CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

December 3, 2018

VIA ELECTRONIC SUBMISSION

Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010, MS 23 11F
Sacramento, California 95812-4010

Comments sent electronically to: P65Public.Comments@oehha.ca.gov

Re: Proposed Amendments to Title 27, California Code of Regulations Section 25821(a) and (c): Calculating the "Level in Question for a Food Product and the Intake by the Average Consumer of a Product"

Dear Ms. Vela:

Herein, the Consumer Healthcare Products Association (CHPA), the 137-year-old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements (chpa.org), provides feedback on the Office of Environmental Health Hazard Assessment (OEHHA) proposal to modify Section 25821, subsections (a) and (c)(2), Level of Exposure to Chemicals Causing Reproductive Toxicity. CHPA believes that these proposals are not consistent with the longstanding use of the average exposure-based assessment under Proposition 65. Further, OEHHA has not identified a need for such changes, stating only that these represent a "clarification" to the existing regulations. As such, we do not believe these proposals should be adopted.

The first of these proposed changes would amend subsection (a) to clarify that where a business presents evidence for the "level in question" of a chemical listed as causing reproductive toxicity in a food product based on the average of multiple samples of that food, the level in question may not be calculated by averaging the concentration of the chemical in food products from different manufacturers or producers, or that were manufactured in different facilities from the product at issue.

Currently, Section 25821(a) does not specify procedures for determining the concentration of a listed chemical in a food product. OEHHA has claimed that a "*lack of clarity on this issue has led to the incorrect conclusion that the existing regulations allow averaging of the measured concentrations of a listed chemical in a food product across products manufactured by different manufacturers, and from manufacturing facilities in different states and countries*."

Prohibiting averaging of concentration across different manufacturing facilities will likely lead to unreliable estimates of concentration levels and increase uncertainty and costs for businesses while at the

same time not providing any tangible benefit to consumers. OEHHA also does not provide the necessary detail of what constitutes a "manufacturing facility", which will likely lead to confusion within the business community and a situation where companies provide a warning simply to avoid litigation. Businesses should be allowed to decide the most appropriate measures for obtaining representative concentration levels on a case-by-case basis and to defend those determinations if challenged. We do not believe OEHHA should adopt this proposal.

The second proposed change would modify subsection (c)(2) to clarify that, when determining whether exposure to a reproductive toxicant in a consumer product requires a warning, that the reasonably anticipated rate of intake or exposure from consumer products to a chemical listed as causing reproductive toxicity be calculated as the arithmetic mean of the rate of intake or exposure for product users. Here, OEHHA claims that "*Clarifying that the arithmetic mean of the intake or exposure level for users of a consumer product is the appropriate approach helps the responsible business to correctly determine the rate of intake or exposure for average users of the consumer product and properly decide whether a warning is required for a given exposure*."

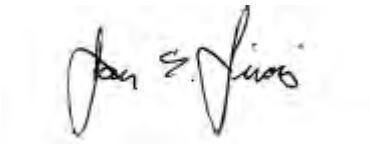
Again, as with OEHHA's proposal to forbid the use of averaging across either different manufacturing facilities or products from different manufacturers or producers, it is not clear what problem is being addressed in this instance. Use of the arithmetic mean is not consistent with sound principles of statistics and data evaluation. The underlying data should be used as a basis to determine whether the arithmetic mean, geometric mean or some other measure should be used to best represent the average. For data whose distribution does not follow a bell-shaped curve, estimates based on the geometric mean may be more appropriate since the geometric mean is less influenced by the highest and lowest values. Use of the arithmetic mean would also contradict the Beech Nut ruling, where geometric mean was declared to be more appropriate in calculating the reasonably anticipated rate of intake for average users.

Use of the arithmetic mean is also not supported by other risk assessment agencies/regulatory bodies. Indeed, the Centers for Disease Control and Prevention has specific guidance addressing the use of the geometric mean (as opposed to the arithmetic mean) for instances where the data distribution is skewed. Nearly a decade ago in the mercury canned tuna case the California Attorney General argued that, when determining the appropriate rate of exposure, the median should be used instead of the arithmetic mean, as use of the arithmetic mean could lead to "a deceptive idea of who is typical". Lastly, as described in more detail in comments submitted by the California Chamber of Commerce (which CHPA has signed onto), use of the arithmetic mean would lead to overwarning consumers. As such, we do not believe that OEHHA should adopt this proposal.

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa

CHPA and our member companies appreciate the opportunity to comment on this process. Should you have any questions, please do not hesitate to contact me.

Regards,



Jay E. Sirois, Ph.D.
Senior Director, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

1625 Eye Street, NW, Suite 600 | Washington, DC 20006 | T 202.429.9260 | F 202.223.6835 | chpa.org | @chpa