INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS
ADOPTION OF NEW SECTION 25704
EXPOSURES TO LISTED CHEMICALS IN COFFEE
POSING NO SIGNIFICANT RISK

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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Summary

The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65[1] and has the authority to promulgate and amend regulations to implement and further the purposes of the Act. OEHHA is proposing to add a new section to Title 27 of the California Code of Regulations[2], section 25704, stating that exposures to Proposition 65 listed chemicals in coffee that are produced as part of and inherent in the processes of roasting and brewing coffee pose no significant risk of cancer. No cancer warning would be required for exposures to these chemicals if this proposed regulation is adopted. This regulation does not address exposures to listed chemicals in coffee that may occur if the chemicals are intentionally added to the coffee mixture or enter the mixture as contaminants through a means other than the inherent process of roasting coffee beans or brewing coffee.

Background/Problem to be Addressed by the Proposed Rulemaking

A. Proposition 65

Proposition 65 was a ballot measure that Californians approved in November 1986 with 63 percent of the popular vote. In part, the statute says:

> "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning…"[3]

Proposition 65 is a right-to-know law based on the concept that members of the public have a right to know when they are being exposed to listed carcinogens or reproductive toxicants. An exemption to the warning requirement for carcinogens is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure to a Proposition 65 listed carcinogen poses no significant risk assuming lifetime exposure at the level in question[4]. OEHHA may also adopt regulations establishing levels of exposure to listed carcinogens that

[1] Health and Safety Code Section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65". Hereafter referred to as "Proposition 65" or "the Act".
[2] All further references are to sections of Title 27, Cal. Code of Regs., unless indicated otherwise.
[3] Health and Safety Code, section 25249.6
[4] Health and Safety Code, section 25249.10(c).

are deemed to pose no significant risk to assist in determinations about whether a warning is required for a given exposure.

"Coffee," as referenced in this document and the proposed regulation, refers to a beverage made by percolation, infusion, or decoction[5] from the roasted seeds of a coffee plant. Coffee is a unique and complex chemical mixture that contains numerous chemicals formed during the roasting of coffee beans[6,7,8]. Chemicals are also formed during the brewing of coffee[9,10,11]. Among the chemicals formed during these processes are a number of carcinogens listed under Proposition 65 (e.g., acetaldehyde, acrylamide, benz(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenz(a,h)anthracene, formaldehyde, furan, furfuryl alcohol, indeno(1,2,3-cd)pyrene, 4-methylimidazole, naphthalene, and pyridine) [12,13,14,15,16,17,18,19]. Coffee also contains numerous compounds that either exhibit or are considered to have cancer chemopreventive properties (e.g., free radical scavengers, antioxidants), as discussed below.

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[5] "Decoction" is the process of extracting flavor by boiling.
[6] Jaiswal R, Matei MF, Golon A, Witt M, Kuhnert N (2012). Understanding the fate of chlorogenic acids in coffee roasting using mass spectrometry based targeted and non-targeted analytical strategies. *Food Funct* 3:976-984.
[7] Amanpour A, Selli S (2016). Differentiation of volatile profiles and odor activity values of Turkish coffee and French press coffee. *J Food Process Preserv* 40:1116-1124.
[8] International Agency for Research on Cancer (IARC, 2018). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Drinking Coffee, Mate, and Very Hot Beverages, Volume 116, World Health Organization, Lyon, France. Available at http://publications.iarc.fr/566. See page 415.
[9] Matei, MF, Jaiswal R, Kuhnert N (2012). Investigating the chemical changes of chlorogenic acids during coffee brewing: Conjugate addition of water to the olefinic moiety of chlorogenic acids and their quinides. *J Agric Food Chem* 60(49):12105-12115.
[10] Deshpande S, Jaiswal R, Matei MF, Kuhnert N (2014). Investigation of acyl migration in mono-and dicaffeoylquinic acids under aqueous basic, aqueous acidic, and dry roasting conditions. *J Agric Food Chem* 62(37):9160-9170.
[11] Swasti YR, Murkovic M (2012). Characterization of the polymerization of furfuryl alcohol during roasting of coffee. *Food Funct* 3:965-969.
[12] Yeretzian C, Jordan A, Badoud R, Lindinger W (2002). From the green bean to the cup of coffee: investigating coffee roasting by on-line monitoring of volatiles. *Eur Food Res Technol* 214(2):92-104.
[13] Jeong HS, Chung H, Song SH, Kim CI, Lee JG, Kim YS (2015). Validation and determination of the contents of acetaldehyde and formaldehyde in foods. *Toxicol Res* 31(3):273-278.
[14] Pavesi Arisseto A, Vicente E, Soares Ueno M, Verdiani Tfouni SA, De Figueiredo Toledo MC (2011). Furan levels in coffee as influenced by species, roast degree, and brewing procedures. *J Agric Food Chem* 59(7):3118-3124.
[15] Jimenez A, Adisa A, Woodham C, Saleh M (2014). Determination of polycyclic aromatic hydrocarbons in roasted coffee. *J Environ Sci Health B* 49(11):828-835.
[16] International Agency for Research on Cancer (IARC, 2013). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Some Chemicals Present in Industrial and Consumer Products, Food, and Drinking-water. Volume 101. World Health Organization. Lyon, France.
[17] Bertuzzi T, Rastelli S, Mulazzi A, Pietri A (2017). Survey on acrylamide in roasted coffee and barley and in potato crisps sold in Italy by a LC-MS/MS method. *Food Addit Contam Part B Surveill* 10(4):292-299.
[18] Amanpour and Selli (2016), full citation provided in footnote 7.
[19] IARC (2018), full citation provided in footnote 8. See pages 65-67.

Warnings related to acrylamide in coffee have been the subject of private-party Proposition 65 enforcement actions since 2010. In a recent trial court ruling in the case, *Council for Education and Research on Toxics (CERT) v Starbucks, et al.*[20], the trial court found the defendants had failed to provide evidence supporting their argument for an alternative risk level for acrylamide in coffee. The effect of this ruling is that exposures to acrylamide in coffee may require Proposition 65 warnings. OEHHA understands that this proposed regulation, if adopted, may cause businesses to ask courts to modify consent judgments or to seek reconsideration of court rulings and may result in businesses that are voluntarily providing warnings to choose not to do so.

B. IARC's findings on coffee

On June 13, 2018, the International Agency for Research on Cancer (IARC), a Proposition 65 authoritative body, released Volume 116 of the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Drinking Coffee, Mate, and Very Hot Beverages[21]. After reviewing more than 1000 studies of coffee and cancer, IARC concluded that there was inadequate evidence for the carcinogenicity of drinking coffee, and placed coffee in Group 3: "Not classifiable as to its carcinogenicity to humans"[22,23]. At the same time, IARC concluded that drinking coffee is inversely associated with cancers of the liver and uterine endometrium (i.e., risk is reduced)[24]. In addition, IARC found moderate evidence of an inverse association (risk reduction) between coffee drinking and colorectal adenoma[25], a precursor lesion for most colorectal cancers[26], and also reported that studies either showed no association or a statistically significant inverse association for coffee intake and breast cancer[27]. IARC also found that there is evidence suggesting lack of carcinogenicity for cancers of the pancreas and prostate[28], noting that "studies conducted worldwide consistently indicated no

[20] *CERT v Starbucks et al*., Los Angeles County Superior Court case #BC435759
[21] IARC (2018), full citation provided in footnote 8.
[22] IARC (2018), full citation provided in footnote 8. See page 425.
[23]Loomis D, Guyton KZ, Grosse Y, Lauby-Secretan B, El Ghissassi F, Bouvard V, Benbrahim-Tallaa L, Guha N, Mattock H, Straif K, on behalf of the International Agency for Research on Cancer Monograph Working Group (2016). Carcinogenicity of drinking coffee, mate, and very hot beverages. *Lancet Oncol* 17:877-878. Available at: http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(16)30239-X.pdf
International Agency for Research on Cancer (IARC, 2018).
Agents Classified by the IARC Monographs, Volumes 1–121. World Health Organization. Lyon, France. Available at URL: http://monographs.iarc.fr/ENG/Classification/latest_classif.php
[24] IARC (2018), full citation provided in footnote 8. See page 425.
[25] IARC (2018), full citation provided in footnote 8. See page 424.
[26] Budhathoki S, Iwasaki M, Yamaji T, Sasazuki S, Tsugane S (2015). Coffee intake and the risk of colorectal adenoma: The colorectal adenoma study in Tokyo. *Int J Cancer*. 137(2):463-70.
[27] IARC (2018), full citation provided in footnote 8. See page 417.
[28] IARC (2018), full citation provided in footnote 8. See page 425.

increased risk of prostate cancer associated with coffee drinking, with inverse or null associations observed in all studies"[29]. IARC concluded there was inadequate evidence of an association between coffee drinking and other types of cancers[30]. IARC also found strong evidence in humans that coffee has antioxidant effects[31], effects that are related to reductions in cancer risk.

IARC's findings on coffee were based on its review of more than 1000 studies in humans, animals, in vitro and other experimental systems. The evaluation included numerous well-conducted prospective cohort and population-based case-control studies. IARC also evaluated several long-term studies of the carcinogenicity of coffee in rats and mice, and concluded that these studies provided inadequate evidence for the carcinogenicity of coffee[32].

C. Implications of IARC's findings that coffee reduces the risk of certain cancers

IARC's findings described above, when applied to American Cancer Society statistics for California, show that coffee reduces or probably reduces 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 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 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. There was also moderate evidence that coffee drinking reduced the risk of colorectal adenoma, a precursor lesion for a cancer that accounts for 6 percent of cancer diagnoses. Consistent results are found when US National Cancer Institute statistics for cancer diagnoses[34] are used. Coffee drinking was not found to increase or probably increase any types of cancer in men or women[35].

[29] IARC (2018), full citation provided in footnote 8. See page 418.
[30] IARC (2018), full citation provided in footnote 8. See pages 33, 415 - 420.
[31] IARC (2018), full citation provided in footnote 8. See pages 33, 422.
[32] IARC (2018), full citation provided in footnote 8. See page 425.
[33] American Cancer Society's 2017 document California Cancer Facts and Figures, Revised June 2017, Table 3, Observed new cancer cases and deaths, 2014.
[34] Estimated new cases in 2018 from the National Cancer Institute's SEER Cancer Statistics Review 1975-2015, Table 1.1: Estimated New Cancer Cases and Deaths for 2018, All Races, by Sex, available at https://seer.cancer.gov/csr/1975_2015/results_single/sect_01_table.01.pdf.
[35] IARC (2018), full citation provided in footnote 8. See page 425.

In epidemiological studies published since IARC completed its literature search in 2016, coffee consumption has consistently been found to be protective for colorectal cancer risk. Of 4 meta-analyses[36, 37,38,39], 2 prospective cohort studies[40, 41] and 5 case-control studies[42,43,44,45,46] conducted in multiple countries with various methods, almost all found significant inverse associations of coffee consumption and colorectal cancer. The exceptions were one meta-analysis[47] that found no association with coffee consumption and colorectal cancer, and one cohort study that found an increase in colorectal cancer[48].

D. Coffee is a complex mixture of carcinogens and anticarcinogens

Coffee is a unique and complex chemical mixture of numerous compounds[49,50]. Coffee contains chemicals that are recognized carcinogens[51], as noted above, as well as numerous chemicals with biological activities associated with protective, anti-carcinogenic effects[52]. Coffee's constituents that exhibit cancer chemopreventive properties include:

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[36] Akter S, Kashino I, Mizoue T, *et al*. (2016). Coffee drinking and colorectal cancer risk: an evaluation based on a systematic review and meta-analysis among the Japanese population. *Jpn J Clin Oncol* 46(8):781-787.
[37] Kashino I, Akter S, Mizoue T, *et al*. (2018). Coffee drinking and colorectal cancer and its subsites: A pooled analysis of 8 cohort studies in Japan. *Int J Cancer* 143(2):307-316.
[38] Wang A, Wang S, Zhu C, Huang H, Wu L, Wan X, Yang X, Zhang H, Miao R, He L, Sang X, Zhao H (2016). Coffee and cancer risk: A meta-analysis of prospective observational studies. *Sci Rep* 6:33711.
[39] Vieira AR, Abar L, Chan DSM, Vingeliene S, Polemiti E, Stevens C, Greenwood D, Norat T (2017). Foods and beverages and colorectal cancer risk: a systematic review and meta-analysis of cohort studies, an update of the evidence of the WCRF-AICR Continuous Update Project. *Ann Oncol* 28(8):1788-1802.
[40] Nakamura T, Ishikawa H, Mutoh M, Wakabayashi K, Kawano A, Sakai T, Matsuura N (2016). Coffee prevents proximal colorectal adenomas in Japanese men: a prospective cohort study. *Eur J Cancer Prev* 25(5):388-394.
[41] Groessl EJ, Allison MA, Larson JC, Ho SB, Snetslaar LG, Lane DS, Tharp KM, Stefanick ML (2016). Coffee Consumption and the Incidence of Colorectal Cancer in Women. *J Cancer Epidemiol* 2016:6918431.
[42] Budhathoki et al. (2015), full citation provided in footnote 26.
[43] Azzeh FS, Alshammari EM, Alazzeh AY, Jazar AS, Dabbour IR, El-Taani HA, Obeidat AA, Katan FA, Tashtoush SH(2017). Healthy dietary patterns decrease the risk of colorectal cancer in the Mecca Region, Saudi Arabia: a case-control study. *BMC Public Health* 17(1):607.
[44] Schmit SL, Rennert HS, Rennert G, Gruber SB (2016). Coffee Consumption and the Risk of Colorectal Cancer. *Cancer Epidemiol Biomarkers Prev* 25(4):634-639.
[45] Nakagawa-Senda H, Ito H, Hosono S, Oze I, Tanaka H, Matsuo K (2017). Coffee consumption and the risk of colorectal cancer by anatomical subsite in Japan: Results from the HERPACC studies. *Int J Cancer* 141(2):298-308.
[46] Ronco AL, De Stefani E, Lasalvia-Galante E, Mendoza B, Vazquez A, Sanchez G (2017). Hot infusions and risk of colorectal cancer in Uruguay: a case-control study. *Eur J Clin Nutr* 71:1429-1436.
[47] Vieira *et al.* (2017), full citation provided in footnote 39.
[48] Groessl *et al*. (2016), full citation provided in footnote 41.
[49] Jaiswal et al. (2012) and Amanpour and Selli (2016), full citations provided in footnotes 6 and 7.
[50] IARC (2018), full citation provided in footnote 8. See page 415.
[51] Jimenez et al. (2014), IARC (2013), Bertuzzi et al. (2017), full citations provided in footnotes 15, 16 and 17.
[52] Priftis A, Stagos D, Konstantinopoulos K, Tsitsimpikou C, Spandidos DA, Tsatsakis AM, Tzatzarakis MN, Kouretas D (2015). Comparson of antioxidant activity between green and roasted coffee beans using molecular methods. *Molecular Medicine Reports* 12:7293-7302.

- Antioxidants and free radical scavengers that protect against oxidative stress. Induction of oxidative stress is a key characteristic of carcinogens[53,54].
- Chemicals that appear to increase the colon's ability to move intestinal contents in a reduced amount of time[55,56], potentially reducing colorectal cancer risk[57].
- Anti-inflammatory chemicals. Chronic inflammation is a key characteristic of carcinogens[58].
- Soluble and insoluble fiber that can reduce the uptake into the body of certain carcinogens.

Examples of chemicals and constituents in coffee with these properties and how they may lead to reductions in cancers are provided below.

Coffee contains considerable amounts of dietary fiber (e.g., 40 mg/cup)[59]. Dietary fiber in coffee is both soluble and insoluble (e.g., cellulose and hemicellulose, including galactomannan and arabinogalactan polysaccharides). These fibers can tightly bind carcinogens in coffee, as well as in the gastrointestinal system (e.g., heterocyclic amines), thereby reducing their uptake into the body[60,61,62]. Coffee contains melanoidins[63], which behave similarly to dietary fiber and appear to increase colon motility (the ability of the colon to move intestinal contents) by activating smooth muscle cholinergic receptors[64]. In

[53] Smith MT, Guyton KZ, Gibbons CF, Fritz JM, Portier CJ, Rusyn I, DeMarini DM, Caldwell JC, Kavlock RJ, Lambert PF, Hecht SS, Bucher JR, Stewart BW, Baan RA, Cogliano VJ, Straif K (2016). Key Characteristics of Carcinogens as a Basis for Organizing Data on Mechanisms of Carcinogenesis. *Environ Health Perspect* 124(6):713-21.
[54] IARC (2018), full citation provided in footnote 8. See page 422.
[55] Rao SSC, Welcher K, Zimmerman B, Stumbo P (1998). Is coffee a colonic stimulant? *Euro J Gastroenterol Hepatol* 10:113-118.
[56] Brown SR, Cann PA, Read NW (1990). Effect of coffee on distal colon function. *Gut* 31:450-453.
[57] Je Y, Liu W, Giovannucci E (2009). Coffee consumption and risk of colorectal cancer: A systematic review and meta-analysis of prospective cohort studies. *Int J Cancer* 124:1662-1668.
[58] Smith et al. (2016), full citation provided in footnote 53.
[59] Kato T, Takahashi S, Kikugawa K (1991). Loss of heterocyclic amine mutagens by insoluble hemicellulose fiber and high-molecular-weight soluble polyphenolics of coffee. *Mutat Res* 246:169-178.
[60] Ludwig IA, Clifford MN, Lean MEJ, Ashihara H, Crozier A (2014). Coffee: biochemistry and potential impact on health. *Food Funct* 5:1695-1717.
[61] Kato et al. (1991), full citation provided in footnote 59.
[62] Gaascht F, Dicato M, Diederich M (2015). Coffee provides a natural multitarget pharmacopeia against the hallmarks of cancer. *Genes Nutr* 10(6):51. DOI 10.1007/s12263-015-0501-3.
[63] nitrogen-containing products of the Maillard reaction
[64] Ludwig et al. (2014), full citation provided in footnote 60.

addition, melanoidins have antioxidant activities, and can protect against oxidative stress in the gastrointestinal tract[65,66].

Coffee also contains numerous phenolic and polyphenolic compounds that can scavenge free radicals and protect against oxidative stress in the gastrointestinal tract, including chlorogenic acids[67,68]. Chronic oxidative stress results in an overabundance of reactive oxygen and/or nitrogen species and these can lead to mutations and may play key roles in many of the processes necessary for the conversion of normal cells to cancer cells[69]. Coffee is considered to be the major dietary source of the antioxidant chlorogenic acids, with estimated daily intake from coffee ranging from 0.5 to 2.0 g[70,71]. Chlorogenic acids are hydrolyzed in the gastrointestinal tract to release phenolic acids (e.g., ferulic acid)[72]. Uptake of a number of these phenolic chlorogenic acid-derived substances into the bloodstream following the consumption of coffee has been demonstrated in humans[73,74,75]. Other antioxidant constituents of coffee include vitamin E (α-tocopherol) and related tocopherol compounds[76,77]. Other coffee substances may indirectly increase cellular antioxidant defenses through effects on gene expression or other mechanisms (e.g., trigonelline, N-methyl pyridinium, cafestol, and kahweol) [78,79,80]. Coffee itself has been shown to have high levels of antioxidant activity. For example, Priftis et al. (2015)[81] tested extracts from

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[65] *Ibid.*
[66] Gaascht et al. (2015), full citation provided in footnote 62.
[67] Ludwig et al. (2014), full citation provided in footnote 60.
[68] Gaascht et al. (2015), full citation provided in footnote 62.
[69] Smith et al. (2016), full citation provided in footnote 53.
[70] Kempf K, Herder C, Erlund I, Kolb H, Martin S, Carstensen M, Koenig W, Sundvall J, Bidel S, Kuha S, Tuomilehto J (2010). Effects of coffee consumption on subclinical inflammation and other risk factors for type 2 diabetes: a clinical trial. *Am J Clin Nutr* 91:950-957.
[71] Ludwig et al. (2014), full citation provided in footnote 60.
[72] *Ibid.*
[73] *Ibid*.
[74] Kempf et al. (2010), full citation provided in footnote 70.
[75] Agudelo-Ochoa GM, Pulgarín-Zapata IC, Velásquez-Rodriguez CM, Duque-Ramírez M, Naranjo-Cano M, Quintero-Ortiz MM, Lara-Guzmán OJ, Muñoz-Durango K (2016). Coffee consumption increases the antioxidant capacity of plasma and has no effect on the lipid profile or vascular function in healthy adults in a randomized controlled trial. *J Nutr* 146:524-531.
[76] Ludwig et al. (2014), full citation provided in footnote 60.
[77] Alves RC, Casal S, Oliveira MBPP (2010). Tocopherols in coffee brews: Influence of coffee species, roast degree and brewing procedure. *J Food Compost Anal* 23:802-808.
[78] Corrêa TA, Monteiro MP, Mendes TM, Oliveira DM, Rogero MM, Benites CI, Vinagre CG, Mioto BM, Tarasoutchi D, Tuda VL, César LA, Torres EA (2012). Medium light and medium roast paper-filtered coffee increased antioxidant capacity in healthy volunteers: results of a randomized trial. *Plant Foods Hum Nutr* 67:277-282.
[79] Ludwig et al. (2014), full citation provided in footnote 60.
[80] Gaascht et al. (2015), full citation provided in footnote 62.
[81] Priftis et al. (2015), full citation provided in footnote 52.

roasted coffee beans, and reported that they exhibited radical scavenging activity, and protected against free radical-induced DNA damage.

Effects of coffee consumption on various antioxidant and anti-inflammatory markers in humans have been studied. For example, IL-18, a marker of inflammation, and 8-isoprotaine, a marker of oxidative stress, were both reduced in a clinical intervention trial following a period of moderately high coffee consumption compared to levels in the same subjects with no coffee consumption for a month[82]. In a randomized intervention trial medium light roast and medium roast coffee both significantly increased plasma "total antioxidant capacity" compared to no coffee consumption[83]. A significant increase in levels of erythrocyte antioxidant enzyme activities (i.e., superoxide dismutase, glutathione peroxidase, catalase) was also observed[84]. In another randomized control trial a significant increase in plasma antioxidant capacity was also observed with coffee drinking[85].

In contrast with the reductions of certain cancers and lack of findings of increased cancers with coffee, there are a number of other complex mixtures of carcinogens that are classified by IARC as *carcinogenic to humans* (Group 1), based on sufficient evidence of carcinogenicity from studies in humans, including:

- Tobacco smoke
- Second hand [environmental] tobacco smoke (ETS)
- Diesel engine exhaust
- Alcoholic beverages

Tobacco smoke induces human cancer at 19 sites in the human body; alcoholic beverages induce cancer at seven sites in humans.

Like coffee, each of these complex chemical mixtures contains a mix of carcinogenic constituents. Many of these complex mixtures contain some of the same carcinogenic constituents that are present in coffee. For example, acrylamide is present in coffee, tobacco smoke, and ETS, and benzo[a]pyrene is present in coffee, tobacco smoke, ETS, and diesel engine exhaust.
Some carcinogenic complex mixtures also contain constituents that have cancer chemopreventive properties. For example, a variety of polyphenols and other

[82] Kempf et al. (2010), full citation provided in footnote 70.
[83] Corrêa et al. (2012), full citation provided in footnote 78.
[84] *Ibid.*
[85] Agudelo-Ochoa et al. (2016), full citation provided in footnote 75.

phenolic compounds with radical scavenger and antioxidant activities are present in some alcoholic beverages.

However, coffee is different from the above complex mixtures: It is associated with reduced risk of some cancers, has not been found to increase the risk of any cancers[86], is particularly rich in chemicals that exhibit or are considered to have anticarcinogenic properties[87,88,89,90], and there is evidence in humans for beneficial effects of coffee itself related to chemoprevention[91,92,93,94]. IARC found "there is strong evidence that coffee drinking induces antioxidant effects" in humans, including in randomised controlled trials, and that coffee has been associated with beneficial effects on liver cirrhosis, an important risk factor for liver cancer[95]. Examples of the mechanisms by which anticarcinogens in coffee may operate are outlined above.

Ultimately, it has not been established why the complex mix of carcinogens and anticarcinogenic substances in coffee appear to have such a different impact on human cancer risks than the other complex mixtures that IARC has identified as *carcinogenic to humans*. However, the abundant data on coffee show that the carcinogens in this particular mixture should be viewed differently. Through extensive research and intense scientific scrutiny, coffee has been shown to reduce the risk of some cancers and has not been shown to increase the risk of any cancer. In contrast, the other complex mixtures discussed above are shown to cause cancer, in the case of tobacco smoke and alcoholic beverages, at a number of sites.

E. Exposure to carcinogens in coffee produced by and inherent in the processes of roasting and brewing coffee does not pose a significant cancer risk.

Coffee is unique in that it shows reductions in certain human cancers, has not been shown to increase any cancers, and is particularly rich in cancer chemopreventive compounds. Coffee is also unusual because it has been the subject of very high scientific interest for many years – IARC reviewed more than

[86] IARC (2018), full citation provided in footnote 8. See page 425.
[87] Kato et al. (1991), full citation provided in footnote 59.
[88] Ludwig et al. (2014), full citation provided in footnote 60.
[89] Gaascht et al. (2015), full citation provided in footnote 62.
[90] Kempf et al. (2010), full citation provided in footnote 70.
[91] IARC (2018), full citation provided in footnote 8. See page 422.
[92] Kempf et al. (2010), full citation provided in footnote 70.
[93] Corrêa et al. (2012), full citation provided in footnote 78.
[94] Agudelo-Ochoa et al. (2016), full citation provided in footnote 75.
[95] IARC (2018), full citation provided in footnote 8. See pages 422 and 424.

1000 observational and experimental studies investigating the potential carcinogenicity of coffee in humans and animals, and in vitro and other experimental systems. Considering the reductions of specific cancers resulting from coffee drinking, the rich mix of cancer-preventative agents in brewed coffee, and the lack of evidence showing increases in cancers, OEHHA has determined that exposure to listed carcinogens in coffee that are produced as part of and inherent in the processes of roasting and brewing coffee does not pose a significant cancer risk under Proposition 65.

This regulation does not address exposures to listed chemicals in coffee that may occur if the chemicals are intentionally added to the coffee mixture or enter the mixture as contaminants through a means other than the inherent process of roasting coffee beans or brewing coffee. For example, this regulation would not cover lead that is added to coffee because the brewing machine or coffee roasting equipment contain lead.

Proposed Regulatory Text

OEHHA is proposing to add the following new section to Title 27, of the California Code of Regulations, Article 7, No Significant Risk Levels:

> **§ 25704. Exposures to Listed Chemicals in Coffee Posing No Significant Risk**
>
> 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.
>
> NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.10, Health and Safety Code.

Purpose

The purpose of the proposed regulation is to state that exposures to Proposition 65 listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee pose no significant risk of cancer for purposes of Proposition 65.

Necessity

Proposition 65 was enacted to provide the public with information about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. This proposed regulation is necessary to clarify that chemicals created by and inherent in the processes of roasting coffee beans and brewing coffee do not pose a significant risk of cancer, and therefore Proposition 65 cancer warnings for exposures to those chemicals from drinking coffee would not be required.

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements pursuant to sections 11346.3(b)(1)(A) through (D).

Creation or elimination of jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California because it does not create additional compliance requirements. The regulatory action simply clarifies that certain Proposition 65 chemicals in coffee pose no significant cancer risk.

Creation of new businesses or elimination of existing businesses within the State of California

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California because it does not create additional compliance requirements. It simply clarifies that certain Proposition 65 chemicals in coffee pose no significant cancer risk.

Expansion of businesses currently doing business within the State of California

This regulatory action will not impact the expansion of businesses within the State of California because it does not create additional compliance requirements. It simply clarifies that certain Proposition 65 chemicals in coffee pose no significant cancer risk.

Benefits of the proposed regulation to the health and welfare of California residents, worker safety, and the state's environment

The health and welfare of California residents will benefit from the proposed regulation because it will clarify that listed carcinogens in coffee that are created by and inherent in the processes of roasting coffee beans or brewing coffee pose no significant cancer risk.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

Citations to documents relied on for this proposal are provided in this document. Copies of these documents will be included in the regulatory file for this action, and are available from OEHHA upon request. No other technical, theoretical or empirical material was relied upon by OEHHA in proposing the adoption of this regulation.

Benefits of the Proposed Regulation

The proposed regulation will further the goals of the authorizing statute by clarifying that there is no significant cancer risk resulting from exposures to listed carcinogens in coffee that are created by and inherent in the processes of roasting coffee beans or brewing coffee. The regulation provides guidance to businesses concerning whether they need to provide Proposition 65 warnings for coffee. This regulation will therefore benefit the health and welfare of California residents by helping to avoid cancer warnings for certain chemicals in coffee that do not pose a significant cancer risk.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

The alternative to this regulatory action is to take no action. This would provide no clarification to businesses and the public that chemicals created by and inherent in the processes of roasting coffee beans and brewing coffee do not pose a signficiant cancer risk. Businesses in most cases would not consider this critical information in determining whether to provide Proposition 65 warnings for coffee. No alternative that is less burdensome yet equally as effective in addressing such confusion has been proposed.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business. In addition, OEHHA has determined that the proposed

regulatory action will not impose any mandatory requirements on small businesses. Proposition 65 expressly exempts businesses with less than 10 employees[96] from the requirements of the Act.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulation will not have any adverse economic impact on businesses because it simply clarifies that certain Proposition 65 chemicals in coffee pose no significant risk pose no significant risk of cancer.

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the proposed regulations do not duplicate and will not conflict with federal regulations.

[96] Health and Safety Code section 25249.11(b).