

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
PROPOSITION 65**

**ADDENDUM TO INITIAL STATEMENT OF REASONS**

**TITLE 27, CALIFORNIA CODE OF REGULATIONS  
PROPOSED ADOPTION OF NEW SECTION 25506**

**EXPOSURES TO ACRYLAMIDE 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. Introduction

The Office of Environmental Health Hazard Assessment (OEHHA), the lead agency that implements Proposition 65<sup>1</sup>, proposed a regulatory action to adopt new Section 25506 into Title 27 of the California Code of Regulations<sup>2</sup>, to address Proposition 65 listed chemicals formed by cooking or heat processing foods. The original regulatory proposal, including the Initial Statement of Reasons (ISOR<sup>3</sup>), was released in August 2020<sup>4</sup>. In April 2021, OEHHA released a proposed modification to the original text of the regulation. OEHHA submitted a final rulemaking file to the Office of Administrative Law (OAL) on September 21, 2021. OAL issued a disapproval decision on March 11, 2022.

OEHHA is releasing a second modification to the proposed regulation text. This Addendum to the ISOR (Addendum) is being published in support of the proposed changes to the regulation. The Addendum corrects the ISOR, explains the additional modifications and the reasons for these modifications, provides additional information to further clarify the regulatory proposal, and makes corrections to the ISOR. This is an Addendum to the ISOR and does not replace it.

## II. Necessity of Second Modification of Text and Further Clarification of the Proposal

The modified proposed regulatory text limits the proposal to acrylamide in cooked and heat processed foods. The problems the proposed regulation addresses are how to further the statutory purposes of (1) reducing exposures to the carcinogen acrylamide present in food due to cooking or heat processing, and (2) requiring

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<sup>1</sup> 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”).

<sup>2</sup> All further references are to sections of Title 27 of the California Code of Regulations, unless indicated otherwise.

<sup>3</sup> Initial Statement of Reasons, Title 27, California Code of Regulations, Proposed Adoption of Article 5, Section 25505, Exposures to Listed Chemicals in Cooked or Heat Processed Foods, (August 7, 2020). Available at: <https://oehha.ca.gov/media/downloads/crn/isor080720.pdf>.

<sup>4</sup> California Regulatory Notice Register, 2020, Number 32-Z, Notice File Number Z2020-0728-02. Available at: <https://oal.ca.gov/wp-content/uploads/sites/166/2020/08/2020-Notice-Register-Number-32-Z-August-7-2020.pdf>.

warnings for avoidable exposures to acrylamide caused by cooking or heat processing, while (3) improving the effectiveness of those warnings that are given by avoiding ubiquitous warnings for unavoidable exposures. These goals are the same as those of the original proposal, except for the narrower focus on acrylamide instead of on all Proposition 65 listed chemicals that may be formed in foods by cooking and heat processing.

Acrylamide is not a food additive. It is formed by the cooking or heat processing of certain foods. A certain amount of the chemical is unavoidable. Acrylamide is one of the most common chemicals created by cooking or heat processing food. The proposed modifications focus the regulation on acrylamide. The specific safe harbor concentration levels of acrylamide in certain foods that were in the April 2021 modified regulatory text remain in place. The proposed modifications also strengthen and clarify Subsection (a), which provides that businesses do not “expose” an individual to acrylamide within the meaning of Proposition 65 when the manufacturer of the food has utilized applicable practices specified in Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009 (2009)<sup>5</sup>, to bring the levels of acrylamide in food down to the lowest level currently feasible.

### **Section 25506**

The proposed section number was changed from 25505 to 25506. Section 25505 was repealed. While that section pertained to Proposition 65, it was unrelated to this proposed rulemaking. This change avoids confusion by using a section number that has not previously been used.

“Listed Chemicals” was changed to “Acrylamide” in the title of Section 25506, which was originally called “Exposures to Listed Chemicals in Cooked or Heat Processed Foods”. OEHHA is narrowing the scope of the proposed regulation from all Proposition 65 chemicals that may be created through cooking and heat processing food to a single listed chemical, acrylamide. This change allows OEHHA to provide greater specificity regarding the methods to reduce exposures pursuant to subsection 25506(a), as discussed below.

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<sup>5</sup> Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009 (2009). Available at: [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B67-2009%252FCXP\\_067e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B67-2009%252FCXP_067e.pdf).

### **Subsection (a)**

Subsection (a) of the modified regulatory text provides that if a manufacturer has reduced exposure to acrylamide created through cooking or heat processing in its food products to the lowest level currently feasible, a business does not “expose” an individual to the chemical within the meaning of Section 25249.6 (and therefore are not subject to the Proposition 65 warning requirements).

A number of modifications to the regulatory text were made to narrow the scope of the proposal to acrylamide. The scope of subsection (a) was narrowed from all Proposition 65 chemicals created through cooking and heat processing to only address acrylamide. This change provides the basis for the more specific identification of methods a business can use to reduce exposures to acrylamide pursuant to this subsection. Guidance on methods to reduce other Proposition 65 listed chemicals created through cooking or heat processing is not as readily available. This narrowing of the scope does not preclude OEHHA from addressing other Proposition 65 listed chemicals in foods in the future.

The modified text has removed “producer”, “distributor, or holder of a food” from subsection (a) because the manufacturer of the food is the entity that has the most control over practices and methods to reduce acrylamide in food. This change does not serve to limit the use of the defense in subsection (a) to just the manufacturer, but acknowledges that the practices in the document incorporated by reference are mainly utilized by the manufacturer.

The modified proposal provides guidance on how a business can achieve the “lowest level currently feasible”. It removes reference to the undefined term, “quality control measures,” and specifies that reductions can be achieved by utilizing practices recommended in the Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009<sup>6</sup>, which the regulation incorporates by reference. The Codex Alimentarius is a collection of standards, guidelines, and practices adopted by the Codex Alimentarius Commission, which was established by the Food and Agriculture Organization of the United Nations and the World Health Organization to protect consumer health and promote fair practices in food trade.

The practices set out in the Codex 2009 Code of Practice identify the amount of acrylamide formed from cooking and other heat processing that can be avoided

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<sup>6</sup> Hereafter referred to as “Codex 2009 Code of Practice”.

through good agricultural and manufacturing practices. For example, in the Codex 2009 Code of Practice, good agricultural and manufacturing practices include:

- Reducing the level of precursors in the raw materials that react to form acrylamide during cooking or heat processing (e.g., by considering factors related to agronomy, sourcing, and/or storage),
- Modifying and/or carefully controlling the food processing or heating (e.g., cooking temperature and/or time).

This part of the proposed regulation can be used by businesses to show that acrylamide has been lowered to the lowest level currently feasible by employing the relevant and applicable practices in the Codex 2009 Code of Practice. This document describes a variety of factors to take into consideration to achieve the lowest level of acrylamide currently feasible in a given food product.

Incorporating the practices provided in the Codex 2009 Code of Practice to define and achieve the lowest level currently feasible is a practical approach to reducing acrylamide formation in foods utilizing an internationally accepted standard of practices.

### **Subsection (b)**

The modifications in Subsection (b) are minor changes for clarity. The proposal changes “in the course of doing business” to “otherwise responsible for an exposure” to clarify that it is specific to businesses that may cause an exposure. Also, “listed chemical” has been changed to “acrylamide” to conform to the narrowed scope of Section 25506. The proposal also removes “alternative” in the term “alternative concentration” to clarify that Articles 7 and 8 can be used to establish a concentration of acrylamide in food whether or not there is a concentration adopted in subsection 25506(d). The term “subdivision” was changed to “subsection” to conform with the term used elsewhere in the regulation and to use the correct term.

### **Subsection (c)**

Subsection (c) has been modified for clarity and does not change the meaning of the provision as originally proposed: Court-ordered settlements or final judgments completed prior to the effective date of the proposed regulation are not affected by the adoption of the levels in subsection (d). The second modification makes the following changes to the original proposal in underline (addition) and ~~strikeout~~ (deletion):

“Nothing in this section shall apply to parties to ~~an existing a~~ court-ordered settlement or final judgment entered before [OAL add the effective date of the regulation] to the extent that such settlement or judgment establishes a concentration of ~~the chemical~~acrylamide in a specific product ~~covered in the settlement or judgment~~that is different from the concentrations provided in subsection (d).”

Thus, if the parties to such a court-ordered settlement or final judgment have agreed that a warning is not required for a product with a concentration of the listed chemical that is different than the levels established in subsection (d), the parties to that court-ordered settlement or final judgment would not be affected by the adoption of this regulation as it is prospective, not retroactive. This provides certainty to parties to Proposition 65 that they can rely on a court-ordered settlement or final judgment, even if the level of acrylamide in a food that is specified in that settlement or judgement is different than the level specified in Section 25506(d)(4). Nothing in the regulation would prevent a party to a consent judgment from moving to modify the consent judgment if the consent judgment includes a modification provision.

As in other subsections, “the chemical” is changed to “acrylamide” since the regulation was narrowed to pertain only to acrylamide.

### **Subsection (d)**

Subsection (d) sets forth nonmandatory safe harbor “maximum average” and “maximum unit” concentrations for acrylamide in foods that would not constitute an exposure pursuant to Section 25506(a), and therefore would not require a warning. Several changes are made for clarity. “Chemicals” was changed to “acrylamide” throughout. The modifications clearly state that both the “maximum average” and “maximum unit” concentrations must be met to claim safe harbor protection. When only one of these two concentration benchmarks is listed in the Subsection (d)(4) table, only that concentration would need to be met to claim the safe harbor.

The proposed modification deletes the definitions for “average concentration” and “unit concentration” in Subsection (d) and instead defines the terms using more specific language in newly added subsections 25506(d)(1) and (d)(2) for clarity.

### **Subsection (d)(1)**

The proposed modifications to Subsection 25506(d)(1) define “unit concentration” with greater specificity than in the original proposal by stating:

The concentration of acrylamide measured in a single food item or individual packaged unit, such as bag, box, or carton, of the specific food product in the form the product is sold to California consumers. The unit concentration is based on a representative composite sample taken from the individual packaged unit.

Basing the unit concentrations on representative composite samples taken from a single unit of the food product being tested is consistent with the process used in several settlements serving as the basis for values set out in subsection (d)(4). This is a commonly used and scientifically sound method of sampling. The original ISOR (footnote 33) explained that the term “representative composite sample” is used by parties to existing settlements:

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).<sup>7</sup>

The modified text clarifies the meaning of “individual packaged unit” with reference to examples such as a bag, box, or carton. It also specifies that the food product must be in the form the product is sold to consumers in California, thus making it clear that product samples different from those sold to consumers in California cannot be used in the calculations.

For clarity, the modified text, in subsection 25506(d)(1) defines “representative composite sample,” as a sample “made up of portions of the food in the same proportion as in the whole individual packaged unit,” and provides the example of a loaf of bread. The modified text would make clear that a representative composite sample could not be made up of all crust<sup>8</sup>, or all crumb (the inner portion of the loaf of bread)<sup>9</sup>. A representative composite sample from a bag of potato chips would involve not sampling from only the lightest colored chips, or

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<sup>7</sup> ISOR page 12.

<sup>8</sup> Crust is the brown, hard outer portion or surface of a loaf or slice of bread (distinguished from crumb). <https://www.dictionary.com/browse/crust>.

<sup>9</sup> Crumb is the soft inner portion of a bread (distinguished from crust). <https://www.dictionary.com/browse/crumb>.



only the darkest colored chips. This definition of terms “unit concentration” and “representative composite sample” provides greater clarity on what is meant by the concentration levels of acrylamide in food for specific foods provided in Section 25506(d)(4).

### **Subsection (d)(2)**

For clarity, the modified regulation provides greater specificity to the definition of “average concentration”. This provides a clearer basis for calculating the maximum average concentration values set out in Subsection 25506(d)(4). It is modified as follows:

The average concentration is determined by adding together the unit concentrations of at least five samples taken over a period of no less than 60 days with no less than 10-day intervals between sampling and then dividing this total by the total number of samples.

This definition provides some flexibility because businesses’ operations are not uniform across the industry and acknowledges that food production processes are not necessarily uniform over time. The required number of samples and the time periods for sampling are consistent with the practices set out in some of the Proposition 65 settlements used as a basis for the proposed levels.

The proposed modifications in this subsection provide a method of calculation for businesses to use, namely the arithmetic mean, and the approach to sampling, including the specific number of samples that must be taken over a specific time period (not less than 60 days), to use to determine the average concentration levels of acrylamide in a given food for comparison with the values set out in section (d)(4). Existing settlements for acrylamide were reviewed in developing this minimum requirement. For example, this approach is consistent with that provided to calculate the average concentration of acrylamide in thin and crispy cookies in the *CEH v. Fantasy Cookie Corporation* settlement (Case No. RG17872866, 2018-01193J3999).

### **Subsection (d)(3)**

The modified regulation provides greater clarity in Subsection (d)(3) with respect to the measurement of acrylamide concentrations in foods by specifying that testing must be conducted by a chemical analysis laboratory with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standard ISO/IEC 17025 accreditation. This means that the laboratory must be accredited by a third party and have demonstrated that it performs to the

latest quality process standards set by ISO. The laboratory would therefore meet general requirements for the “competence, impartiality and consistent operation of laboratories” to demonstrate that they “operate competently and generate valid results...”.<sup>10</sup> Accreditation to this standard is a widely used and acknowledged approach for ensuring laboratory competency for achieving reliable results.

#### **Subsection (d)(4)**

This section was renumbered from 25506(d)(1) to 25506(d)(4) in the modified text to accommodate the new subsections in subsection 25506(d) discussed above.

Subsection 25506(d)(4) provides maximum average and maximum unit concentration levels of acrylamide in certain foods. A business can determine the maximum average concentration and maximum unit concentration (as appropriate) present in its product and compare that to the value(s) in subsection 25506(d)(4). If the product’s acrylamide concentration is equal to or less than the value set out in this subsection, a business does not “expose” an individual within the meaning of Section 25249.6 of the Act, and therefore no Proposition 65 warning is required.

A number of modifications to the regulatory text were made in this subsection for clarity. The main modification is a reorganization of food entries in the maximum unit and average concentration table. However, no substantive changes were made in the second modification of text. No foods were added or removed from the proposed regulation (as modified in April 2021), and no safe harbor concentration levels were changed.

The reorganization of the table was done to more clearly show how the food groups and foods relate to one another. Non-substantive changes in wording in the description of food types were made to accommodate the reorganization.

In addition to the reorganization of information in the table other non-substantive wording changes were made for clarity. The word “level” was removed from the column headings because it was redundant given the use of the word “concentration”. The sentence preceding the table was changed to clarify that the

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<sup>10</sup> International Organization for Standardization. See <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>.

term “ppb” in the table means parts per billion by weight. The table is shown below without the additions and strikeouts to show how the information would be presented in final form. Following the table, the specific language changes are described for the different food categories.

The modified regulatory text for subsection 25506(d)(4) is given below.

“(4) Acrylamide concentrations are given in the table below in parts per billion by weight (ppb).

Foods/Food groups	Maximum average concentration (ppb)	Maximum unit concentration (ppb)
Almonds, specifically roasted almonds, and chocolate-covered roasted almonds	225	---
Bread, including loaves, rolls, buns, baguettes:		---
a. non-wheat-based products	100	
b. wheat-based products	50	
Cookies:		
a. animal and animal crackers (sweet)	75	100
b. thin and crispy	281	300
c. sandwich wafers	115	---
Crackers, specifically savory crackers, including crispbread	350	490
Potato or sweet potato products:		
a. French fried potatoes	280	400
b. sliced chips	281	350
c. all other products, including hash browns and potato puffs	350	490
Waffles	280	---

In setting the safe harbor levels for acrylamide in foods provided in the table, OEHHA started by gathering data for acrylamide in specific foods from agencies such as the US FDA and from published studies, as well as from target levels identified in regulations or rules and Proposition 65 settlements. OEHHA used these data sources to establish the levels in Section 25506(d)(4), as explained in the original ISOR, pages 13-29. The data from the US FDA, Proposition 65 court-approved settlements, and the European Union (EU) were most informative for addressing the feasibility issue because they reflect measured levels of

acrylamide in foods (US FDA) and levels agreed upon as attainable by food manufacturers (court-approved settlements) and regulators (EU). The careful evaluation of a variety of scientific sources for each of the listed food groups is why the levels are set using different sources of data for different foods.

OEHHA explained in the original ISOR at page 6 that court-approved settlements indicate the level of acrylamide that is feasible to achieve. Manufacturers who cannot meet the acrylamide levels agreed upon agree to withdraw and not sell their products in California, agree to a reformulation, or agree to give a warning. The settlements used to set the levels in this proposed regulation all had court approval. This check helps ensure that the levels in the settlement agreements are achievable and in the public interest.

Safe harbor concentration levels may not be achievable for every business, regardless of the size of the business. The proposed regulation is non-mandatory guidance for businesses. The concentration levels set out in the proposed regulation are not maximum levels of acrylamide allowed in specific foods. The levels are safe harbor levels, meaning a food that has a lower level of acrylamide need not provide a warning. If a business determines that it cannot reduce the concentration of the listed chemical in its product to the lowest level currently feasible, or to the safe harbor concentration established in subsection (d)(4) of the regulation, it is not required to do so. The business may use other provisions of the regulations to defend an enforcement action (e.g., Section (a) or Article 7) or provide a warning for its product. If the business is unable to establish an alternative level, the business is not required to reformulate the product. It can still sell the product in California; it just needs to provide a warning for the product.

It should be noted that certain products, such as prunes and almond butter, were removed from the proposed regulation in the first 15-day modification in response to comments from businesses stating they could not achieve the levels set out in the proposed regulation.

### **Almonds: Roasted almonds and chocolate-covered roasted almonds**

In the second modified regulatory text the name of the roasted almond food group was changed:

Almonds, **specifically** roasted **almonds**, ~~roasted almond butter,~~ and chocolate-covered **roasted** almonds.

This change clarifies that, consistent with OEHHA’s intent, the concentration provided for this food group only applies to roasted almonds and chocolate-covered roasted almonds. The original ISOR on page 14, stated that, “This food group covers roasted almonds, almond butter made from roasted almonds, and chocolate-covered roasted almonds.” However, as noted earlier, almond butter was removed in the first modification of text. In the second modification the addition of the word “specifically” clarifies that the maximum average concentration of 225 ppb set out in the regulation only applies to roasted almonds and chocolate-covered roasted almonds and not to other types of almonds such as raw almonds.

As discussed in the ISOR (p. 15), the level for acrylamide in these products was based on the level established in two settlements. This level is lower by a factor of 2.4 and 3.2 than the highest values observed in two studies by the Almond Board of California (726 and 544 ppb). While it is higher than levels reported by the US FDA in 2011 and 2015, the number of samples reported by the US FDA was quite small, and the representativeness of the sample was unclear. The level of 225 ppb in the settlement is higher than the average level in the Almond Board of California studies in 2014 (194 ppb for oil roasted, 169 ppb for dry roasted) demonstrating feasibility and the potential to produce lower concentrations. In addition, other businesses not parties to the settlement stand to benefit from the level established in the proposed regulation. The level set for this food group is feasible, fair, and promotes the public’s right to know about high exposures to acrylamide.

## **Bread**

The modified text makes it easier to see that the food group “bread” is comprised of two sub-groups: “non-wheat-based products” and “wheat-based products.” The levels used for bread are based on both the European Union (EU) benchmark levels<sup>11</sup> and the US FDA data, as discussed in the ISOR pages 16-18. The US FDA data is specific to wheat-based breads. OEHHA did not find a settlement for breads with levels lower than those listed by the EU. In fact, the levels set for breads established by the EU are feasible given the data from both the EU and the US FDA. The ISOR (page 17) explains that, in support of EU

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<sup>11</sup> 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>.

regulations, the European Food Safety Authority (EFSA)<sup>12</sup> reviewed acrylamide data in bread, including data from rolls and reported an average of 46 ppb (95th percentile = 203 ppb) in 99 non-wheat-based bread samples from different European countries.

For wheat-based products, EU data reported an average of 38 ppb and the US FDA reported an average of 22 ppb<sup>13</sup>. In light of the EU and US FDA data, the 50 ppb level set for this category is feasible.

One settlement for breads covers both “wheat-based products” and “non-wheat-based products” and established a level that is identical to the EU benchmark for “non-wheat-based products”; this settlement also enabled maximum levels at 200 ppb,<sup>14</sup> and thus does not appear to be set at the lowest level currently feasible. For this reason, separate values based on the EU and US FDA data were proposed for breads (e.g., one value for “wheat-based products” and one value for “non-wheat-based products”), as these are feasible and attainable for these food groups. The levels set for these food groups are feasible, fair, and promote the public’s right to know.

## **Cookies**

OEHHA has not changed its regulatory proposal for maximum average and unit concentrations and provides safe harbor concentrations for three specific subcategories of cookies – “animal and animal crackers (sweet)”, “thin and crispy” and “sandwich wafers” under one cookie category with specific subcategories of cookies. These categories do not include all types of cookies sold in California. There are some types of cookies that do not have proposed concentrations. The categories chosen were cookies with available Proposition 65 settlements specific to these products.

Regarding animal crackers, as stated in the original ISOR on page 18, “This group covers sweet animal-shaped hard cookies and animal crackers.” In this addendum OEHHA is removing the word “hard” from this sentence in the ISOR

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<sup>12</sup> 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.

<sup>13</sup> ISOR page 17.

<sup>14</sup> See, e.g., AG Number 2017-1797. Available from: <https://oag.ca.gov/system/files/prop65/judgments/2017-01797J4416.pdf>.

to provide clarity that the category for this type of cookies, is “animal and animal crackers (sweet)” commonly referred to as animal cookies or animal crackers, as indicated in the food category label in the subsection (d)(4) table. This is consistent with the current modification - “Cookies: animal and animal crackers (sweet)” and the original regulatory proposal - “Cookies, animal and animal crackers (sweet).”

The levels for each of the specific subcategories of cookies are based on settlement data, as described in the ISOR (pages 18-21). These settlement data were carefully selected by reviewing the applicable categories of cookies in the settlements, and not using values from any settlement that was not feasible. For example, a settlement was not used that set a lower acrylamide level for a product that is no longer available in the marketplace. There are several settlements that use the values being proposed for cookies: seven for animal and animal crackers, nine for thin and crispy cookies, and two for sandwich wafers. The large number of settlements for animal and animal crackers and for thin and crispy cookies that use the values proposed here indicates the levels set for these cookie groups are feasible, fair, and promote the public’s right to know. Similarly, the levels set for sandwich wafers, which are based on values used in two settlements, are consistent with the available data from US FDA<sup>15</sup>, and thus are also feasible, fair, and promote the public’s right to know.

## **Crackers**

The text has been modified to clarify that the “cracker” food group is “specifically” limited to savory crackers:

“Crackers, **specifically** savory **crackers**, including crispbread.”

The use of the word “specifically” is to indicate that all crackers are not covered by this proposed regulation. The level establish in the table is limited to savory crackers including crispbreads. Sweet crackers are not covered.

As discussed in the ISOR on page 22, the safe harbor level for acrylamide for crackers is based on two Proposition 65 settlements. While US FDA data<sup>16</sup> show lower average values, they also show considerably higher values for some crackers. By using the settlement numbers while still taking into consideration the

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<sup>15</sup> See ISOR page 21.

<sup>16</sup> See ISOR page 22.

range of US FDA data, OEHHA chose to rely on the settlements to establish a feasibility level that provides an incentive to businesses to reach concentrations below the levels at the high end of the range.

### **Potato and sweet potato products**

While the safe harbor levels and foods covered in this subsection remain unchanged, the modification of text clarifies that all potato products are covered in the proposed regulation and the values that apply to different types of potato products:

- Potato or sweet potato products;
- a. French fried potatoes
- b. sliced chips
- c. all other products, including hash browns and potato puffs

All potato and sweet potato products are grouped in one category. The phrase “all other products” was added to clarify that all other products in that category are included in the concentration provided for that category. Additionally, for clarity “such as,” is replaced by “including,” with the two specific examples, previously included in the original proposal, hash browns and potato puffs.

For the potato and sweet potato category of foods, more than 20 settlements and US FDA data (see ISOR pages 27-28) for each product within the category were used to set the levels. The levels of acrylamide in potatoes can be very high and the focus of efforts to reduce acrylamide in potato products has resulted in the development of practices that result in lower levels. The more than 20 settlements used to set the levels for this category of foods leveraged this knowledge and have been designed to reduce acrylamide in the products considered. This relatively large number of Proposition 65 settlements has resulted in established levels that can be considered the lowest levels currently feasible for purposes of the proposed regulation.

### **Waffles**

While the regulatory text for this food category has not been modified since the original proposal, OEHHA is clarifying that the proposed concentration applies to all waffles as sold to consumers in California, whether frozen, or otherwise packaged. The level set for this food group (280 ppb maximum average concentration level) is based on a value used in a 2020 settlement, which has been used in the two subsequent settlements for this food group that set



maximum average concentration levels for acrylamide and that aim at reducing acrylamide in the products considered.

### **III. Erratum to Original ISOR**

OEHHA is making corrections to the original ISOR on pages 19 and 20. The maximum unit concentration level (ppb) for “Cookies, thin and crispy” is 300 ppb. The current text of the ISOR on pages 19 and 20 incorrectly states the level is 350 ppb. The corrected text in strikethrough (for deletion) and in bold and underline (for addition) is as follows:

- “The proposed levels for acrylamide in thin and crispy cookies are 281 ppb for the maximum average level and ~~350~~**300** ppb for the maximum unit level. These levels are based on nine court-approved settlements<sup>57</sup> in which the same or nearly the same levels (maximum average concentration of 280 or 281 ppb; maximum unit concentration level of ~~350~~**300** ppb) were used as in the regulatory proposal.
- Footnote 57. These seven settlements set the maximum average concentration at 281 ppb and maximum unit concentration at ~~350~~**300** ppb.

### **IV. Necessity**

The original ISOR stated that there is a need for safe harbor levels and proposed specific levels of acrylamide in cooked foods to ensure that warnings are provided when individuals are being exposed to high levels of a listed chemical, while at the same time incentivizing businesses to reduce the levels of acrylamide in their products to the lowest level technically feasible, thus furthering the purposes of the statute. OEHHA narrowed the scope of the regulation to only acrylamide since there is sufficient information available to establish feasible concentration levels for that chemical. The necessity discussion in the original ISOR is specific to acrylamide in cooked or heat processed foods; therefore, it supports the necessity for this modified proposal.

### **V. 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 does not impose new regulatory requirements on businesses. Instead, the regulation provides regulatory guidance concerning levels of acrylamide in specific kinds of foods that do not require a Proposition 65 warning. Businesses that manufacture and sell these foods are not required to meet these levels. Businesses that do not meet these levels may need to provide a warning as currently required pursuant to Health and Safety Code Section 25249.6 unless they have a prior settlement agreement or can show their products do not pose significant risks pursuant to Article 7.

## **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 does not impose new regulatory requirements on businesses. Instead, the regulation provides regulatory guidance concerning levels of acrylamide in specific kinds of foods that do not require a Proposition 65 warning. Businesses that manufacture and sell these foods are not required to meet these levels. Businesses that do not meet these levels may need to provide a warning as required under Health and Safety Code Section 25249.6. No new businesses will be created because the proposed regulation does not impose a new regulatory requirement, and no businesses will be eliminated because the costs for compliance are optional, minor, and potentially outweighed by savings, as discussed below.

### *Summary of Costs and Savings to Businesses*

The overall cost to businesses is estimated to be \$2,151,000, a sum of \$976,000 for product labeling and \$1,175,000 for testing of products.

The overall savings to businesses is estimated to be \$5,223,000, the sum of \$2,385,000 for avoided attorneys' fees and \$2,838,000 for avoided penalties, attorneys' fees, and other payments.

Because of the reduction in litigation, a reduction from the Safe Drinking Water and Toxic Enforcement Fund of approximately \$300,000 is also estimated.

### *Explanation of Costs and Savings to Businesses*

OEHHA estimates that the proposed regulation may have minor costs for existing businesses for testing products and updating labels on products. OEHHA estimates, using the North American Industrial Classification System<sup>17</sup>, the businesses affected include commercial bakeries, frozen cakes, pies, and other pastries manufacturing, and snack food manufacturing totaling 652 businesses in California in 2019 of which 367 have 10 or more employees (2019 is the most recent year for which data are available). The costs for testing products are approximately \$200 per test according to an internet search in 2022<sup>18</sup>. Many businesses are already testing their products for levels of acrylamide. For example, the European Union has a law and measures aimed at reducing acrylamide exposure<sup>19</sup> and acrylamide has been on the Proposition 65 list since 1990 for cancer, and 2011 for developmental and male reproductive harm<sup>20</sup>. OEHHA assumes that about 70% of businesses out of the 367 described above already test for acrylamide in their products.

To test a representative sample including duplicates, we estimate each business not already testing would perform 50 tests. Section 25506(d) outlines that there must be a minimum of 5 tests, given duplicates and a variety of products per business, an estimate would be 50 tests per business on average. At approximately \$200 per test this may result in a testing cost of approximately \$1,100,000. (110 companies x 50 tests x \$200 per test = \$1,100,000.) Adjusting for 2023 dollars<sup>21</sup> brings the total to **\$1,175,000**.

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<sup>17</sup> United States Census Bureau (2022), US & State 6 digit NAICS (Excel file), 2019 SUSB Annual Data Tables by Establishment Industry. Available at: [https://www2.census.gov/programs-surveys/susb/tables/2019/us\\_state\\_6digitnaics\\_2019.xlsx](https://www2.census.gov/programs-surveys/susb/tables/2019/us_state_6digitnaics_2019.xlsx) on site: <https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html>:

<sup>18</sup> Test information was obtained from Euofins (\$125) via email June 3, 2022; Medallion Labs (\$216) information, available at: <https://www.medallionlabs.com/tests/acrylamide/> (accessed on October 5, 2022), and Murray-Brown Laboratories Inc. (\$150), available at: <https://mb-labs.com/services/acrylamide-testing/> (accessed on October 5, 2022). The average cost is \$163.66, rounded up to \$200.

<sup>19</sup> European Union (2017), full citation provided in footnote 11.

<sup>20</sup> See Office of Environmental Health Hazard Assessment, Acrylamide. Available at: <https://oehha.ca.gov/proposition-65/chemicals/acrylamide> (last accessed on October 5, 2022).

<sup>21</sup> Department of Finance (DOF, 2022), Consumer Price Index Forecast – Annual and Monthly (Excel Spreadsheet), on Economic Forecasts, U.S. and California webpage. DOF, State of California. Available at: <https://dof.ca.gov/wp-content/uploads/Forecasting/Economics/Documents/US-CA-Inflation-Forecast-MR-2022-23.xlsx>

The costs for providing warnings for products if the business decides it needs to include a warning, can be spread out over several years, depending upon the stock of product on hand and the implementation date for the regulation. In 2015 OEHHA estimated that each warning added to a label would cost \$1000 relating to minor label redesigns to accommodate the warning<sup>22</sup>. In 2023 dollars, this is estimated to be \$1330. In a review of the settlements for acrylamide in food that are required to be reported to the California Office of the Attorney General, the majority of the settlements involved one product, some involved two, and many did not specify a number but identified one specific product. Assuming that each of the approximately 367 businesses potentially impacted by this proposal adds warnings, on average, to two of their products as a result of this regulation, OEHHA estimates that businesses will spend approximately \$976,000 as a onetime cost to add a warning to the product label or container. (367 businesses x 2 products x \$1330 per warning added = **\$976,000**).

OEHHA also anticipates that businesses in California would save money from the proposed regulation in the form of reduced litigation and settlements costs for businesses. Looking at the past four years of court-approved settlements for acrylamide in food, 56% of them are for foods covered by safe harbor concentrations in the proposed regulation.

In absence of the proposed regulation, we assume that 56% of cases would still be related to safe harbor concentrations. Multiplying this percentage by the average sum of penalties, attorney fees and other payments, in 2023 dollars, results in approximately **\$2,838,000** (= \$5,067,966 [Average per year penalties, attorneys' fees, and other payments] x 0.56 [cases covered by the proposed regulation]).

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<sup>22</sup> Office of Environmental Health Hazard Assessment (2016), Final Statement of Reasons, Title 27, California Code of regulations, Proposed Repeal of Article 6 and Adoption of New Article 6 regulations for Clear and Reasonable Warnings. Available at: <https://oehha.ca.gov/media/downloads/cnr/art6fsor090116.pdf>.

**Proposition 65 60-Day Notices of Intent to Sue and Settlements for Acrylamide**

Source: Office of the Attorney General (OAG)

Year	60-day Notices	Settlements	Payments by Defendants (\$)				
			Civil Penalties	Attorney Fees	Other Payments	Total per year all cases	Average per case
2021	313	68	\$363,284	\$2,813,936	\$50,630	\$3,227,850	\$47,468
2020	555	126	\$824,444	\$6,121,876	\$46,930	\$6,993,250	\$55,502
2019	268	60	\$436,495	\$3,685,520	\$74,985	\$4,197,000	\$69,950
2018	192	34	\$600,569	\$2,062,824	\$360,707	\$3,024,100	\$88,944
Average per year			\$556,198	\$3,671,039	\$133,313	\$4,360,550	\$65,466

**Proposition 65 60-Day Notices of Intent to Sue and Settlements for Acrylamide in 2023 dollars\***

Year	60-day Notices	Settlements	Civil Penalties	Attorney Fees	Other Payments	Total	Average per case
2021	313	68	\$401,555	\$3,110,373	\$55,964	\$3,567,891	\$52,469
2020	555	126	\$954,127	\$7,084,830	\$54,312	\$8,093,269	\$64,232
2019	268	60	\$514,247	\$4,342,017	\$88,342	\$4,944,606	\$82,410
2018	192	34	\$728,066	\$2,500,750	\$437,283	\$3,666,099	\$107,826
Average per year in 2023 dollars			\$649,499	\$4,259,492	\$158,975	\$5,067,966	\$76,734

\*Adjusted to 2023 dollars using the consumer price index for California provided at <https://dof.ca.gov/wp-content/uploads/Forecasting/Economics/Documents/US-CA-Inflation-Forecast-MR-2022-23.xlsx>

An additional cost for businesses is to pay for their own attorneys' fees. OEHHA assumes that these are comparable to what the plaintiffs' attorneys' fees are approximately **\$2,385,000** (= \$4,259,492 [average attorneys' fees in 2023 dollars] x 0.56 [cases covered by the proposed regulation]).

Proposition 65 warnings are very common in California, and OEHHA has not seen evidence suggesting that warnings have a severe economic impact on businesses, even for foods. For example, some brands of balsamic vinegar have

carried Proposition 65 warnings for many years and some potato chip brands provide Proposition 65 acrylamide warnings. Many nutritional supplements carry warnings. Most significantly, many coffee products continue to carry warnings for acrylamide despite a 2019 OEHHA regulation expressly clarifying that warnings for coffee are not required. For these reasons, OEHHA does not believe there is a basis for assuming job losses and severe economic impact on businesses will result for businesses that choose to provide warnings for food products as a result of this regulation.

### **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 does not impose new regulatory requirements on businesses. Instead, the regulation provides regulatory guidance concerning levels of acrylamide in specific kinds of foods that do not require a Proposition 65 warning. Businesses that manufacture and sell these foods are not required to meet these levels. Businesses that do not meet these levels would need to provide a warning as currently required pursuant to Health and Safety Code Section 25249.6.

### **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 overwarning for foods.

The regulation would have no impact on worker safety. Acrylamide and other chemicals created by the cooking or heat processing of foods present a potential hazard to those who eat the food. Workers who prepare the foods do not handle these chemicals and are not exposed to them because they must be consumed for exposure to occur.

The regulation would have no impact on the state's environment. Acrylamide and other chemicals created by the cooking or heat processing of foods present a potential hazard to those who eat the food. These chemicals are not considered

to be environmental contaminants at levels found in cooked or heat-processed foods.

## **VI. Additional Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon**

This document is proposed for incorporation by reference in Section 25506(a):

- Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods (CAC/RCP 67-2009). Available at: [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B67-2009%252FCXP\\_067e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B67-2009%252FCXP_067e.pdf)

OEHHA is adding the following additional documents relied on to the administrative record for this action:

- Office of Environmental Health Hazard Assessment (OEHHA, 2016), Final Statement of Reasons, Title 27, California Code of Regulations, Proposed Repeal of Article 6 and Adoption of New Article 6 Regulations for Clear and Reasonable Warnings. Available at: <https://oehha.ca.gov/media/downloads/crn/art6fsor090116.pdf>
- Department of Finance (DOF, 2022), Consumer Price Index Forecast – Annual and Monthly (Excel Spreadsheet), on Economic Forecasts, U.S. and California webpage. DOF, State of California. Available at: <https://dof.ca.gov/wp-content/uploads/Forecasting/Economics/Documents/US-CA-Inflation-Forecast-MR-2022-23.xlsx>
- United States Census Bureau (2022), US & State 6 digit NAICS (Excel Spreadsheet), on webpage: 2019 SUSB Annual Data Tables by Establishment Industry, February 2022. Available at: [https://www2.census.gov/programs-surveys/susb/tables/2019/us\\_state\\_6digitnaics\\_2019.xlsx](https://www2.census.gov/programs-surveys/susb/tables/2019/us_state_6digitnaics_2019.xlsx)
- Office of Environmental Health Hazard Assessment, Acrylamide (webpage). Available at: <https://oehha.ca.gov/proposition-65/chemicals/acrylamide> (last accessed on October 5, 2022)