderate cocoa or dark chocolate consumption may reduce cancer risks.)
2. Maria A. Martin, Luis Goya, and Sonia Ramos. "Preventative Effects of Cocoa and Cocoa Antioxidants in Colon Cancer," *Diseases*, (22 Jan. 2016). <https://www.mdpi.com/2079-9721/4/1/6/htm> (Daily consumption of small amounts of flavanols and procyanidins from cocoa or chocolate, together with an ordinary dietary intake of flavonoids, would constitute a natural approach to potentially prevent colon cancer with minimal toxicity.)
3. Gertraud Maskarinec, "Cancer Protective Properties of Cocoa: A Review of the Epidemiologic Evidence, *Nutrition and Cancer*, 61:5, pp. 573-579 (Feb. 2009). <https://www.tandfonline.com/doi/full/10.1080/01635580902825662?scroll=top&needAccess=true> (Cocoa and chocolate products may have beneficial health effects against oxidative stress and chronic inflammation, risk factors for cancer and other chronic diseases.)
4. Daniela Mastroiacovo et al. "Cocoa Flavanol Consumption Improves Cognitive Function, Blood Pressure Control, And Metabolic Profile in Elderly Subjects: The Cocoa, Cognition, And Aging (Cocoa) Study—A Randomized Controlled Trial," *The American Journal of Clinical Nutrition*, Vol. 101, Issue 3, pp. 538-48 (Mar. 2015). <https://academic.oup.com/ajcn/article/101/3/538/4569408> (Regular cocoa flavanols consumption can reduce some measures of age-related cognitive dysfunction, possibly through an improvement in insulin sensitivity.)
5. Franz H. Messerli, M.D. "Chocolate Consumption, Cognitive Function, and Nobel Laureates," *The New England Journal of Medicine*, 367: 1562-1564 (Oct. 2012). https://www.nejm.org/doi/full/10.1056/NEJMon1211064?url_ver=Z39.88-

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2003&rfr_id=ori%3Arid%3Aacrossref.org&rfr_dat=cr_pub%3Dpubmed (Chocolate consumption improves brain function.)

6. A. Spadafranca, et al. "Effect of Dark Chocolate on Plasma Epicatechin Levels, DNA Resistance to Oxidative Stress, and Total Antioxidant Activity in Healthy Subjects," *British Journal of Nutrition*, 103: 1008-1014 (2010). https://www.cambridge.org/core/services/aop-cambridge-core/content/view/274A6585B6DE4024CEACF8DA2D0BD726/S0007114509992698a.pdf/effect_of_dark_chocolate_on_plasma_epicatechin_levels_dna_resistance_to_oxidative_stress_and_total_antioxidant_activity_in_healthy_subjects.pdf (Dark chocolate consumption is encouraging in the field of diet therapy and obesity, and should be considered in weight loss programs.)

7. Robyn Stoller, "Cocoa Can Help Fight Cancer," *National Foundation for Cancer Research*, Aug. 15, 2016. <https://www.nfcr.org/blog/blogcancer-fighting-cocoa/> (Cocoa can help fight cancer.)

8. S. Shah, et al. "Use of Dark Chocolate for Diabetic Patients: A Review of the Literature and Current Evidence," *Journal of Community Hospital Internal Medicine Perspectives*, (Oct. 2017) 7(4): 218-221. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5699188/pdf/zjch-7-1361293.pdf> (Cocoa may be useful in slowing the progression to type 2 diabetes and ameliorating insulin resistance in metabolic syndrome. Additionally, results from several small studies indicate that cocoa may also have therapeutic potential in preventing cardiovascular complications in diabetic patients.)

9. Chun Kwok et al. "Habitual Chocolate Consumption and Risk of Cardiovascular Disease Among Healthy Men and Women," *Heart* 2015; 101 1279-1287. <https://heart.bmj.com/content/101/16/1279> (Higher chocolate (both dark and milk) consumption associated with a lower risk of hospitalization or mortality due to coronary heart disease.)

10. Anthony Komaroff. "Is Chocolate Heart-Healthy?" *Harvard Health Letter*. (Aug. 2017). <https://www.health.harvard.edu/heart-health/is-chocolate-heart-healthy> (Chocolate consumption reduces atrial fibrillation.)

11. Ulrike Heinrich, et al. "Long-Term Ingestion of High Flavanol Cocoa Provides Photoprotection against UV-Induced Erythema and Improves Skin Condition in Women." *The Journal of Nutrition*, Vol. 136, Issue 6, pp. 1565-1569 (Jun. 2006). <https://academic.oup.com/jn/article/136/6/1565/4664397#111002051> (Consumption of a flavanol-rich cocoa provides photoprotection against UV rays.)

12. Ki Won Lee, et al. "Cocoa Has More Phenolic Phytochemicals and a Higher Antioxidant Capacity than Teas and Red Wine." *Journal of Agricultural and Food Chemistry*, 2003; 51, 25, pp. 7292-7295. <https://pubs.acs.org/doi/10.1021/jf0344385> (Cocoa has more chemopreventive agents based on antioxidant capacities than black tea, green tea, and red wine. Cocoa is more beneficial to health than teas and red wine in terms of its higher antioxidant capacity.)

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A handwritten signature in black ink, appearing to read "Debra Miller". The signature is fluid and cursive, with the first name "Debra" and last name "Miller" clearly distinguishable.

Debra Miller, PhD
SVP, Scientific & Regulatory Affairs
National Confectioners Association (NCA)