



FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION OF THE UNITED STATES

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6 June 2016

Via E-Mail (P65PublicComments@oehha.ca.gov)

Ms. Monet Vela
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

Re: Proposed Changes to
Proposition 65, Article 6
Clear and Reasonable
Warning Regulations

Dear Ms. Vela:

The Flavor and Extract Manufacturers Association of the United States (“FEMA”) appreciates the opportunity to comment on the proposed regulations released for public comment by the Office of Environmental Health Hazard Assessment (“OEHHA”) on May 20 2016.

FEMA, founded in 1909, is the trade association for the United States flavor industry. FEMA’s membership includes companies that create and market flavors for addition to food and other consumer products, companies that use flavors in their products, and others with an interest in the flavor industry. FEMA’s flavor-manufacturing members market more than 95% of the flavors added to foods in the United States. A primary mission of FEMA is to assure the safety of flavoring substances through its FEMA GRAS program, long recognized as the standard of excellence in food industry safety assessment programs. Foods containing flavors are sold in large volumes throughout California with many food products containing flavors manufactured in California.

The proposed regulations appear to fundamentally expand Proposition 65 warning requirements in an unworkable and unnecessary direction. Food ingredients not sold to the public should not be directly subject to the Proposition 65 warning requirement. Sellers of food ingredients do not know: (1) what products their ingredients are used in, (2) how much of their ingredient is used in a particular final product, or (3) how much of or how often a particular

food is consumed. Thus, they are not in a position to analyze whether a warning is required. Nevertheless, it appears that OEHHA proposes to include food ingredients in the definition of consumer products via language added to proposed section 25600.1(d). This would place a totally unworkable, unjustified burden on food ingredient suppliers, who normally have no relationship with or understanding of how their products are used or where their products are sold at retail and thus have no ability to label what the consumer sees or communicate with retailers.

FEMA further notes that this significant reversal of thirty years of Proposition 65 implementation has been proposed with no initial statement of reasons and was not signaled by the November 2015 notice of the Article 6 amendments at issue, and therefore violates the California Administrative Procedure Act, including Government Code section 11346.8.

FEMA respectfully requests that the phrase "or component part thereof" be removed from the definition of "Consumer Product" in proposed section 25600.1.

FEMA has not been able to identify any public comment requesting that "consumer product" be defined to include all of the separate component parts of consumer products. Thus, FEMA has asked OEHHA whether any such comment was submitted, and OEHHA has not identified one. For this additional reason, FEMA requests that OEHHA return to the definition of consumer product that it proposed on November 27, 2015.

Sincerely,

A handwritten signature in black ink, appearing to be "JC" or similar initials, written in a cursive style.

John H. Cox
Executive Director