INITIAL STATEMENT OF REASONS

PROPOSITION 65

TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED ADOPTION OF ARTICLE 5, SECTION 25505

EXPOSURES TO LISTED CHEMICALS IN COOKED OR HEAT PROCESSED FOODS

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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I. 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 amend Title 27 of the California Code of Regulations[2], by adopting a new Section 25505, to address listed chemicals formed by cooking or heat processing foods. The proposed regulation would provide that intake of such chemicals does not represent an exposure for the purposes of the Act if the concentrations are reduced to the lowest level currently feasible using appropriate quality control measures. The regulation would also establish maximum concentration levels for listed chemicals in foods that are produced by cooking or heat processing that are deemed by OEHHA to be the lowest levels currently feasible. Concentrations of the chemical at or below the level identified for the specified products would not require a warning. OEHHA could add other foods or chemicals in future rulemaking. The regulation would not apply to parties to an existing court-ordered settlement or final judgment establishing a concentration of acrylamide in a specific product covered in that settlement or judgment. "Parties" are the persons or entities directly affected by a mandatory provision of a court-ordered settlement or judgment establishing a concentration of acrylamide in a specific product covered in the settlement or judgment.

II. Background/Problem to be Addressed by the Proposed Rulemaking

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 based on the concept that the public has a right to know when they are being exposed to carcinogens and reproductive toxicants. The Act sets

[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.

out processes for listing chemicals known to cause cancer or reproductive toxicity and requires a warning for exposures to those chemicals unless an exemption applies. The Act also identifies circumstances where a warning for exposures to listed chemicals is not required. These include, among other exemptions, exposures to listed carcinogens that do not pose a significant cancer risk, and exposures to listed reproductive toxicants that have no observable effect at exposures 1000 times the level in question.

In addition to the statutory exemptions, the lead agency previously has determined that exposures to naturally occurring chemicals in food, to the extent the chemical in the food is not avoidable by good agricultural or good manufacturing practices, do not constitute "exposures" for purposes of Section 25249.6 of the statute.[4] In *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, the Court of Appeal affirmed that excluding certain naturally occurring chemicals in food from the warning requirement was consistent with the statutory purpose of Proposition 65 to regulate toxic substances that are "deliberately added or put into the environment by human activity."[5] It upheld the agency's objective in adopting the regulation to avoid reducing the availability of certain foods by requiring unnecessary warnings, and to avoid warnings that would "distract the public from other important warnings on consumer products."[6] The court noted that "warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products."[7]

Under the existing regulation for naturally occurring chemicals in foods, a chemical is naturally occurring only to the extent that the chemical "did not result from any known human activity."[8] Some chemicals on the Proposition 65 list, including acrylamide, that are found in food are not added to food, but instead are formed by the cooking or heat processing of the foods, which is human activity. Certain amounts of these chemicals are unavoidable. On the other hand, in many circumstances the level of chemical formed can be lowered by optimizing certain practices. In the case of acrylamide[9], which is formed when

[4] Cal. Code Regs., tit. 27, § 25501.
[5] *Id.* at p. 659.
[6] *Id.* at p. 661, quoting Final Statement of Reasons.
[7] *Id.* at p. 661.
[8] Cal. Code Regs., tit. 27, § 25501(a)(2).
[9] Acrylamide is formed during cooking or heat processing at high temperatures of certain plant-based foods when the free amino acid asparagine reacts with reducing sugars, such as glucose, fructose and maltose, in the Maillard reaction.

certain plant-based foods are cooked at high temperatures, these practices include[10]:

- Agricultural practices: for example, optimizing the type and timing of fertilizer use can reduce the formation of acrylamide precursors such as asparagine in crops such as potatoes, wheat, and barley.
- Selection, storage conditions, and handling of ingredients: for example, choice of potato variety and management of storage temperatures after harvest can reduce the formation of sugars, which are acrylamide precursors.
- Cooking duration and temperature, and other cooking, heating, or manufacturing processes: for example, reducing cooking duration or temperature can lead to less formation of acrylamide.

Ubiquitous warnings prevent consumers from distinguishing between products with very high concentrations of a listed chemical from those with considerably lower levels. Over the past several years there has been an increase in enforcement activity related to chemicals such as acrylamide that can be formed in a multitude of foods during heat processing and cooking. In the absence of regulatory action, the proliferation of enforcement actions related to listed chemicals formed in food could result in businesses putting warnings on foods that do not require them, which is contrary to the statutory purpose of enabling consumers to make informed choices.

The problems this regulation addresses are how to further the statutory purposes of (1) reducing exposures to listed chemicals present in food due to the human activities of cooking or heat processing, (2) providing warnings for avoidable exposures to acrylamide, and (3) safeguarding the effectiveness of those warnings. The regulation achieves these objectives by incentivizing food manufacturers and producers to reduce listed chemicals formed through cooking or heat processing to the lowest level currently feasible, while continuing to require warnings for such chemicals in food when present at levels above the lowest levels currently feasible.

In addition, there are court-approved Proposition 65 settlements that establish reformulation levels for chemicals in food formed through cooking or heat processing that do not require a warning under the statute. Absent evidence to

[10] Raffan S and Halford NG (2019). Acrylamide in food: Progress in and prospects for genetic and agronomic solutions. Annals of Applied Biology. 175:259-281.

the contrary, OEHHA presumes that a company's agreement to such a level indicates that it is currently feasible to achieve the level. Moreover, a court's approval indicates that, for the type of product at issue in the case, exposures to the chemical resulting from concentrations at or below the reformulation level do not require a warning. These settlements thus provide reference points for the lead agency to identify uniform targets for manufacturers that will bring consistency and transparency to Proposition 65 compliance, enforcement activities, and warnings for food.

Each provision of the proposed regulation is discussed below.

III. Section 25505

OEHHA is proposing to add Section 25505 to Title 27, California Code of Regulations for listed chemicals formed in foods through cooking or heat processing.

Cooking is a human activity. Therefore, chemicals in food created by cooking or heat processing are not considered to be naturally occurring in Section 25501 of the implementing regulations[11]. But not every potential exposure to a listed chemical in food that was created by cooking or other heat processing is a deliberate, or intentional, exposure that requires a warning. Some degree of formation of listed chemicals in many foods is unavoidable when the foods are cooked or otherwise processed with heat; the chemicals are byproducts of the processing, as opposed to being the intended result.[12] Exposures to these chemicals in food are not necessarily the type of "knowing and intentional" exposures that require a warning[13]. However, in many cases the levels of these chemicals can be substantially reduced[14].

[11] A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Section 25501(a)(3). *See also* Initial Statement of Reasons, Section 12501, Exposures to Naturally Occurring Chemicals In Food (1989) (chemicals in food which are caused by cooking, fermentation, or any other processing are not naturally occurring because the chemicals are added to the food by human agency), p. 2.

[12] For example, acrylamide is formed during the cooking or heat processing at high temperatures of certain plant-based foods when the free amino acid asparagine reacts with reducing sugars, such as glucose, fructose, and maltose, in the Maillard reaction.

[13] A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Section 25501(a)(3).

[14] Gökmen, V. (2016). *Acrylamide in food: analysis, content and potential health effects*. Academic Press. Raffan S and Halford NG (2019). Acrylamide in food: Progress in and prospects for genetic and agronomic solutions. *Ann Appl Biol*. 175:259-281.

When there are feasible ways to cook or heat process a food that result in reduced levels of the listed chemical in the food, then failing to reduce the level is considered a deliberate act for purposes of the proposed regulation because it unnecessarily increases the level of exposure to the listed chemical.

This regulation draws a distinction between exposures to listed chemicals in food that result from cooking or heat processing that cannot be feasibly avoided and those that can be feasibly avoided. Pursuant to the proposed regulation, exposures that cannot be feasibly avoided are not deemed to be knowing and intentional exposures for purposes of Proposition 65. Exposures to levels of the chemical that could be feasibly avoided, on the other hand, are considered knowing and intentional exposures that require a warning, unless another exception applies. Proposition 65 ensures that individuals in California receive a warning about these avoidable or intentional exposures.

The proposed regulation provides that a person otherwise responsible for an exposure to a listed chemical in a food does not "expose" an individual within the meaning of Section 25249.6 of the Act, to the extent the chemical was created by cooking or other heat processing, if the producer, manufacturer, distributor, or holder of the food has utilized quality control measures that reduce the chemical to the lowest level currently feasible. Heat processing can include pasteurization, blanching, and canning of food.

Businesses can use good manufacturing and agricultural practices to minimize the formation of acrylamide[15] and other listed chemicals when they cook or heat-process foods. In the case of acrylamide, various federal and international authorities recognize it as a hazard and have issued guidance to businesses on how to reduce its concentrations in foods, including the

- US Food and Drug Administration (US FDA)[16],

[15] FoodDrinkEurope (2019) Acrylamide Toolbox 2019. Available at https://www.fooddrinkeurope.eu/uploads/publications_documents/FoodDrinkEurope_Acrylamide_Toolbox_2019.pdf.

[16] US FDA (2016) Guidance for Industry: Acrylamide in Foods, Center for Food Safety and Applied Nutrition, College Park, Maryland, available online at: https://www.fda.gov/media/87150/download (last accessed Jun. 23, 2020).

- United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO) Codex Alimentarius[17],
- UK Food Standards Agency[18], and
- European Union[19].

Businesses can employ the measures identified by these authorities to reduce the acrylamide formed in food to the lowest feasible concentrations.

Subsection (a)

Subsection (a) adopts the concept of "good manufacturing practices" wherein the producer, manufacturer, distributor, or holder of the food utilizes quality control measures that reduce the chemical to the lowest level currently feasible. The proposed regulation draws from the concept of good manufacturing practices used by US FDA. For example, US FDA requires that manufacturers, distributors, and holders of food must "at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible."[20] OEHHA similarly adopted the concept of good manufacturing practices in the "naturally occurring" regulation[21]. In the Initial Statement of Reasons (ISOR) for Section 25501 (formerly Section 12501), OEHHA stated:[22]

> "Subsection (a) (4) provides that even where a chemical contaminant in food may be naturally occurring, any increase in the amount of chemical which was avoidable by good manufacturing practices or other intervening measures is not naturally occurring. This is because some chemicals, such as aflatoxin, which is produced by the natural growth of fungi on food in moist environments, are naturally occurring substances in that the presence of the chemical may not be the result of human activity.

[17] FAO/WHO Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods" (CAC/RCP 67-2009). Available via: http://www.fao.org/fao-who-codexalimentarius/roster/detail/en/c/468937/.
[18] UK Food Standards Agency, Acrylamide Legislation, https://www.food.gov.uk/print/pdf/node/459.
[19] European Union (2017). Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food. Available from: https://eur-lex.europa.eu/eli/reg/2017/2158/oj.
[20] Title 21, Code of Federal Regulations, Section 110.110, subdivision (c) (2001).
[21] Cal. Code Regs., tit. 27, § 25501, subsection (a)(4).
[22] Cal. Code Regs., tit. 22, § 12501 was renumbered to Cal. Code Regs., tit. 27, § Section 25501 in a later rulemaking.

However, the level of these toxins will increase with prolonged storage in damp unventilated areas, a condition which could have been avoided by better storage practices. Contaminated food items may also be eliminated by careful inspection and sorting."[23]

In a similar way, this regulation distinguishes between levels of listed chemicals formed from cooking and other heat processing that can be avoided through good agricultural and manufacturing practices versus those levels that cannot.

Examples of specific ways to feasibly reduce acrylamide, perhaps the best-known food chemical formed by cooking or heat processing, include:

- Changing the temperature at which the food is cooked, and avoiding unnecessary browning[24] [25] [26], for example, cooking cut potato products, such as frozen French fried potatoes or potato slices, to a golden yellow color rather than a brown color[27], along with other recommendations for potato products[28].
- Modifying baking times to lower thermal input[29].
- Sourcing ingredients from growers that grow specific varieties (e.g., certain potatoes, types of rye, wheat) and adopting good agricultural practices to reduce levels of free asparagine and reducing sugars in the crops (e.g., potatoes, rye, wheat).
- Further reducing[30] acrylamide precursors at various processes or steps. For example, controlling storage temperature and humidity from farm to factory to minimize sweetening of potatoes, adding asparaginase to potato doughs when making fabricated potato chips, and in bakery goods, replacing fructose with glucose, and adding asparaginase to reduce asparagine.

Using such practices for acrylamide reduction is considered following good manufacturing practices for purposes of this regulation.

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[23] Section 12501 ISOR, p.2.
[24] US FDA (2017) Acrylamide and Diet, Food Storage, and Food Preparation, available at https://www.fda.gov/food/chemicals/acrylamide-and-diet-food-storage-and-food-preparation (last accessed Jun. 23, 2020); US FDA (2016), full citation provided in footnote 16.
[25] European Union (2017), full citation provided in footnote 19.
[26] FoodDrinkEurope (2019), full citation provided in footnote 15.
[27] US FDA (2017), full citation provided in footnote 24; US FDA (2016), full citation provided in footnote 16.
[28] US FDA (2016), full citation provided in footnote 16.
[29] FoodDrinkEurope (2019), full citation provided in footnote 15.
[30] *Ibid*.

Subsection (a) also clarifies that if a person in the course of doing business does not reduce the level of the chemical in a food to the lowest level currently feasible, the resulting exposure must be calculated without regard to the levels set out in subsection (d). For example, pursuant to Section 25721, the level of exposure to a carcinogen would be determined by multiplying the concentration of the chemical in the food by the reasonably anticipated rate of exposure over a lifetime. Thus, if a business sells products with acrylamide levels that exceed the applicable levels set forth in subsection (d), the level established in subsection (d) for a given product may not be subtracted from the total concentration before making this calculation.

Subsection (b)

Subsection (b) provides that Section 25505 does not preclude businesses from using evidence, standards, risk assessment methodologies, principles, assumptions, or levels in Articles 7 and 8 of the Proposition 65 regulations to establish whether a warning is required for a listed chemical in a food that is created by cooking or other heat processing. This includes the calculation of No Significant Risk Levels for carcinogens and Maximum Allowable Dose Levels for reproductive toxicants. Thus, the concentration levels established in this proposed regulation in subsection (d), are provided as guidance that can be used by businesses to establish that a warning is not required for a given exposure. Businesses may instead choose to rely on other provisions of the existing regulations such as the safe harbor levels established in Sections 25705 or 25805, or the alternative risk level described in Section 25703(b)(1), or food intake calculations pursuant to Section 25721, or a combination of these, among other provisions, to show a warning is not required.

Subsection (c)

Subsection (c) states that Section 25505 is not applicable to parties to an existing court-ordered settlement or final judgment establishing a concentration of acrylamide in a specific product covered in that settlement or judgment. “Parties” are the persons or entities directly affected by a mandatory provision of a court-ordered settlement or judgment establishing a concentration of acrylamide in a specific product covered in the settlement or judgment. This is simply a

statement of existing law; OEHHA has, however, included this provision because many stakeholders had requested similar language in a previous rulemaking.[31]

Subsection (d)

Subsection (d) sets forth maximum concentration levels for chemicals in foods that would not constitute an exposure that requires a warning under the Act, pursuant to subsection (a). Subsection (d)(1) proposes maximum concentration levels of acrylamide in certain foods. The derivation of each of these levels is set out in detail below. With two exceptions (wheat-based and non-wheat based bread categories), the levels are based on recent court-approved settlements that establish a maximum average concentration, a maximum unit concentration, or both, of acrylamide in a product or category of products above which a Proposition 65 warning is required, and below which a warning is not required. OEHHA is relying on these levels for two reasons. First, the approval of a settlement by a court means that compliance by the defendant with the levels established in that settlement will not require a warning under the statute. Second, where a food industry defendant has agreed to a given concentration level in a court-approved settlement, OEHHA is presuming that the level is currently feasible. This may not always be the case, but absent evidence demonstrating otherwise, OEHHA is treating the levels established in the selected court-approved settlements as identifying the lowest levels currently feasible.

When the levels cited in the regulation are lower than the measured levels in a product produced by a manufacturer who was not a party to the applicable settlement, OEHHA nonetheless presumes that reductions of the acrylamide levels in these products is feasible. In the event a business is unable to or chooses not to reduce the levels of acrylamide in a product to the level adopted in the regulation for that product, a warning would be required if the exposure exceeds the No Significant Risk Level[32] for that chemical, unless another defense is proven.

Subsection (d) adopts the approach in most acrylamide settlements whereby one or two concentration levels are established: The Maximum Average Concentration and/or the Maximum Unit Concentration. In these settlements, 'Average Concentration' refers to the average of concentrations measured in

[31] *See,* Initial Statement of Reasons, Title 27 California Code of Regulations, Clear and Reasonable Warnings, Adoption of Article 6, (Nov. 2015), p. 12.
[32] Cal. Code Regs., tit. 27, § 25705.

multiple items/individual packaging units[33] of a specific food product (i.e., the form(s) in which that food product is sold to California consumers). The Maximum Unit Concentration in a Food Item is the maximum concentration measured in a single item/individual packaging unit[34] of the specified food product.

Methods for reducing acrylamide in food may continue to improve and OEHHA may reconsider and adopt new values in subsection (d) when there is sufficient evidence that they can be lowered and that the lower levels can be feasibly achieved.

IV. Proposed Acrylamide Concentration Levels in Subsection (d)

Table 1 on the following page sets out the maximum concentrations of acrylamide in foods that are being proposed in this rulemaking. In the first column of values, the maximum average concentrations measured in multiple items/individual packaging units of the specific food product are given, and in the second column of values, the maximum unit concentrations measured in a single item/individual packaging unit of the specific food product are given. In subsequent sections the sources of these values are described. Court-approved settlements entered within the past four years were retrieved from the California Attorney General's Office website[35,36]. Settlements are cited with identification of the plaintiffs and defendants, the court case number, and the specific alphanumerical code assigned by the Attorney General.

The US FDA has been monitoring acrylamide levels in foods since 2002, and the results of the most recent US FDA datasets (US FDA, 2011 and 2015)[37] relevant to the specific foods included in Table 1 are also summarized below, where

[33] Several acrylamide settlements define "unit level" as the representative composite sample taken from the individual unit being tested; see, for example, *Center for Environmental Health v. Foods Should Taste Good, Inc., et al.* (Super. Ct. Alameda, 2017, No. RG 17851469 [AG No. 2016-01126; Judg. No. J3557, Live Better Brands LLC]), available at https://oag.ca.gov/system/files/prop65/judgments/2016-01126J3557.pdf (last accessed Jun. 26, 2020).
[34] *Ibid.*
[35] State of California Department of Justice Office of the Attorney General 60-Day Notice Search, https://oag.ca.gov/prop65/60-day-notice-search (last accessed Jul. 27, 2020).
[36] In some cases, court approval was verified from the court websites (Alameda and San Diego).
[37] US FDA (2011 and 2015). Survey data on acrylamide in food. Webpage content current as of 09/27/2019. Available from: https://www.fda.gov/food/chemicals/survey-data-acrylamide-food.

available. The US FDA values are typically from several different products sampled within the same food group.

Table 1. Summary of proposed maximum acrylamide concentration levels

Foods/Food groups	Maximum average concentration level (ppb)	Maximum unit concentration level (ppb)
Almonds, roasted, roasted almond butter, and chocolate-covered almonds	225	---
Bread, non-wheat-based products including loaves, rolls, buns, baguettes	100	---
Bread, wheat-based products including loaves, rolls, buns, baguettes	50	---
Cookies, animal and animal crackers (sweet)	75	100
Cookies, thin and crispy	281	300
Cookies, sandwich wafers	115	---
Crackers, savory, including crispbread	350	490
Potato products, French fried potatoes	280	400
Potato or sweet potato products, not otherwise specified, such as hash browns and potato puffs	350	490
Potato or sweet potato products, sliced chips	281	350
Prune juice, 100% (not from concentrate)	---	250
Prune juice, made with concentrate	---	150
Waffles	280	---

A. Almonds, roasted, roasted almond butter, and chocolate-covered almonds

This food group covers roasted almonds, almond butter made from roasted almonds, and chocolate-covered roasted almonds. The proposed maximum average concentration level is 225 parts per billion (ppb). Since there are no additional heating processes involved in making almond butter from roasted almonds, the same settlement level applies to both roasted almonds and almond butter. The level is based on two court-approved settlements: *Embry v. Frito Lay, et al*. (Case Number HG 19021174, AG Notice No. 2019-01037; Judg. No. J4260), and *Embry v. Hayden Valley Foods* (Case Number RG 20052449, AG Notice No. 2020-01201; Stlmt. No. S8608).

The *Embry v. Frito Lay, et al*. settlement cover roasted almonds that are uncoated. The *Embry v. Hayden Valley Foods* settlement covers uncoated roasted almonds and roasted almonds that are covered with various coatings, including confectionary coatings (e.g., chocolate) and non-confectionary coatings (e.g., seasonings).

The *Embry v. Frito Lay, et al*. settlement states the following regarding determination of the average level:

> "The Average Level is determined by randomly selecting and testing, over no less than a ten-day period, one sample from at least five batches (or from as many batches as are available, if fewer than five) and a maximum of ten batches of Products produced at locations that supply such Products to California ("Sampling Data"). The mean and standard deviation shall be calculated using the Sampling Data. Any data points that are more than three standard deviations outside the mean shall be discarded once, and the mean and standard deviation recalculated using the remaining data points. The arithmetic mean determined in accordance with this procedure shall be deemed the "Average Level"."

Levels reported for almonds by the Almond Board of California and the US FDA are on average lower than the proposed feasible level, indicating feasibility, and with some products or samples showing values considerably higher than the proposed level. The Almond Board of California (2014)[38] reported that the

[38] Almond Board of California (2014). Technical summary: Acrylamide in roasted almonds. Available from: https://www.almonds.com/sites/default/files/content/attachments/aq0104_acrylamide_in_roasted_almonds.pdf.

average acrylamide concentration in 89 dry-roasted almond samples is 169 ppb, with a range of 4-726 ppb and the average in 41 oil-roasted almond samples is higher, at 194 ppb, with a range 28-544 ppb. The US FDA (2015)[39] reported an average of 117 ppb (range: 60 to 160 ppb) in a small number (six) roasted almond samples. Based on the limited US FDA data[40], almond butters, on average, had concentrations lower than the proposed level, although some products were found with higher levels. The average of six almond butter samples is 193 ppb (range not detected [ND, detection limit: 10 ppb][41] to 570 ppb) (US FDA 2015)[42].

Zhang et al. (2011)[43] demonstrated that use of a roasting temperature below 146ºC and short-term elevated temperature storage (i.e., three-day storage of roasted almonds at 60ºC) could effectively reduce acrylamide levels in California almonds. This type of information may have been used by almond roasters to implement effective mitigation strategies to reduce acrylamide levels in recent years.

B. Bread

In 2017, recognizing the hazard of acrylamide in foods, the European Union (EU) adopted regulations to encourage the reductions by the food industry by various mitigation methods. The EU regulations set the benchmark levels[44] with the goal of ensuring the reduction of exposures. The EU notes that the benchmark levels "should be established at a level as low as reasonably achievable with the application of all relevant mitigation measures." However, OEHHA found numerous settlements between plaintiffs and defendants showing levels lower than the EU benchmark levels that could be achieved in other food groups. For bread, OEHHA did not find a settlement that was below the EU benchmark levels, so OEHHA is proposing the EU levels as the lowest feasible level in this case.

[39] US FDA (2011 and 2015), full citation provided in footnote 37.
[40] *Ibid.*
[41] In our calculations for all food groups in this ISOR, 5 ppb was used for samples reported as not detected (< 10 ppb).
[42] US FDA (2011 and 2015), full citation provided in footnote 37.
[43] Zhang G, Huang G, Xiao L, Seiber J, Mitchell AE (2011). Acrylamide Formation in Almonds (Prunus dulcis): Influences of Roasting Time and Temperature, Precursors, Varietal Selection, and Storage. J Agric Food Chem. 2011 Aug 10;59(15):8225-32. doi: 10.1021/jf201595q.
[44] Benchmark levels are performance indicators to be used to verify the effectiveness of the mitigation measures and are based on experience and occurrence for broad food categories.

The European Union (EU 2017)[45] set different benchmark levels for two categories of bread: soft wheat-based bread vs soft bread other than wheat-based bread (defined as "non-wheat-based bread" in this regulation). The EU guidance document states that bread products include "wheat bread, rye bread, whole meal bread, multi grain bread, malt bread, steamed breads and baguettes"[46], and adopts in its regulation different levels for wheat-based and non-wheat-based bread. OEHHA is proposing levels for these two bread groups in accordance with the EU regulation.

1. Bread, non-wheat-based products including loaves, rolls, buns, baguettes

This group covers non-wheat-based bread products such as loaves, rolls, buns, and baguettes, including toasted and non-toasted products. Products covered under this group do not include wheat-based bread (see section B.2) or crispbread (see section D). The proposed average for non-wheat-based bread products is 100 ppb. This level is based on the European Union (EU 2017)[47] benchmark level of 100 ppb for non-wheat-based soft bread (containing less than 50% wheat, including toasted bread). In support of EU regulations, the European Food Safety Authority (EFSA)[48] reviewed acrylamide data in bread, including data from rolls. EFSA reported an average of 46 ppb (95th percentile = 203 ppb) in 99 non-wheat-based bread samples from different European countries and the European food associations reported an average of 181 ppb in 8 pumpernickel samples. The US FDA data did not have specific data on non-wheat-based bread products.

2. Bread, wheat-based products including loaves, rolls, buns, baguettes

This group covers wheat-based loafed bread, such as white and whole-wheat loaves, rolls, buns, and baguettes including toasted and non-toasted products. This group does not cover "non-wheat-based bread products" (see section B.1) or crispbread (see section D). The proposed average level for wheat-based

[45] EU (2017), full citation provided in footnote 19.
[46] EU (2018). Guidance on the implementation of Commission regulation (EU) 2017/2158 of 20 November 2017 Establishing mitigation measures and benchmark levels for the presence of acrylamide in food. Available from: https://ec.europa.eu/food/sites/food/files/safety/docs/cs_contaminants_catalogue_acrylamide_guidance-doc_en.pdf
[47] EU (2017), full citation provided in footnote 19.
[48] EFSA (2015). Scientific Opinion on acrylamide in food. EFSA Panel on Contaminants in the Food Chain (CONTAM). European Food Safety Authority (EFSA), Parma, Italy. EFSA Journal. 13(6):4104

bread products is 50 ppb. This level is based on the European Union (EU 2017)[49] benchmark level of 50 ppb for wheat-based soft bread (containing more than 50% wheat, including toasted bread).

EFSA[50] reported an average of 38 ppb in 302 wheat-based bread samples (95th percentile = 120 ppb) from different European countries. According to the US FDA data[51], the average level of acrylamide in the wheat-based breads (such as sandwich bread, hamburger or hot dog buns, and toast) was 22 ppb (N = 39, range: ND – 70) in 2015, and 18 ppb (N = 156, range: ND – 102) in 2011. Both EU data and US FDA data show that the proposed average level is feasible.

C. Cookies

OEHHA is proposing maximum average and unit levels for three different categories of cookies.

1. Cookies, animal and animal crackers (sweet)

This group covers sweet animal-shaped hard cookies and animal crackers. The proposed levels for animal cookies and animal crackers are 75 ppb for the maximum average level and 100 ppb for the maximum unit level. These levels are based on seven court-approved settlements[52,53] on animal crackers and/or animal cookies that agreed to the levels consistent with the regulatory proposal, except one settlement that set a lower level for a product no longer on the market[54]. A recent settlement, the *Center for Environmental Health (CEH) v.*

[49] EU (2017), full citation provided in footnote 19.
[50] EFSA (2015), full citation provided in footnote 48.
[51] US FDA (2011 and 2015), full citation provided in footnote 37.
[52] The settlements and consent judgments cited within this document are publicly available by searching the Office of the Attorney General 60-day Notice Search webpage, https://oag.ca.gov/prop65/60-day-notice-search (last accessed Jul. 23, 2020).
[53] *CEH v. Fantasy Cookie Corporation, et al*. (Super. Ct. Alameda, 2019, No. RG 17872872 [AG. No. 2017-01528; Judg. No. J4333, Bay Valley Foods, LLC]); *CEH v. Fantasy Cookie Corporation, et al.* (Super. Ct. Alameda, 2018, No. RG 17872872 [AG No. 2017-1527; Judg. No. J3946, Pure's Food Specialties, LLC]); *CEH v. Fantasy Cookie Corporation, et al.* (Super Ct. Alameda, No. RG 17872872 [AG No. 2017-00592; Stlmt. No. 6462, Dollar Only Wholesale, LLC]); *CEH v. Fantasy Cookie Corporation, et al.* (Super. Ct. Alameda, 2019, No. RG 17872872 [AG No. 2017-00378; Judg. No. J4278, Panos Brands, LLC]); *CEH v. Fantasy Cookie Corporation, et al.* (Super Ct. Alameda, 2019, No. RG 17872872 [AG No. 2017-00378; Judg. No. J4277, Fantasy Cookie Corporation]); *CEH v. Biscomerica Corp., et al*. (Super. Ct. Alameda, 2019, No. RG 17881931 [AG No. 2017-00378; Judg. No. J4083, Pagasa, S.A. de C.V.]); and *CEH v. Biscomerica Corp., et al.* (Super. Ct. Alameda, 2019, No. RG 17881931 [AG No. 2017-01759; Judg. No. J4276, Biscomerica Corp.]).
[54] One settlement, CEH v. Fantasy Cookie Corporation, et al. (Super. Ct. Alameda, 2018, No. RG 17872872 [AG No. 2017-00378; Judg. No. J3966, Weetabix Company, LLC]) set a lower unit

Fantasy Cookie Corporation, et al. settlement (Case No. RG 17872872, AG No. 2017-01528; Judg. No. J4333), states the following regarding determination of the average level and the unit level:

> "The average acrylamide concentration shall not exceed 75 parts per billion ("ppb") by weight (the "Average Level"). The Average Level is determined by randomly selecting and testing at least one sample each from at least five and up to 30 different lots of Covered Products (or the maximum number of lots available for testing if fewer than five) during a testing period of at least 60 days. The mean and standard deviation shall be calculated using the sampling data. Any data points that are more than three standard deviations outside the mean shall be discarded once, and the mean and standard deviation recalculated using the remaining data points. The mean determined in accordance with this procedure shall be deemed the "Average Level."
>
> The acrylamide concentration of any individual unit of Covered Products shall not exceed 100 ppb by weight (the "Unit Level"), based on a representative composite sample taken from the individual unit being tested."

US FDA (2015)[55] does not report any data on animal crackers or animal cookies. US FDA (2011)[56] reported levels from two samples of animal crackers (524 and 539 ppb).

2. Cookies, thin and crispy

This group covers all thin and crispy cookies, including but not limited to ginger snaps, gingerbread cookies, Graham crackers, and biscuit cookies. This group does not cover sandwich wafer cookies (see section C.3).

The proposed levels for acrylamide in thin and crispy cookies are 281 ppb for the maximum average level and 350 ppb for the maximum unit level. These levels

level of 75 ppb for animal cookies, but that specific product is no longer available in the marketplace.

[55] US FDA (2011 and 2015), full citation provided in footnote 37.

[56] *Ibid.*

are based on nine court-approved settlements[57] in which the same or nearly the same levels (maximum average concentration of 280 or 281 ppb; maximum unit concentration level of 350 ppb) were used as in the regulatory proposal. The value of 281 ppb was selected for the maximum average concentration level because seven out of the nine settlements were set at this level.

These settlements were for ginger snaps, gingerbread cookies, Graham crackers, biscuit cookies, or double chocolate thins. One settlement set a lower level, but the product is no longer on the market[58].

The *CEH v. Fantasy Cookie Corporation et al.* court-approved settlement (Case No. RG 17872866, AG No. 2018-01193; Judg. No. J3999) states the following regarding determination of the average level and the unit level:

> "The average acrylamide concentration shall not exceed 281 parts per billion ("ppb") by weight (the "Average Level"). The Average Level is determined by randomly selecting and testing at least one sample each from five different lots of Covered Products (or the maximum number of lots available for testing if fewer than five) during a testing period of at least 60 days. The acrylamide concentration of any individual unit of Covered Products shall not exceed 300 ppb by weight (the "Unit Level"), based on a

[57] These seven settlements set the maximum average concentration at 281 ppb and maximum unit concentration at 350 ppb: *CEH v. Fantasy Cookie Corporation, et al.* (Super. Ct. Alameda, 2018, No. RG 17872866 [AG No. 2018-01193; Judg. No. J3999, J&J Snack Foods Sales Corp. and J&J Snack Foods Corp. of California]); *CEH v. Enjoy Life Natural Brands, LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 17872866 [AG No. 2017-00378; Judg. No. J4334, Kellogg USA, LLC, Kellogg USA, Inc., Kellogg Sales Company, and Murray Biscuit Company LLC]); *CEH v. Enjoy Life Natural Brands LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17872866 [AG No. 2017-01526; Judg. No. J3978, Nature's Path Foods, Inc.]); *CEH v. Barrel O'Fun Snack Foods Co., LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17881932 [AG No. 2017-01526; Judg. No. J3935, Shearer's Foods, LLC and Barrel O'Fun Snack Foods, Co., LLC]); *CEH v. Barrel O'Fun Snack Foods Co., LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17881932 [AG No. 2017-01526; Judg. No. J3934, Shearer's Foods, LLC and Barrel O'Fun Snack Foods Co., Inc.]); *CEH v. Barrel O'Fun Snack Foods Co., LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17881932 [AG No. 2017-00036; Judg. No. J3998, D.F. Stauffer Biscuit Co., Inc.]); and *CEH v. Barrel O'Fun Snack Foods Co., LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17881932 [AG No. 2017-00587; Judg. No. J3937, Pamela's Products, Incorporated]). These two settlements set the maximum average level at 280 ppb and maximum unit level at 350 ppb: *Embry v. The Kroger Company, et al.* (Super. Ct. Alameda, 2020, No. HG 19024517 [AG No. 2018-00772; Judg. No. J4367, Mondelez Global, LLC]); and *Embry v. Mondelez Global LLC, et al.* (Super. Ct. Alameda, 2019, No. HG 19023388 [AG No. 2019-00852; Judg. No. J4318, Mondelez Global, LLC]).

[58] *CEH v. Enjoy Life Natural Brands LLC, et al*. (Super. Ct. Alameda, 2017, No. RG 17872866 [AG No. 2017-00158; Judg. No. J3680, Mary's Gone Crackers, Inc.]) set a lower unit level (75 ppb) for ginger snaps, but that specific product is no longer available on the market.

representative composite sample taken from the individual unit being tested."

Data on thin and crispy cookies from US FDA (2011 and 2015)[59] are limited. For ginger snap cookies, the average was 940 ppb (N = 10, range: 256 – 1796) measured in 2011, and 490 ppb (N = 19, range: 50 – 1450) measured in 2015. US FDA measured acrylamide in three Graham cracker samples in 2011, with acrylamide levels of 1240, 1247 and 2110 ppb.

3. Cookies, sandwich wafers

This group covers sandwich wafer cookies that are made from thin biscuit cookies sandwiched with cream filling. The proposed maximum average concentration level for sandwich wafer cookies is 115 ppb. This level is based on two court-approved settlements: *Embry v. A. Loacker USA Inc., et al.* (Case No. RG 19001295, AG No. 2017-01994; Judg. No. J4302) and *Embry v. Colombina USA, et al.* (Case No. RG 19041476, AG No. 2019-00512; Stlmt. No. S8383)[60]. These two settlements set a maximum average concentration level of 115 ppb on sandwich wafer products.

The court-approved settlement, *Embry v. A. Loacker USA, et al.* (Case No. RG 19001295, AG No. 2017-01994; Judg. No. J4302) states the following regarding determination of the average level:

> "Commencing on the Effective Date, and continuing thereafter, Defendant Releasees shall only manufacture, ship, sell, or offer for sale Covered Products that: (a) contain an average acrylamide concentration by weight (the "Average Level") of 115 parts per billion or less; or (b) are labeled with a clear and reasonable warning pursuant to Section 2.2. The Average Level shall be determined: (a) by randomly selecting and testing at least one sample each from five different lots of the product (or the maximum number of lots available for testing if less than five) that were produced on dates spread out roughly evenly over a period of at least 60 days."

US FDA (2011 and 2015)[61] reported limited data on wafer cookies. According to the US FDA data, the acrylamide levels in two wafer cookies samples reported in 2015 were 50 and 80 ppb. The average level of acrylamide in this product type reported by US FDA in 2011 was 171 ppb (N = 11, range: 56 – 275 ppb).

[59] US FDA (2011 and 2015), full citation provided in footnote 37.
[60] Consent judgment was entered by the Superior Court in Alameda County on 6/24/2020.
[61] US FDA (2011 and 2015), full citation provided in footnote 37.

D. Crackers, savory, including crispbread

This group covers all savory crackers, such as saltine crackers and crispbread. This group does not include sweet crackers (e.g., Graham crackers or animal crackers, see section C). The proposed levels of acrylamide for savory crackers and crispbread are 350 ppb (maximum average concentration level) and 490 ppb (maximum unit concentration level). The levels are based on two court-approved settlements: the *CEH v. FoodShouldTasteGood, Inc., et al.* settlement (Case No. RG 17851469; AG No. 2016-01426; Judg. No. J3933) on gluten-free crackers, and *Van Patten v. Dare Foods, Inc., et al.* (Case No. 37-2019-00053698-CU-PO-CTL, AG No. 2019-01267)[62] on multigrain crackers.

The *CEH v. FoodShouldTasteGood, Inc., et al.* settlement states the following regarding determination of the average level and the unit level:

> "The average acrylamide concentration shall not exceed 350 parts per billion ("ppb") by weight (the "Average Level"). The Average Level is determined by randomly selecting and testing at least 5 samples from 5 different lots of Covered Products (or the maximum number of lots available for testing if less than 5) during a testing period of at least 60 days.
>
> The acrylamide concentration of any individual unit shall not exceed 490 ppb by weight based on a representative composite sample taken from the individual unit being tested (the "Unit Level"). An "individual unit" means the bag or other individual packaging unit by which the Covered Product is sold to California consumers."

According to the US FDA data[63], the average level of acrylamide in crackers was 233 ppb (N = 41, range: ND – 967) in 2011, and 97 ppb (N = 50, range: ND – 800) in 2015.

E. Potato products, French fried potatoes

This group covers French fried potatoes. OEHHA proposes to set the levels for acrylamide in French fried potatoes to be 280 ppb (maximum average

[62] Consent judgment was entered by Super. Ct. San Diego County on 6/9/2020.
[63] US FDA (2011 and 2015), full citation provided in footnote 37.

concentration level) and 400 ppb (maximum unit concentration level), based on two court-approved settlements[64,65].

Both *CEH v. Lamb Weston Holdings, Inc., et al*. settlements[66] state the following regarding determination of the average level and the unit level:

> "The Average Level is determined by randomly selecting and testing at least one sample each from at least five (5) different lots of a particular Product Type (or the maximum number of lots available for testing if fewer than five (5)). The mean and standard deviation shall be calculated using the sampling data. Any data points that are more than three standard deviations outside the mean shall be discarded once, and the mean and standard deviation recalculated using the remaining data points. The mean determined in accordance with this procedure shall be deemed the "Average Level." Further testing conditions are specified in Exhibit B."
>
> "The Unit Level shall be determined based on a representative, composite sample taken from the individual unit being tested and as further specified in Exhibit B."

According to the US FDA data[67], the average level of acrylamide found in samples of French fried potatoes products in 2011 was 287 ppb (N = 101) with a range of ND – 1570, and in 2015 was 322 ppb (N = 45), with a range of ND – 1330.

[64] *CEH v. Lamb Weston Holdings, Inc., et al*. (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-01412, Judg. No. J3851, Lamb Weston Holdings, Inc.]); and *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00951; Judg. No. J3850, J.R. Simplot Company]).
[65] Another settlement by *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 16838609 [AG No. 2016-00955; Judg. No. J4050, Inventure Foods, Inc.]) sets the average level to be 350 ppb and unit level to be 490 ppb, for crinkle fries. Section 25505(c) of the proposed regulation provides that the regulation is not applicable to parties to an existing court-ordered settlement or final judgment establishing a concentration of acrylamide in a specific product covered in the settlement or judgment.
[66] *CEH v. Lamb Weston Holdings, Inc., et al*. (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-01412, Judg. No. J3851, Lamb Weston Holdings, Inc.]); and *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00951; Judg. No. J3850, J.R. Simplot Company]).
[67] US FDA (2011 and 2015), full citation provided in footnote 37.

F. Potato or sweet potato products, not otherwise specified, such as hash browns and potato puffs

This group covers potato or sweet potato-based products other than sliced chips (see section G) or French fried potatoes (see section E). Examples of food in this group include hash browns, potato puffs (e.g., potato tots and tater puffs), and extruded products (e.g., potato-based pellet chips and sticks).

OEHHA proposes to set the level for acrylamide in this group of food products to be 350 ppb (maximum average concentration level) and 490 ppb (maximum unit

concentration level), based on more than 20 court approved CEH settlements[68]. These CEH settlements set the maximum average concentration level at 350 ppb and the maximum unit concentration level at either 490 ppb or 500 ppb[69].

[68] For example, *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00951; Judg. No. J3850, J.R. Simplot Company]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 16838609 [AG No. 2016-00955; Judg. No. J4050, Inventure Foods, Inc.]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 16838609 [AG No. 2016-00956; Judg. No. J4064, Dishaka LLC and Simply 7 Snacks, LLC]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 16838609 [AG No. 2016-00955; Judg. No. J4281, The French's Food Company, LLC]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 16838609 [AG No. 2016-00955; Judg. No. J4336, Utz Quality Foods, LLC, Snikiddy, LLC, and Good Health Natural Products, LLC]); *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00957; Judg. No. J3852, Basic American, Inc.]); *CEH v. FoodShouldTasteGood, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17851469 [AG No. 2016-01126; Judg. No. J4337, General Mills, Inc., and FoodShouldTasteGood, Inc.]); *CEH v. FoodShouldTasteGood, Inc., et al.* (Super. Ct. Alameda, 2017, No. RG 17851469 [AG No. 2016-01126; Judg. No. J3557, Live Better Brands, LLC]); *CEH v. FoodShouldTasteGood, Inc., et al.* (Super. Ct. Alameda, 2017, No. RG 17851469 [AG No. 2016-01426; Judg. No. J3629, FGF Brands, Inc.]); *CEH v. Snack Innovations, et al.* (Super. Ct. Alameda, 2018, No. RG 17851470 [AG No. 2017-00038; Judg. No. J3775, Warnock Food Products, Inc.]); *CEH v. Snack Innovations, et al.* (Super. Ct. Alameda, 2018, No. RG 17851470 [AG No. 2016-01426; Judg. No. J3777, Naturebox, Inc.]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17870238 [AG No. 2018-00134; Judg. No. J4330, Amplify Snack Brands, Inc.)]; *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2017-00038; Judg. No. J4167, Old Lyme Gourmet Company]); *CEH v. Think Food Group LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 17881940 [AG No. 2017-00155; Judg. No. J4280, Nugget Market, Inc.]); *CEH v. Galleria Market LP, et al.* (Super. Ct. Alameda, 2019, No. RG 18928947 [AG No. 2018-01192; Judg. No. J4335, Aldi, Inc.]); *CEH v. Galleria Market LP, et al.* (Super. Ct. Alameda, 2018, No. RG 17851470 [AG No. 2016-01126; Judg. No. J3986, Snack Innovations Inc.]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2016-01258; Judg. No. J3773, Nongshim America, Inc.]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2016-01258; Judg. No. J3961, Daiso California LLC]); *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-01412; Judg. No. J3851, Lamb Weston Holdings, Inc.]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2017-00381; Judg. No. J4051, KSF Acquisition Corp.]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 16838609 [AG No. 2017-01524; Judg. No. J3980, R.W. Garcia Co., Inc.]); *CEH v. FoodShouldTasteGood, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17851469 [AG No. 2016-00956; Judg. No. J3963, Kettle Foods, Inc. and Late July Snacks, LLC.]); *CEH v. Reser's Fine Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17851466 [AG No. 2016-01241; Judg. No. J3849, Reser's Fine Foods, Inc.]); and *CEH v. Galleria Market, LP, et al.* (Super. Ct. Alameda, 2019, No. RG 18928947 [AG No. 2018-02051; Judg. No. J4279, Dickinson Frozen Foods, Inc.]).

The four most recent settlements[70] vary in their description of how the average level is to be determined. As an example, the *CEH v. Galleria Market LP, et al.* settlement (Case No. RG 18928947, AG No. 2018-01192; Judg. No. J4335) states the following regarding determination of the average level and the unit level. This language is commonly used by recent settlements.

> "The average acrylamide concentration shall not exceed 350 ppb by weight (the "Extruded Products Average Level"). The Extruded Products Average Level is determined by randomly selecting and testing at least 1 sample each from 5 different lots of a particular type of Covered Product that is an Extruded Product (or the maximum number of lots available for testing if less than 5) during a testing period of at least 60 days."
>
> "The acrylamide concentration of any individual unit of Extruded Products shall not exceed 490 ppb by weight, based on a representative composite sample taken from the individual unit being tested (the "Extruded Products Unit Level")."

According to the US FDA data[71], the average level of acrylamide in various potato products (except sliced chips and French fried products) was 369 ppb (N = 93, range ND – 1999) in 2011, and 466 ppb (N = 48, range ND – 1770) in 2015. For sweet potato products other than sliced chips, the average level of acrylamide was 344 ppb (N = 30, range: ND – 1480) in 2011, and 232 ppb (N = 73, range: ND – 1030) in 2015.

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[69] *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-01412; Judg. No. J3851, Lamb Weston Holdings, Inc.]); *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00951; Judg. No. J3850, J.R. Simplot Company]); *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00957; Judg. No. J3852, Basic American, Inc.]); *CEH v. Reser's Fine Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17851466 [AG No. 2016-01241; Judg. No. J3849, Reser's Fine Foods, Inc.]); and *CEH v. Galleria Market, LP, et al.* (Super. Ct. Alameda, 2019, No. RG 18928947 [AG No. 2018-02051; Judg. No. J4279, Dickinson Frozen Foods, Inc.]).

[70] *CEH v. Galleria Market LP, et al.* (Super. Ct. Alameda, 2019, No. RG 18928947 [AG No. 2018-01192; Judg. No. J4335, Aldi, Inc.]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 16838609 [AG No. 2016-00955; Judg. No. J4336, Utz Quality Foods, LLC., Snikiddy, LLC, and Good Health Natural Products, LLC]); *CEH v. FoodShouldTasteGood, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17851469 [AG No. 2016-01126; Judg. No. J4337, General Mills, Inc, and FoodShouldTasteGood, Inc.]); and *CEH v. Goya Foods, Inc. et al.* (Super. Ct. Alameda, 2019, No. RG 17870238 [AG No. 2018-00134; Judg. No. J4330, Amplify Snack Brands, Inc.]).

[71] US FDA (2011 and 2015), full citation provided in footnote 37.

G. Potato or sweet potato products, sliced chips

This group covers sliced potato or sweet potato chips and does not cover other potato or sweet potato products such as potato crisps (see section F) or French-fried potatoes (see section E).

OEHHA proposes to set the level for acrylamide in sliced potato chips to be 281 ppb (maximum average concentration level) and 350 ppb (maximum unit concentration level).

These proposed levels are based on more than 10 court approved CEH settlements[72], all of which set the same levels: 281 ppb for the maximum average concentration level and 350 ppb for the maximum unit concentration level.

As an example, the *CEH v. Galleria Market LP, et al.* settlement (Case No. RG 18928947, AG No. 2018-01192; Judg. No. J4335) states the following regarding determination of the average level and the unit level. This language is commonly used by recent settlements.

> "The average acrylamide concentration shall not exceed 281 parts per billion ("ppb") by weight (the "Sliced Chips Average Level"). The Sliced Chips Average Level is determined by randomly selecting and testing at least 1 sample each from 5 different lots of a particular type of Covered

[72] *CEH v. Galleria Market LP, et al.* (Super. Ct. Alameda, 2019, No. RG 18928947 [AG No. 2018-01192; Judg. No. J4335, Aldi, Inc.]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 16838609 [AG No. 2016-00955; Judg. No. J4281, The French's Food Company, LLC]); *CEH v. Snikiddy, LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 16838609 [AG No. 2016-00956; Judg. No. J3776, Dieffenbach's Potato Chips, Inc.]); *CEH v. Think Food Group LLC, et al.* (Super. Ct. Alameda, 2019, No. RG 17881940 [AG No. 2017-00155; Judg. No. J4280, Nugget Market, Inc.]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17870238 [AG No. 2018-00134; Judg. No. J4330, Amplify Snack Brands, Inc.)]; *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2017-00381; Judg. No. J4051, KSF Acquisition Corp.]); *CEH v. Think Food Group, LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17881940 [AG No. 2017-00381; Judg. No. J3962, Shearer's Foods, LLC and Barrel O'Fun Snack Foods Co., LLC]); *CEH v. FoodShouldTasteGood, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17851469 [AG No. 2016-01126; Judg. No. J4337, General Mills, Inc, and FoodShouldTasteGood, Inc.]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2016-01258; Judg. No. J3985, Calbee North America, LLC]); *CEH v. Goya Foods, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17870238 [AG No. 2016-01258; Judg. No. J3961, Daiso California, LLC]); *CEH v. Snack Innovations, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17851470 [AG No. 2016-01426; Judg. No. J3777, Naturebox, Inc.]); *CEH v. Snack Innovations, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17851470 [AG No. 2017-00038; Judg. No. J3775, Warnock Food Products, Inc.]); and *CEH v. Think Food Group LLC, et al.* (Super. Ct. Alameda, 2018, No. RG 17881940 [AG No. 2016-01258; Judg. No. J3805, Think Food Group LLC]).

Product that is a Sliced Chip (or the maximum number of lots available for testing if less than 5) during a testing period of at least 60 days."

"The acrylamide concentration of any individual unit of Sliced Chips shall not exceed 350 ppb by weight, based on a representative composite sample taken from the individual unit being tested (the "Sliced Chips Unit Level")."

According to the US FDA data[73], the average level of acrylamide found in a range of sliced potato chip products was 295 ppb (N = 66, range ND – 1040) in 2011, and 517 ppb (N = 28, range 140 – 1410) in 2015. In sliced sweet potato chips, the average level of acrylamide found by US FDA was 1401 ppb (N = 8, range: 717 – 3515) in 2011. In 2015, only 2 samples of sweet potato chips were taken, with very different results, 260 and 8440 ppb.

H. Prune juice:

OEHHA proposes two different maximum unit concentration levels for prune juice based on how the prune juice is made, 100% juice (i.e., not from concentrate) or made with concentrate.

1. Prune juice, 100% (not from concentrate)

This group covers 100% prune juice (not from concentrate). The proposed maximum unit concentration level is 250 ppb.

2. Prune juice, made with concentrate

This group covers prune juice made with concentrate. The proposed maximum unit concentration level is 150 ppb.

These proposed maximum unit levels for prune juice are based on the levels set in three court approved settlements[74]. A recent *CEH v. Mrs. Gooch's Natural Food Markets, Inc., et al.* settlement (Case No. RG 17852777, AG No. 2017-01722; Judg. No. J4331) states the following regarding determination of the unit levels:

[73] US FDA (2011 and 2015), full citation provided in footnote 37.
[74] *CEH v. Mrs. Gooch's Natural Food Markets, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 17852777 [AG No. 2016-01318; Judg. No. J3799, Cliffstar LLC and Cliffstar California LLC.]); *CEH v. Mrs. Gooch's Natural Food Markets, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17852777 [AG No. 2017-01722; Judg. No. J4331, Lassonde Pappas and Company, Inc.]); and *CEH v. Mrs. Gooch's Natural Food Markets, Inc., et al.* (Super. Ct. Alameda, 2019, No. RG 17852777 [AG No. 2017-02289; Judg. No. J4332, Smucker Natural Foods, Inc.]).

> "For 100% Single Strength Covered Products (Not Made from Concentrate): the acrylamide concentration of any individual unit of Covered Products shall not exceed 250 ppb, based on a representative composite sample taken from the individual unit being tested.
>
> For Covered Products Made only from Concentrate: the acrylamide concentration of any individual unit of Covered Products shall not exceed 150 ppb, based on a representative composite sample taken from the individual unit being tested."

US FDA (2015)[75] reported four prune juice samples (type unspecified) at 60, 160, 170, and 200 ppb. These values are consistent with what was reported in an older US FDA dataset (2004) of 13 prune juice samples (type unspecified), an average of 159 ppb with ranges between 53 to 267 ppb (OEHHA 2005)[76]. No values on prune juice were reported by US FDA in 2011.

I. Waffles

This group covers frozen packaged waffle products of all flavors and sizes. OEHHA proposes to set the maximum average concentration level of acrylamide in waffles at 280 ppb. This level is based on the court-approved *Embry v. Sprouts Farmers Market, et al.* settlement (Case No. RG 19011780, AG No. 2020-01096; Stlmt. No. S8556). A maximum unit concentration level was not part of the settlement.

The *Embry v. Sprouts Farmers Market, et al.* settlement states the following regarding determination of the average level:

> "Compliance with the Reformulation Level shall be determined after preparing the Product as if prepared for consumption in accordance with the instructions on the packaging label of the Product and in accordance with the sample preparation protocol in Exhibit B. In addition, in determining compliance with the Reformulation Level, the average of at least three samples drawn from three different production lots of each type of Product (or from as many lots or batches as are available if there are

[75] US FDA (2011 and 2015), full citation provided in footnote 37.
[76] OEHHA (2005). Characterization of acrylamide intake from certain foods. Available from: https://oehha.ca.gov/media/downloads/crnr/acrylamideintakereport_1.pdf.

fewer than three), but no more than ten samples drawn from ten different product lots of each type of Product, shall be controlling."

According to the US FDA data[77], the average level of acrylamide in waffles (breakfast foods) was 89 ppb (N = 30, range: ND – 353) in 2011. Only two waffle samples were reported in 2015, both with levels below the detection limit. Given the 2011 findings, is unclear how representative those two samples were.

V. Necessity

Proposition 65 was enacted to provide the public with information about exposures to chemicals that cause cancer, birth defects, or reproductive harm. The proposed regulation will encourage businesses to reduce significant exposures where it is feasible to avoid providing warnings for their products. Thus, this regulatory action will protect the health and welfare of the California public by avoiding the negative impact to public health that could result from a proliferation of warnings for unavoidable exposures to listed chemicals in foods, thus frustrating the ability for consumers to differentiate between foods with high and low levels of listed chemicals created by heating or food processing. The proposed regulation thus furthers the purposes of the Act by incentivizing businesses to lower the levels of these chemicals when feasible, and will encourage consistency, predictability, and lower overall levels of exposure. It will also help ensure that businesses provide warnings for food products with levels of these chemicals that can be feasibly reduced, while avoiding a potential proliferation of warnings on many foods where the levels have been reduced to the lowest levels currently feasible, using the levels established in the regulation. The regulation accomplishes these objectives by establishing that there is no exposure requiring a warning for purposes of Proposition 65 to listed chemicals in foods created by cooking or heat processing if the concentrations are reduced to the lowest feasible level using current good agricultural and manufacturing practices, quality control measures, and changes in methods of processing. The regulation also establishes achievable levels of acrylamide for foods that are cooked or heat processed. OEHHA will modify the levels in the event a feasible method for lowering the levels further is identified in the future. Levels for other chemicals or food groups may be adopted later.

[77] US FDA (2011 and 2015), full citation provided in footnote 37.

VI. 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. The proposed regulation will help businesses comply with the requirements of Proposition 65 by establishing feasible concentration levels for chemicals formed in foods by cooking or heat processing.

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. The proposed regulation will help businesses comply with the requirements of Proposition 65 by establishing feasible concentration levels for chemicals formed in foods by cooking or heat processing.

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. The proposed regulation will help businesses comply with the requirements of Proposition 65 by establishing feasible concentration levels for chemicals formed in foods by cooking or heat processing.

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

OEHHA has concluded that the public would benefit from the proposed amendments because sound considerations of public health support the establishment of feasible concentration levels for chemicals formed in foods by cooking or heat processing. OEHHA recognizes the importance of promoting healthy eating choices and the important role a balanced diet plays in promoting and maintaining optimal health. This regulatory action will protect the health and welfare of the California public by avoiding consumer confusion and the negative impact to public health that could result from over warning for foods.

VII. 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.

VIII. Benefits of the Proposed Regulation

The proposed regulation will encourage businesses to reduce significant exposures where it is feasible to avoid providing warnings for their products. Thus, this regulatory action will protect the health and welfare of the California public by avoiding the negative impact to public health that could result from a proliferation of warnings for unavoidable exposures to listed chemicals in foods, thus frustrating the ability for consumers to differentiate between foods with high and low levels of listed chemicals created by heating or food processing.

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

OEHHA has determined there are no reasonable alternatives to the proposed regulatory action that would carry out the purposes of the Act. The proposed action provides clarification on the application of the warning requirement to exposures to listed chemicals in foods resulting from necessary cooking or other heat processing.

A coalition of chocolate and nut producers, confectioners, retailers and related trade associations requested[78] that OEHHA take at least one of three actions:

1) Provide a regulatory exemption for roasted nuts and cocoa/chocolate,
2) Substantially increase the No Significant Risk Level (NSRL) for acrylamide based on scientific studies, and/or
3) Adopt an Alternative No Significant Risk Level for acrylamide for their products.

[78] Letter from Agricultural Council of California, et al., to Lauren Zeise, Ph.D., Director, OEHHA (November 13, 2019).

With regard to the first action, the coalition requested that OEHHA make a finding that acrylamide in certain specified cooked and heat processed foods does not pose a significant risk of cancer, similar to OEHHA's finding in Section 25704 that listed chemicals created by the roasting of coffee beans and brewing of coffee do not pose a significant cancer risk. OEHHA is not able to take such an action. Section 25704 was based on several findings: a large body of human studies finding inadequate evidence for the carcinogenicity of drinking coffee, inverse associations indicating decreasing cancer risk for specific cancers with increasing coffee intake in human studies, animal studies also showing protective effects, and the rich mix of cancer-preventative agents in brewed coffee. To OEHHA's knowledge, there is no comparable body of evidence that could serve as a basis for a similar regulation covering other acrylamide-containing foods.

As to the second action, OEHHA researched the possibility that the NSRL for acrylamide could be substantially increased based on current scientific evidence and found that the science would not support this. This determination included a careful review of recent state-of-the-art laboratory-animal carcinogenicity studies of acrylamide[79] and its metabolite glycidamide[80], along with a number of

[79] National Toxicology Program (2012). NTP Technical Report on the Toxicology and Carcinogenesis Studies of Acrylamide (CAS No. 79-06-1) in F344/N rats and B6C3F1 mice (Feed and drinking water studies). Technical Report Series No. 575. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from: https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr575_508.pdf.

[80] National Toxicology Program (2014). NTP Technical Report on the Toxicology and Carcinogenesis Studies of Glycidamide (CASRN 5694-00-8) in F344/N NCTR Rats and B6C3F1/NCTR Mice (Drinking Water Studies). Technical Report Series No. 588. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from: https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr588_508.pdf.

pharmacokinetic studies and other related data[81] bearing on the extrapolation of animal results to humans and the variation within the human population of acrylamide metabolisms.

Related to the third request, OEHHA considered, pursuant to Section 25705(b), the possibility of a higher alternative to the no significant risk level of one cancer per 100,000 exposed for acrylamide in specific cooked foods. OEHHA considered the request and determined that the approach taken in this proposed regulation would be preferable. This approach incentivizes reductions in acrylamide levels across a wide variety of foods that contain avoidable levels of acrylamide.

In OEHHA's view, the adoption of an alternative risk level could create a patchwork of safe-harbor acrylamide benchmarks for foods because of the substantial number of acrylamide-related settlements and pending enforcement actions. Food products covered by a settlement would still be covered by the acrylamide levels in those settlements unless the settlements were modified to incorporate the lower alternative risk level. Food products not covered by a settlement, on the other hand, would need only to meet the alternative risk level to receive safe-harbor protection. In sum, adoption of an alternative risk level would likely result in inconsistent acrylamide warnings among many competing

[81] For example, Fennell TR, Friedman MA (2005). Comparison of acrylamide metabolism in humans and rodents. Adv Exp Med Biol. 561:109-16. Doerge DR, Young JF, McDaniel LP, Twaddle NC, Churchwell MI (2005). Toxicokinetics of acrylamide and glycidamide in B6C3F(1) mice. *Toxicol Appl Pharmacol* 202(3):258-267. Doerge DR, Young JF, McDaniel LP, Twaddle NC, Churchwell MI (2005). Toxicokinetics of acrylamide and glycidamide in Fischer 344 rats. *Toxicol Appl Pharmacol*. 208(3):199-209. Walker K, Hattis D, Russ A, Sonawane B, Ginsberg G (2007). Approaches to acrylamide physiologically based toxicokinetic modeling for exploring child-adult dosimetry differences. *J Toxicol Environ Health A*. 70(24):2033-2055. Young JF, Luecke RH, Doerge DR (2007). Physiologically based pharmacokinetic/pharmacodynamic model for acrylamide and its metabolites in mice, rats, and humans. *Chem Res Toxicol*. 20(3):388-399. Sweeney LM, Kirman CR, Gargas ML, Carson ML, Tardiff RG (2010). Development of a physiologically-based toxicokinetic model of acrylamide and glycidamide in rats and humans. *Food Chem Toxicol*. 48(2):668-685. Doerge DR, Young JF, Chen JJ, Dinovi MJ, Henry SH (2008). Using dietary exposure and physiologically based pharmacokinetic/pharmacodynamic modeling in human risk extrapolations for acrylamide toxicity. *J Agric Food Chem*. 56(15):6031-6038. Vesper HW, Ospina M, Meyers T, et al. (2006). Automated method for measuring globin adducts of acrylamide and glycidamide at optimized Edman reaction conditions. *Rapid Commun Mass Spectrom*. 20(6):959-964. Bjellaas T, Olesen PT, Frandsen H, et al. (2007). Comparison of estimated dietary intake of acrylamide with hemoglobin adducts of acrylamide and glycidamide. *Toxicol Sci*. 98(1):110-117. Duale N, Bjellaas T, Alexander J, et al. (2009). Biomarkers of human exposure to acrylamide and relation to polymorphisms in metabolizing genes. *Toxicol Sci*. 108(1):90-99. Vesper HW, Caudill SP, Osterloh JD, Meyers T, Scott D, Myers GL (2010). Exposure of the U.S. population to acrylamide in the National Health and Nutrition Examination Survey 2003-2004. *Environ Health Perspect*. 118(2):278-283.

products that would prevent consumers interested in minimizing exposure to acrylamide from making informed comparisons of those products. Manufacturers of products covered by a settlement could have a competitive advantage over a competing manufacturer of a product not covered by a settlement, or vice versa. The proposed rulemaking avoids these problems by promulgating consistent safe-harbor acrylamide concentrations that apply to all products in a given category.

X. 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.

The current proposal furthers the purposes of Proposition 65 by providing an incentive for businesses to reduce the levels of chemicals formed in cooking and heat processing to the lowest feasible levels that can be achieved by good agricultural and manufacturing practices, quality control measures, and changes in methods of processing. 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[82] from the requirements of the Act.

XI. Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulatory action facilitates compliance by affected businesses by helping them determine when the warning requirements may apply to a given food product.

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

XII. 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 regulations do not duplicate and will not conflict with federal regulations.