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SUBJECT: Proposed Adoption of New Section Under Article 7 No Significant Risk Levels Section 25704 Exposures to Listed Chemicals in Coffee Posing No Significant Risk (Corrected)[1]

Introduction

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to submit comments to OEHHA on its proposal (hereinafter, "the proposal") that would add a new section (section 25704) to Article 7 of Title 27 of the California Code of Regulations, stating, "Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer." No cancer warning for consumers would be required for exposures to these chemicals if this proposed regulation is adopted, as stated in the Initial Statement of Reasons (ISOR).[2]

CSPI recognizes that coffee poses a dilemma with respect to Proposition 65, given that it is a complex mixture that, on the one hand contains listed (carcinogenic) chemical constituents and on the other is asserted by some to protect against cancer. In fact, coffee is not classifiable as to its carcinogenicity to humans according to the International Agency for Research on Cancer (IARC) (i.e., the evidence is neither adequate to conclude either that it is possibly or probably carcinogenic, or probably not carcinogenic).

We find the proposal problematic, as we explain below, because the proposed statement is misleading, confusing, and unsupportable. The evidence linking cancer with listed chemicals (notably acrylamide) in

[1] In the comments submitted on August 30, the acrylamide levels cited in coffee included unbrewed coffee. This version clarifies levels in both brewed and unbrewed coffee.
[2] Office of Environmental Health Hazard Assessment (OEHHA). Initial Statement of Reasons (ISOR). Title 27, California Code of Regulations, Adoption of New Section 25704, Exposures to Listed Chemicals in Coffee Posing No Significant Risk. June 2018. https://oehha.ca.gov/media/downloads/crnr/coffeeisor061418.pdf

coffee *is* adequate and sufficient to trigger the requirement under Proposition 65 for clear and reasonable warning.

Additionally, the proposal runs counter to the right-to-know intent of Proposition 65 by failing to warn consumers about chemicals "known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning.:[3] By failing to warn, it fails to incentivize companies to reduce consumer exposure to carcinogenic chemicals in a commonly consumed product. Finally, the justification for the proposal goes beyond the science and relies on a mischaracterization of IARC's evaluation of coffee.

In addition to addressing the flaws inherent in its proposal, OEHHA should conduct a review of the evidence on health risks for pregnant women and their offspring and evaluate whether a warning for that population is warranted based on the risk of acute lymphoblastic leukemia in children or the risk of miscarriage and other adverse pregnancy outcomes, prior to finalizing its proposal.

Proposed Statement Is Misleading, Confusing, and Unsupportable

The proposal states that exposures *to listed chemicals* [emphasis added] in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

We understand that there is some debate over whether coffee consumption is associated with cancer. But because this statement refers to listed chemicals specifically, it is unsupportable.

For example, the listed chemical acrylamide, which is considered a probable human carcinogen by IARC, is formed in the process of roasting coffee beans. California established a No Significant Risk Level (NSRL) for acrylamide of 0.2 ug/day.[4] Acrylamide levels in coffee vary widely, ranging from 3 to 13 ppb in brewed coffee and as high as 609 ppb unbrewed, according to data collected by FDA.[5] Other countries report even higher levels (e.g., as high as 3800 ppb unbrewed).[6] Consuming even a small[7] (8-ounce) serving of coffee containing just 3 ppb would exceed the NSRL.[8]

Since acrylamide *is* undeniably present in coffee, and is present at levels that considerably exceed the NSRL, by definition it poses a significant risk of cancer under Proposition 65, whether or not coffee taken on the whole does, and therefore the proposed language is not accurate.

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[3] California Health and Safety Code section 25249.6

[4] Office of Environmental Health Hazard Assessment. Acrylamide. https://oehha.ca.gov/proposition-65/chemicals/acrylamide

[5] U.S. Food and Drug Administration. Survey Data on Acrylamide in Food: Individual Food Products. https://www.fda.gov/food/foodborneillnesscontaminants/chemicalcontaminants/ucm053549.htm

[6] Claeys W, De Meulenaer B, Huyghebaert A et al. Reassessment of the acrylamide risk: Belgium as a case-study. Food Control 59: 628-635, 2016.

[7] The smallest hot coffee size offered at Starbucks is 8 fluid ounces and the largest is 20 fluid ounces. https://customerservice.starbucks.com/app/answers/detail/a_id/3113

[8] An 8 ounce (0.23658824 liters) serving of coffee containing 3 ppb (3 ug/liter) provides 3ug/l x 0.23658824 l or 0.7 ug of acrylamide, which exceeds the 0.2 ug NSRL for acrylamide.

We understand that California argues in the ISOR that other components in coffee counteract the carcinogenic effects of acrylamide and other listed chemicals in coffee, such that coffee itself does not pose a significant risk of cancer. Whether or not that contention is true, the proposed statement clearly fails to disclose the presence of a listed carcinogen, and therefore is inconsistent with the letter of Proposition 65.

Proposal Runs Counter to the Intent of Proposition 65

Moreover, the proposal is not consistent with the intent of Proposition 65. As stated in the ISOR, Proposition 65 is a right-to-know law based on the concept that the public has a right to know when it is being exposed to listed carcinogens or reproductive toxicants. Many companies have found ways to lower or eliminate carcinogenic chemicals in their products to avoid having to provide a warning to the public. In this way, Proposition 65 promotes not only disclosure, but also the public health.

For example, Procter and Gamble agreed to reduce acrylamide levels in Pringles potato chips by 50% so that no warning would be required.[9]

The fact that acrylamide levels in coffee vary widely illustrates the feasibility of lowering acrylamide levels. For example, the U.S. Food and Drug Administration notes that acrylamide levels vary (are reduced) by a number of factors, such as roast time (e.g., dark roast coffee vs. light roast), storage time (long vs. short), and preparation method (e.g., filter brewed vs. espresso).[10] Others point to mitigation methods that reportedly have no or minimal adverse impact on flavor, including asparaginase and/or aspartase treatment, vacuum roasting, supercritical carbon dioxide extraction, and curing under nitrogen.[11] These latter treatments could be especially useful in lowering acrylamide levels in a variety of coffee products (e.g., including coffee products that tend to have higher levels of acrylamide such as light roast coffees, espresso, and robusta bean coffees). Potatoes genetically engineered to reduce acrylamide precursors can reduce acrylamide levels in French fries and potato chips; a similar approach might be taken for coffee.[12]

Furthermore, as noted in the ISOR, other listed chemicals are formed during coffee roasting and brewing processes and present in coffee.

Surely it is in the public interest to reduce levels of carcinogens in products whenever feasible, whether or not there is adequate evidence to classify coffee as to its carcinogenicity.

ISOR Overstates IARC Conclusions to Justify its Proposal

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[9] State of California Department of Justice. Press Release: Atty. Gen. Brown Settles Potato Chip Lawsuit with Heinz, Frito-Lay, and Kettle Foods. August 1, 2008. https://oag.ca.gov/news/press-releases/atty-gen-brown-settles-potato-chip-lawsuit-heinz-frito-lay-kettle-foods

[10] U.S. Food and Drug Administration. Guidance for Industry: Acrylamide in Foods. March 2016. https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/UCM374534.pdf

[11] Trial Testimony of Dr. Ronald Melnick, CERT vs. Starbucks et al., PowerPoint presentation, and Declaration of Dr Ronald L. Melnick in support of Plaintiff's Motion for Summary Adjudication of Defendants' Alternative Significant Risk Level Defense, August 6, 2016.

[12] Ibid.

The rationale in the ISOR for not requiring warning labels for listed carcinogenic chemicals relies to a large extent on citing IARC to justify its assertion that coffee, despite the presence of listed chemicals, actually reduces the risk, or has no effect, on the risk of a substantial proportion of several cancers. The ISOR states:

> IARC's findings described above, when applied to American Cancer Society statistics for California, *show* [emphasis added] that coffee *reduces or probably reduces* [emphasis added] the risk of human cancers that account for 40 percent of cancer diagnoses in women (liver, endometrium, breast) and about 4 percent of cancer diagnoses in men (liver)[33]. Evidence also *showed* [emphasis added] lack of carcinogenicity for cancers that account for 25 percent of the cancer diagnoses in men (prostate, pancreas), and 3 percent in women (pancreas). In total, there is *moderate or strong evidence* [emphasis added] that coffee either reduces risk or does not affect risk of cancers that account for 43 percent of cancers diagnosed in women and 29 percent of cancers diagnosed in men in California.

Elsewhere the ISOR states, that "IARC concluded that drinking coffee is inversely associated with cancers of the liver and uterine endometrium (i.e., risk is reduced)."

These statements misrepresent IARC's "overall evaluation" of the carcinogenicity of drinking coffee to humans (which considers the body of evidence as a whole), that "Drinking coffee is *not classifiable* as to its carcinogenicity to humans (Group 3)."[13] IARC clarifies that "An evaluation in Group 3 is not a determination of non-carcinogenicity or overall safety. It often means that further research is needed." It states that a Group 3 classification "is used most commonly for agents for which the evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals."[14]

We emphasize that IARC did not classify coffee as Group 4, "The agent is probably not carcinogenic to humans."

Moreover, OEHHA mischaracterizes IARC's conclusions with respect to the specific cancers it cites. Far from concluding that coffee "reduces or probably reduces" certain cancers, IARC actually concludes with respect to those cancers:

> There is evidence *suggesting* [emphasis added] lack of carcinogenicity of drinking coffee in humans for cancers of the pancreas, liver, female breast, uterine endometrium, and prostate. Inverse associations with drinking coffee *have been observed* [emphasis added] with cancers of the liver and uterine endometrium.[15]

This conclusion is at odds with the language in the ISOR in 3 ways: (1) IARC refers to evidence *suggesting* a lack of carcinogenicity for certain cancers; it does not make a definitive conclusion, for example, that the evidence is strong or moderate; (2) it notes that inverse associations have been observed, but does not conclude that the inverse association is or probably is causally related to drinking

[13] International Agency for Research on Cancer (IARC). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Drinking Coffee, Mate, and Very Hot Beverages, Volume 116, World Health Organization, Lyon, France, 2018, p. 425. http://publications.iarc.fr/566.
[14] IARC 2018, p. 30.
[15] IARC 2018, p. 425.

coffee, nor that coffee reduces or probably reduces certain cancers, and (3) it does not include breast cancer amongst the cancers where inverse associations have been observed.

Maternal Coffee Consumption: Risks to Pregnant Women and Their Offspring

OEHHA should carefully review the evidence suggesting that maternal coffee consumption is linked to reproductive problems and harm to fetuses and children and consider providing clear and reasonable advice to pregnant women before finalizing its proposal on coffee.

For example, earlier this year (after the IARC evaluation) a new analysis was published suggesting that coffee intake during pregnancy is associated with an increase in the risk of childhood acute lymphoblastic leukemia,[16] consistent with the findings of all four previously published meta-analyses.[17] It is the first to pool original data from studies in different continents. The primary author of the new analysis was a member of the IARC Working Group. The new analysis uses data from 8 studies, whereas the IARC Working Group only considered seven.

In addition, evidence on adverse pregnancy outcomes should be considered. A recent extensive review concluded that maternal consumption was associated with low birth weight (odds ratio 1.31, 95% confidence interval 1.03 to 1.67), preterm birth in the first (1.22, 1.00 to 1.49) and second (1.12, 1.02 to 1.22) trimester, and pregnancy loss (1.46, 1.06 to 1.99).[18]

Thank you for considering our comments.

[16] Milne E, Greenop KR, Petridou E et al. Maternal consumption of coffee and tea during pregnancy and risk of childhood ALL: a pooled analysis from the childhood Leukemia International Consortium. *Cancer Causes Control* 29(6):539-550, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29600472

[17] Milne E, Royle JA, Bennett LC, de Klerk NH, et al. Maternal consumption of coffee and tea during pregnancy and risk of childhood ALL: results from an Australian case-control study. *Cancer Causes Control*, 22(2):207–18, 2011. doi:10.1007/s10552-010- 9688-1; Cheng J, Su H, Zhu R, et al. Maternal coffee consumption during pregnancy and risk of childhood acute leukemia: a metaanalysis. *Am J Obstet Gynecol*, 210(2):151.e1–10, 2014. doi:10.1016/j. ajog.2013.09.026; Thomopoulos TP, Ntouvelis E, Diamantaras AA, et al. Maternal and childhood consumption of coffee, tea and cola beverages in association with childhood leukemia: a meta-analysis. *Cancer Epidemiol*, 39(6):1047–59, 2015. doi:10.1016/j.canep.2015.08.009; Yan K, Xu X, Liu X et al. Corrigendum: The associations between maternal factors during pregnancy and the risk of childhood acute lymphoblastic leukemia: A meta-analysis. *Pediatr Blood Cancer* 63(5):953-4, 2016. Doi: 10.1002/pbc.25962 (corrected results showing coffee drinking during pregnancy was a risk factor for childhood ALL).

[18] Poole R, Kennedy OJ, Roderick P et al. Coffee consumption and health: umbrella review of meta-analyses of multiple health outcomes. BMJ 359: j5024, 2017, doi: 10.1136/bmj.j5024.