

TITLE 27, CALIFORNIA CODE OF REGULATIONS

CHAPTER 1. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 7. NO SIGNIFICANT RISK LEVELS

Section 25705. Specific Regulatory Levels Posing No Significant Risk.

Amend Section 25705(b) as follows:

(b) Levels of exposure deemed to pose no significant risk may be determined by the lead agency based on a risk assessment conducted by the lead agency pursuant to the guidelines set forth in Section 25703, or a risk assessment reviewed by the lead agency and determined to be consistent with the guidelines set forth in Section 25703.

(1) The following levels based on risk assessments conducted or reviewed by the lead agency shall be deemed to pose no significant risk:

<i>Chemical Name</i>	<i>Level (micrograms/day)</i>
Acrylonitrile	

Methylhydrazine sulfate	0.18
4-Methylimidazole	16
<u>4-Methylimidazole</u>	<u>29</u>
5-Morpholinomethyl-3-[(5-nitrofurfurylidene) -amino]-2-oxazolidinone	0.18

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.



March 5, 2012

Dr. Margaret Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket FDA-2011-P-0407

Dear Dr. Hamburg:

On February 16, 2011, the Center for Science in the Public Interest (CSPI) petitioned the Food and Drug Administration (FDA):

to revoke sections 21 CFR 73.85 and 21 CFR 182.1235 (generally recognized as safe or "GRAS" regulations), which authorize the use in foods of caramel colorings that are produced by means of an ammonia or ammonia-sulfite process and contain 2-methylimidazole [2-MI] and 4-methylimidazole [4-MI], both of which are carcinogenic in animal studies. In addition, the FDA immediately should change the name "caramel coloring" to "chemically modified caramel coloring" or "ammonia-sulfite process caramel coloring" (and similar terms for other classes of the colorings) and should not allow products to be labeled "natural" if they contained any type of caramel coloring.

Please consider this letter an amendment to that petition.

To date, judging from the lack of response from the FDA and from a meeting with officials of the FDA's Center for Food Safety and Applied Nutrition, the FDA has done nothing in the past year to protect the millions of consumers who have been consuming dangerously contaminated soft drinks and possibly other products with ammoniated caramel colorings.

To help clarify the risk posed by caramel colorings in soft drinks, last month CSPI commissioned laboratory analyses of popular soft drinks purchased in the Washington, D.C. area. The tests found the following levels of 4-MI:

(continued)

<u>Product</u>	<u>4-MI (micrograms/12 fl. oz.)</u>
Coca-Cola (2 samples)	142, 146
Diet Coke (2 samples)	103, 113
Pepsi-Cola (2 samples)	151, 153
Diet Pepsi (2 samples)	146, 152
Dr Pepper (2 samples)	10, 11
Diet Dr Pepper (2 samples)	10, 137
Whole Foods 365 cola (1 sample)	47

The State of California considers 4-MI to be a carcinogen of sufficient potency that it must be regulated under Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986). The state has concluded that consumption of 29 micrograms (ug) per day is, as determined by a conservative calculation, associated with a possible lifetime risk of 1 cancer in 100,000 people, the state's threshold for regulation (potentially triggering a warning label).¹ The average amount (138 ug) of 4-MI that our tests found in a 12-ounce can of Coke/Pepsi/Diet Coke/Diet Pepsi is 4.8 times greater than California's 29 ug-per-day limit, indicating a lifetime risk of cancer of 5 out of 100,000 people. Limiting the calculation to people who consume soft drinks would approximately double that estimated risk to about 10 cancers in 100,000 people.² If that were further adjusted to cover only people who consume soft drinks containing caramel coloring,³ the risk would rise to about 13 cancers per 100,000, assuming consumption of one can a day over a 70-year lifetime.

While the Delaney amendment of the Food, Drug, and Cosmetic Act bans any cancer-causing food additive, the FDA has a different standard for contaminants in food additives. For those contaminants, the FDA allows a lifetime cancer risk of no greater than 1 in 1,000,000, or one-tenth California's risk target. The risk related to 4-MI in the most popular soft drinks is about 48 cancers in 1,000,000 people (again, assuming consumption of one can per day). Again, limiting the calculation to people who drink soft drinks, the cancer risk would roughly double to 96 out of 1,000,000, or about 128 out of 1,000,000 people who drink soft drinks that contain caramel coloring. Males in their teens and 20s are probably at greatest risk, because they consume especially large amounts of caramel-containing drinks and because younger people may be more sensitive to carcinogens than older people.⁴

¹ http://oehha.ca.gov/prop65/law/pdf_zip/4MEIregs020812.pdf; accessed March 2, 2012.

² Ogden CL, Kit BK, Carroll MD, Park S. Consumption of sugar drinks in the United States, 2005–2008. NCHS data brief, no 71. Hyattsville, MD: National Center for Health Statistics. 2011.

³ In Beverage Digest's 2010 list (March 17, 2011) of the top ten best-selling brands of carbonated soft drinks, products made with caramel coloring account for about 75 percent of sales. http://www.beverage-digest.com/pdf/top-10_2011.pdf; accessed Feb. 29, 2012.

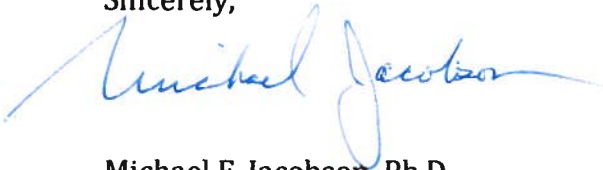
⁴ Hattis D, Goble R, Russ A, et al. Age-related differences in susceptibility to carcinogenesis—a quantitative analysis of empirical animal bioassay data, *Environ Health Persp*, 2004;112(11):1152-8.

Some soft drinks are now made with caramel colorings that are relatively low in 4-MI. A can of Whole Foods 365 cola contains only about one-third as much (47 ug) 4-MI as the leading brands, but it still poses a cancer risk of about 32 in 1,000,000 soft-drink consumers drinking one 12-ounce can per day. And even the 10–11 ug of 4-MI found in two samples of Dr Pepper and one sample of Diet Dr Pepper poses a risk of roughly 7 in 1,000,000 soft-drink consumers.

We understand that because of California's Proposition 65, PepsiCo and Coca-Cola have switched to caramel colorings that are lower in 4-MI and compliant with Proposition 65. However, the levels of 4-MI may still exceed the FDA's 1-in-a-million standard.

The caramel coloring added to soft drinks serves a totally cosmetic function. As we noted in our petition, both Coca-Cola Co. and PepsiCo have marketed clear colas without added colorings. We suspect that most consumers would prefer a clear beverage without an unnecessary carcinogen over a dark-brown beverage with a carcinogen. We urge the FDA to act promptly to protect the public's health and ban the use of ammoniated caramel colorings.

Sincerely,



Michael F. Jacobson, Ph.D.
Executive Director

cc: Michael Landa, Michael Taylor