



August 5, 2019

Via Email to P65Public.Comments@oehha.ca.gov and monet.vela@oehha.ca.gov (Subject: “Calculating Exposure”)

Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, CA 95812

Re: **Comments on OEHHA’s Revised Proposal for Calculating Exposure for Proposition 65 Reproductive Toxicants in Food (Title 27, Section 25821(a))**

To Whom It May Concern:

This is submitted on behalf of the National Confectioners Association (NCA) and its members with respect to the California Office of Environmental Health Hazard Assessment’s (OEHHA’s) revised proposal to amend Sections 25821(a) of Title 27 of the California Code of Regulations. NCA also endorses and incorporates by reference the comments being submitted on OEHHA’s revised proposal by the California Chamber of Commerce and Coalition.

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.

Comments. NCA previously submitted extensive public comments on OEHHA’s proposal to amend Sections 25821(a) and (c) of Proposition 65’s regulations on November 29, 2018, which are incorporated herein by reference. Those comments, which in part addressed OEHHA’s previous proposal to address Section 25821(a), have not yet been responded to so as to unfairly constrain NCA’s (and others’) ability to comment on OEHHA’s newly revised proposal for this section of the Proposition 65 regulations.

In part, it appears that OEHHA's newly proposed revisions are intended to make Section 25821(a)'s proposed requirement that the level in question for a chemical listed under Proposition 65 for reproductive harm effects, when present in a food product, be separately determined based on test results from each manufacturing facility that may have produced the food product made available to consumers in California such that, when more than one manufacturing facility is used to produce that consumer product, the test results from them may not be combined with the test results from the other relevant manufacturing facilities and averaged into a single level in question. We further understand that it is OEHHA's intent that the proposed new rule reach only to facilities that produce the food product offered to consumers in California and not upstream to ingredient or commodity suppliers related to the consumer product in question, such that such suppliers' test results may still utilize averaging if multiple ingredient processing facilities or farms are involved.

NCA applauds OEHHA for narrowing the reach of its Section 25821(a) proposal in this regard (and with regard to OEHHA's decision to drop its prior proposal to mandate use an arithmetic mean), but does not think the proposed revisions have gone far enough in addressing NCA's previously-stated concerns concerning (a) the basis for this rule in terms of the structure of the statute as enacted by the voters, and (b) the lack of a scientific/empirical basis for OEHHA's assumptions that food manufacturing facilities add listed chemicals to the food products they produce and do so in amounts that vary more than the range of inherent variation of the chemical in the food product or constituent ingredients/commodities themselves.

In addition, as with its initial proposal, no analysis of the costs to be imposed on manufacturers of consumer food products, including confections, has been provided with the proposed revised rule, even though the cumulative cost of establishing a testing program for each consumer food product manufactured at each facility is still likely to be economically significant. This is particularly problematic in the absence of OEHHA specifying parameters for a reasonable and affordable amount of testing that will be deemed sufficiently representative for purposes of establishing the level in question for a Proposition 65 defense, and it further specifying that private plaintiffs' claims concerning a food product are necessarily limited to those coming from the particular facility that manufactured the consumer food product based on information set forth in or appended to their 60-day notice, such as the manufacturing code that appears on the container or label of the consumer food product they are seeking to put at issue.

We appreciate the opportunity to offer our views and comments on these issues and again strongly urge to OEHHA withdraw or, at least, further constrain its proposal as currently revised.

Monet Vela
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Sincerely yours,

A handwritten signature in cursive script, appearing to read "Debra Miller".

Debra Miller, Ph.D.
Senior Vice President of Scientific & Regulatory Affairs
National Confectioners Association