



## Council for Responsible Nutrition

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October 2, 2017

Ms. Michelle Ramirez  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, California 95814  
Via Email: [p65public.comments@oehha.ca.gov](mailto:p65public.comments@oehha.ca.gov)

***Re: OEHHA Request for Comments on Possible Listing of Coumarin***

Dear Ms. Ramirez:

The Council for Responsible Nutrition (CRN) respectfully submits the following comments regarding the availability of hazard identification materials for coumarin and the possible listing of coumarin by the Carcinogen Identification Committee (CIC) at a public meeting scheduled for November 2, 2017. The hearing follows the Office of Environmental Health Hazard Assessment's (OEHHA's) March 3, 2017 notice of intent to list coumarin as a chemical known to the state of California to cause cancer.

CRN, founded in 1973 and based in Washington, DC, is the leading trade association representing the manufacturers and marketers of dietary supplements, functional foods, and their nutritional ingredients. CRN companies produce a large portion of the dietary supplements marketed in California and throughout the United States, and are committed to marketing safe, beneficial products in compliance with Proposition 65.

CRN requests that the CIC clearly identify at the public hearing and in all future communications that coumarin is naturally occurring in food plants. Likewise, we also urge OEHHA to follow the recommendations outlined in the American Herbal Products Association's (AHPA's) April 17, 2017 comments on coumarin<sup>1</sup> and ensure that all communications clarify that coumarin is naturally occurring in food plants.

Although Proposition 65 requires that a warning be provided for an "exposure" to a chemical listed by the state, the regulation provides the following:

Human consumption of a food shall not constitute an "exposure" for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure can show that the chemical is naturally occurring in the

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<sup>1</sup> American Herbal Products Association, *Comments to Michelle Ramirez Re: OEHHA's request for information on coumarin*, April 17, 2017, available at: [http://www.ahpa.org/Portals/0/PDFs/Advocacy/17\\_0417\\_AHPA\\_OEHHA\\_Comments\\_Coumarin\\_FINAL.pdf](http://www.ahpa.org/Portals/0/PDFs/Advocacy/17_0417_AHPA_OEHHA_Comments_Coumarin_FINAL.pdf).

food...For the purposes of this section, a chemical is “naturally occurring” if it is a natural constituent of a food...<sup>2</sup>

OEHHA’s hazard identification document entitled “Evidence on the Carcinogenicity of Coumarin” states that “[c]oumarin is a *naturally occurring* compound found in many plants, such as tonka beans, green tea leaves, some fruits (e.g., strawberries, apricots), and some spices and herbs (e.g., cinnamon, lavender, sweet woodruff, sage, dill, chamomile, peppermint)...” (emphasis added), and can be extracted from plants or synthesized.<sup>3</sup>

AHPA’s comments to OEHHA also note that coumarin is a natural constituent of lavender oil (*Lavandula angustifolia* syn. *L. officinalis*); some species of cinnamon, such as *Cinnamomum cassia*; and, of sweet woodruff (*Galium odoratum* syn. *Asperula odorata*). The two former species are identified as sources of “essential oils, oleoresins (solvent-free), and natural extractives (including distillates) that are generally recognized as safe for their intended use” under U.S. Food and Drug Administration (FDA) regulations;<sup>4</sup> the latter is identified in FDA regulation as a natural flavoring substance that may be safely used in alcoholic beverages.<sup>5</sup> FDA regulations also restrict the use of coumarin when added directly to foods, or when present from tonka beans or tonka extract.<sup>6</sup> However, FDA permits the use of flavoring that contains naturally-occurring coumarin in foods.<sup>7</sup> This information clearly demonstrates that coumarin is “naturally occurring” in plants that are part of the food supply. Accordingly, if the CIC determines that coumarin should be added to the Proposition 65 list of chemicals, the CIC and OEHHA should clarify in all forthcoming communications that coumarin is a natural constituent of food plants.

CRN urges OEHHA to take similar actions in future communications concerning coumarin. We share AHPA’s concern that the March 3, 2017 notice of intent to list coumarin failed to recognize that this chemical is a natural constituent of food plants. CRN further agrees with AHPA that OEHHA (and the CIC to the extent appropriate) should make clear that if the specific chemical “coumarin, CAS No. 91-64-5” is listed, it would not impact any other chemicals that may be classified as “coumarins.” OEHHA has historically qualified listings to ensure the accuracy and specificity of the chemical at issue, which is crucial for businesses seeking to comply fully with Proposition 65.

Finally, although CRN’s comments focus primarily on naturally-occurring coumarin, we also request that the CIC and OEHHA consider establishing a safe harbor level/ No Significant Risk Level for synthesized coumarin. FDA regulations provide a list of synthetic flavoring substances and adjuvants, including vanillin and cinnamaldehyde (cinnamic aldehyde), that are

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<sup>2</sup> 27 CCR § 25501(a)(1).

<sup>3</sup> OEHHA, [Proposition 65, Evidence on the Carcinogenicity of Coumarin](#) (August 2017), at 6.

<sup>4</sup> 21 CFR § 182.20.

<sup>5</sup> 21 CFR § 172.510.

<sup>6</sup> 21 CFR § 189.130.

<sup>7</sup> 21 CFR § 182.60.

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considered to be “generally recognized as safe for their intended use.”<sup>8</sup> Therefore, both naturally-occurring and synthesized coumarin can be consumed safely in foods.

Thank you for the opportunity to provide these comments. Please do not hesitate to contact me should you have any questions or require additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Rend Al-Mondhiry". The signature is fluid and cursive, with a long horizontal stroke at the end.

Rend Al-Mondhiry  
Associate General Counsel  
Council for Responsible Nutrition

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<sup>8</sup> *Id.*