Safe Drinking Water and Toxic Enforcement Act of 1986
Proposition 65

Final Statement of Reasons

Title 27, California Code of Regulations

Adoption of Article 5, Section 25506

Exposures to Acrylamide in Cooked or Heat Processed Foods

November 2022

California Environmental Protection Agency

Office of Environmental Health Hazard Assessment

Contents

General Information

Overview of the Regulation

This is the Final Statement of Reasons (FSOR) for the adoption of Section 25506 into Title 27 of the California Code of Regulations[1], originally proposed as Section 25505. The new section addresses acrylamide in food formed by cooking or heat processing.

The proposed regulation provides that intake of acrylamide that is formed during the cooking or heat processing of foods does not represent an exposure for the purposes of Proposition 65 if the concentrations of acrylamide are reduced to the lowest level currently feasible using practices in the Codex Alimentarius 2009 Code of Practice[2], which is incorporated by reference in Section 25506. The regulation also establishes maximum concentration levels for acrylamide in certain listed foods, and food groups, that are deemed to be the lowest levels currently feasible. Concentrations of acrylamide at or below the levels identified in the regulation would not require a warning. The proposed 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.

Process and Timeline

The Office of Environmental Health Hazard Assessment (OEHHA) published the Notice of Proposed Rulemaking and Initial Statement of Reasons (ISOR) for this action on August 7, 2020, initiating a public comment period that was to close on October 6, 2020. The comment period was extended to October 21, 2020. The Notice announced that a public hearing would be held upon request. None was requested for this regulatory proposal.

Following careful consideration of the relevant comments received during the initial comment period, on April 16, 2021, OEHHA published a Notice of Modification of Text of Proposed Regulation and the proposed modified regulatory text, and initiated a 15-day comment period, which closed on May 7, 2021. OEHHA received three public comments during the 15-day comment period.

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[1] All further citations are to sections of Title 27 of the California Code of Regulations, unless otherwise stated.

[2] 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.

The final rulemaking was submitted to the Office of Administrative Law (OAL) on September 21, 2021. OAL issued a disapproval decision on March 11, 2022.

On October 6, 2022, OEHHA proposed a second modification of text, incorporated a document by reference in the regulation text, added documents to the rulemaking file and provided errata and an Addendum to the ISOR for public comment. OEHHA initiated a 15-day comment period, which closed on October 21, 2022. OEHHA received six public comments during the second 15-day comment period.

OEHHA's responses to the relevant comments received during the three public comment periods described above are incorporated within this Final Statement of Reasons (FSOR). Some comments submitted do not constitute an objection or recommendation directed at the proposed action or the procedures followed in this rulemaking action. OEHHA is not required under the Administrative Procedure Act (APA) to respond to remarks received during the rulemaking process that are not relevant to the specific action open for public comment. The absence of responses to such comments should not be construed to mean that OEHHA in any way agrees or disagrees with them.

Update of Initial Statement of Reasons

As authorized by Government Code section 11346.9(d), OEHHA incorporates by reference the ISOR, the Addendum to the ISOR and the first and second notices of modification to this rulemaking. Unless specifically discussed otherwise below, or in these documents, the ISOR's and the Addendum to the ISOR's stated basis for the necessity of the proposed regulation continue to apply to the regulation as adopted. All modifications from the initial proposed text of the regulation are summarized below.

The Addendum to the ISOR included an Erratum to the Original ISOR, which made corrections to pages 19 and 20 of the original ISOR.[3] ,The proposed regulation text and several places in the ISOR correctly listed the maximum unit concentration level (ppb) for "Cookies, thin and crispy," as 300 ppb. The text of the ISOR on pages 19 and 20 inadvertently stated it as 350 ppb. OEHHA provided a 15-day public notice of this error in the Addendum to the ISOR October 6, 2022.

Additionally, the Notice of Proposed Rulemaking includes Health and Safety Code sections 25249.5 and 25249.9 under "References." These Health and Safety Code sections are not being implemented, interpreted, or made specific by the Office in this

[3] Addendum to ISOR page 17.

regulatory action. As such, they should not have been included as reference citations in that Notice.

Modifications to the Proposed Rulemaking

First Modification, April 16, 2021

In the Notice of Modification of Text published on April 16, 2021[4], OEHHA proposed modifications to the text of the proposed regulation. The modifications clarified that a business that has measured levels of listed chemicals[5] in its products that are below the concentration levels established in the proposed regulation is not required to make any further showing of feasibility or compliance with good manufacturing practices to rely on the concentration levels established in Subsection 25505(d) of the proposed regulation. In addition, the concentration levels for roasted almond butter and prune juice were removed from proposed Subsection 25505(d) based on comments received.

Second Modification, October 7, 2022

The second modification changed the proposed section number from 25505 to 25506[6], and narrowed the scope of the proposed regulation from all listed chemicals in cooked and heat processed foods to just acrylamide. The second modification also clarified that if the food manufacturer reduced the levels of acrylamide to the "lowest level currently feasible" by using the applicable practices recommended in the 2009 Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009[7], which is incorporated by reference into the regulation, a business does not "expose" an individual within the meaning of the Act. For clarity, the modification reformatted information displayed in Subsection 25506(d)(4) for foods and associated acrylamide levels deemed to be "lowest level currently feasible" but did not change any of the listed foods or listed maximum levels of acrylamide. The second modification also defined the methods of measurement for unit concentration and for calculation of the

[4] Hereafter referred to as "first modification."

[5] The original proposal and first modification referred to exposures to all Proposition 65 listed chemicals. The second modification changed the regulation to exposures to acrylamide.

[6] The regulation was originally proposed as a new Section 25505 but was subsequently changed to Section 25506 because Section 25505 was an unrelated and formerly repealed section. This change avoids confusion by using a section number that has not previously been used.

[7] 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.
Hereafter referred to as the "Codex 2009 Code of Practice".

average concentration of acrylamide. It also defined how to form a representative composite sample and required the lab performing the tests for determining the levels of acrylamide in food for comparison with the values in Subsection 25506(d)(4) to have International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) standard ISO/IEC 17025 accreditation.

Summary of and Response to Comments on Original Proposed Regulation - August 2020

The following organizations and individuals submitted written comments on the original proposed regulation during the August 7, 2020, to October 21, 2020, comment period:

Agricultural Council of California (AgCC)

Almond Alliance of California (AlmondAC)

American Bakers Association (ABA)

Anonymous #1

Anonymous #2

Calsafe Research Center (CRC)

Center for Environmental Health (CEH)

Chemistries of Heated Carbohydrates Consortium (CHCC)

Consumer Brands Association, California Chamber of Commerce and 32 other signatories (CalChamber/CB Coalition)[8]

Council for Education and Research on Toxics (CERT)

Diamond Foods

Frozen Potato Products Institute (FPPI)

Independent Bakers Association (IBA)

Justin's LLC (Justin's)

Key Sciences

Lawrence Gratt (LGratt)

National Confectioners Association (NCA)

Parks & Solar LLP (P&S)

[8] The signatories are California Chamber of Commerce, Consumer Brands Association, Agricultural Council of California, American Bakers Association, American Beverage Association, American Chemistry Council, American Frozen Food Institute, American Herbal Products Association, California Attractions and Parks Association, CA Automatic Vendors Council, California Farm Bureau Federation, California League of Food Producers, California Manufacturers & Technology Association, California Restaurant Association, California Retailers Association, Chemistries of Heated Carbohydrates Consortium, Civil Justice Association of California, Flexible Packaging Association, Frozen Potato Products Institute, Independent Bakers Association, Institute of Shortening and Edible Oils, International Dairy Foods Association, International Food Additives Council, International Technical Caramel Association, Juice Products Association, National Automatic Merchandising Association, National Confectioners Association, National Seasoning Manufacturers Association, Peanut and Tree Nut Processors Association, SNAC International, The Vinegar Institute, The Food Industry Association, Western Growers Association, and Western Independent Refiners Association.

Peanut and Tree Nut Processors Association (PTNPA)

S Nava (SNava)

Shahir Masri (SMasri)

Simply Good Foods (SGF)

SNAC International (SNAC)

Steve Sujimoto (SSujimoto)[9]

Sunsweet Growers Inc. (Sunsweet)

Western Agricultural Processors Association (WAPA)

The comments are summarized and responded to below. As described above, changes have been made to the substance and numbering of the final proposed regulation. When a commenter referred to Section 25505 or used verbiage from the original proposal, such as "listed chemical," that language is maintained in the summary of the comment. Where applicable, responses to comments acknowledge the subsequent modifications.

General Comments

Statements of support

Comment 1 (AgCC, CHCC, CalChamber/CB Coalition, Diamond Foods, FPPI, NCA, PTNPA, and SNAC): Several commenters expressed support for the adoption of the proposed regulation. In general, these commenters appreciated OEHHA's efforts to address circumstances in which the chemical acrylamide is formed during cooking or heat processing at the lowest level currently feasible when using available quality control measures. The regulation incentivizes businesses to reduce the levels of acrylamide to the lowest level feasible and will assist them in compliance. For example, CHCC expressed support for OEHHA's proposed concentration levels where the acrylamide exposure for which a company is responsible can be demonstrated to be at the lowest level currently feasible based on either an adopted safe harbor level or, if a company prefers, or there is no adopted safe harbor level, a case-by-case showing based on evidence concerning the product at issue.

Response: OEHHA acknowledges the supportive comments.

No changes were made to the proposed regulation based on these comments.

[9] Comment was received February 19, 2021, and although it was received outside of the public comment period, OEHHA chose to include it in the Final Statement of Reasons.

Scope of regulation

Comment 2 (CEH): The commenter stated that it is important to ensure that any warning exemption is narrowly tailored to address the unavoidable presence of chemicals in foods. As presently framed, Section 25505 applies "to the extent the chemical was created by cooking or other heat processing." Does this include using a brass cooking pot that leaches lead into a food (and if so, why)? Does this include completely superfluous cooking or heating that is unrelated to palatability or microbiological contamination (and if so, why)?

Response: This regulation does not apply to chemicals that may leach into a food during cooking from any source. As originally framed, the regulation applied to listed chemicals that result from cooking or heat processing; but it now applies to only one such chemical, acrylamide. The ISOR notes methods to reduce the occurrence of acrylamide, and the Addendum to the ISOR explains the rationale for incorporating by reference the Codex 2009 Code of Practice for reducing acrylamide in food into the final version of the regulation. The regulation does not require any particular reduction method. As the ISOR at page 8 explains:

> 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.

No changes were made to the proposed regulation based on this comment.

Comment 3 (Key Sciences): The commenter stated that there is an open question as to whether the proposed regulation will apply to pending and previously filed notices and complaints.

Response: The proposed regulation will be final when it is filed with the Secretary of State. It is not retroactive. However, the new regulation could be used as a defense in a pending action.

No changes were made to the proposed regulation based on this comment.

Comparison with "naturally occurring" regulation

Comment 4 (CEH and CERT): The commenters stated that OEHHA's "naturally occurring" regulation provides some precedent for considering technical feasibility in the Proposition 65 context (see Cal. Code Regs., tit. 27, § 25501), but disagreed with the approach of the naturally occurring regulation since consumers should be warned about

actionable levels of listed chemicals in their food regardless of whether that chemical is present due to human or natural causes.

CERT stated that in affirming the validity of the naturally occurring regulation, the Court of Appeal explicitly relied in part on its view "that Proposition 65 sought to regulate toxic substances which are deliberately added or put into the environment by human activity." *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 659. By contrast, in the proposed regulation, exposures are occurring solely due to human activities, i.e., cooking or heat processing. These knowing and intentional exposures to listed chemicals from Proposition 65's warning requirement should not be exempted based on feasibility concerns.

CEH stated consumers in California deserve to know whether the food they choose for themselves and their families will expose them to listed chemicals above certain risk thresholds established by Proposition 65 and its implementing regulations, irrespective of whether the companies producing and selling that food could reduce or eliminate the presence of such chemicals. CERT stated that a manufacturer must provide a cancer hazard warning regardless of the efforts it has taken to reduce the levels of carcinogens in its products if it presents a significant risk of cancer. The proposed regulation would prevent Californians from receiving warnings regarding carcinogens in food. CERT stated there is no exemption in the statute for "best efforts" or "good manufacturing practices".

Response: 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. As explained in the ISOR, the lead agency previously 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 Health and Safety Code section 25249.6.[10] As noted by the commenters, this approach was upheld by the Court of Appeal.[11] The court 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."[12] The court also noted that "warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products."[13]

[10] Section 25501.

[11] *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652.

[12] *Id.* at p. 661, quoting Final Statement of Reasons.

[13] *Id.* at p. 661.

Acrylamide is not added to food but is formed by the cooking or heat processing of food, which is a human activity. A certain amount of acrylamide is unavoidable. On the other hand, in many circumstances the level of acrylamide formed can be lowered by optimizing certain practices, such as those specified in the Codex 2009 Code of Practice.

The regulation will help focus consumers on the highest exposures by providing safe harbor levels in subsection (d)(4); therefore, warnings on those products would be provided on products with acrylamide concentrations at higher levels than in those listed in subsection (d)(4). Also, the defenses provided in subsection (a) provide businesses an incentive to reduce the acrylamide content in their products to the lowest level currently feasible, utilizing manufacturing practices that reduce acrylamide in food laid out in the Codex 2009 Code of Practice.

No changes were made to the proposed regulation based on this comment.

Comment 5 (CalChamber/CB Coalition): The commenters stated that OEHHA and the courts have long recognized that foods require special regulatory treatment. The naturally occurring regulation and judicial precedent exempt from the definition of "exposure" under the statute chemicals that are naturally occurring in foods where they are reduced to the lowest level currently feasible. *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652 is consistent with the findings of numerous courts in numerous contexts that over-warning is against the public interest. *See, e.g.*, *Johnson v. Am. Standard, Inc.*, 43 Cal.4th 56, 70 (2008) (over-warning "invite[s] mass consumer disregard and ultimate contempt for the warning process"); *Thompson v. Cty. Of Alameda*, 27 Cal.3d 741, 754-55 (1980) (recognizing that excessive warnings "produce a cacophony . . . that by reason of their sheer volume would add little to the effective protection of the public"); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010) (concluding that over-warning "can dilute the effectiveness of valid warnings"). OEHHA's policy against over-warning is longstanding and consistent and has been upheld by the courts.

In *Nicolle-Wagner*, the Court of Appeal recognized OEHHA's ability to define the term "expose" by enacting regulations. The proposed regulation fits within this judicially approved regulatory approach because, like the naturally-occurring regulation, the proposed regulation defines the term "expose" based on a feasibility standard.

Response: OEHHA agrees that the proposed regulation will protect the health and welfare of the California public by avoiding consumer confusion and the negative impact on public health that could result from over-warning for exposures in foods. Another goal of the proposed regulation is to encourage businesses to reduce acrylamide

concentrations to avoid high consumer exposures and to avoid the need to provide warnings for their food products for which levels have been reduced (ISOR page 31).

No changes were made to the proposed regulation based on this comment.

Comment 6 (CERT): The commenter stated that in resolving an appeal in *AFL-CIO et al. v. Deukmejian*, OEHHA

> "agree[d] to repeal the regulation" and "that any provision which is adopted after the date of this agreement to define the term 'no significant risk' of the Act for any food, drug, cosmetic or medical device product, and which employs standards derived from existing state or federal law shall be based upon specific numeric standards for the chemical, as evidence by the rulemaking file."

By defining exposure to listed heat-formed carcinogens in food as not constituting an "exposure" for purposes of Proposition 65, OEHHA is effectively declaring that exposures to acrylamide in such foods present no significant risk of cancer.

The commenter alleges that the proposed regulation breaches that agreement.

Response: The quoted statement from the *AFL-CIO* settlement does not apply to this action because the proposed regulation does not define "no significant risk" and instead establishes feasible concentrations for acrylamide in food that are not based on existing federal or state authority. Thus, to the extent the settlement continues to be binding on OEHHA, the proposed regulation does not implicate or violate it.

No changes were made to the proposed regulation based on this comment.

Burden of proof

Comment 7 (Sunsweet): The commenter stated that a food manufacturer may be required to show and share what it is doing but should then not bear the burden to further prove there are no feasible processes it might apply to further reduce concentration levels. If a bounty hunter does not bear the burden to show feasibility failure when first making its case, then that burden should at least shift away from the manufacturer once it has presented its processes with an accompanying feasibility analysis. Any "lowest level currently feasible" standard established for food processors should be defined with sufficient clarity so that if the processor makes the requisite showing of appropriate quality control measures based on the regulatory definition or guidance, the burden of proof should shift to the enforcer or State.

Response: Shifting the burden of proof in an enforcement action is beyond the scope of OEHHA's regulatory authority. The regulation sets out defenses a business can use to

defend an enforcement action. Further, in the second modification, subsection (a) was revised to incorporate the Codex 2009 Code of Practice, which provides guidance on how a business can achieve the "lowest level currently feasible" of acrylamide in its food product using an internationally accepted standard of practices.

Comment 8 (CEH, CERT): The commenters stated that OEHHA cannot legally place the burden on the plaintiff as to any new defense since Proposition 65 itself places the burden on the defendant to prove that any exposure is below the level requiring a warning (which is in effect what Section 25505 contemplates). Cal. Health & Safety Code § 25249.10(c). Section 25505 suffers from serious ambiguities (e.g., who has the burden of proof).

The commenters stated that by defining an exposure to listed carcinogens as being no exposure at all, OEHHA impermissibly places the burden of proving exemption from the warning requirement on the plaintiff, rather than the defendant. If the proposed regulation placed the burden of proof on the defendant as in the naturally occurring regulation, the proposed regulation would state: “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 that the person responsible for the exposure can show that the chemical was created by cooking or other heat processing and the producer, manufacturer, distributor, or holder of the food has utilized quality control measures that reduce the level of the chemical in a food to the lowest level currently feasible.”

Response: The proposed regulation does not shift the burden of proof onto the plaintiff. If the level of the chemical in the defendant’s product exceeds the level(s) in subsection (d)(4), the defendant must either prove that it has achieved the “lowest level currently feasible” by utilizing the practices recommended in the Codex 2009 Code of Practice, prove no warning is required pursuant to the methods set out in subsection (b), or provide a warning. The regulation is therefore consistent with the statute.

No changes were made to the proposed regulation based on this comment.

Request withdrawal of proposed regulation

Comment 9 (Key Sciences): The commenter stated that OEHHA’s method of determining the safe harbor levels appears inconsistent. In some instances, OEHHA followed prior consent judgments, but for bread, OEHHA adopted the EU standard. Other times, it appears OEHHA used a comparison of test results from a category of product testing to determine if the level set was “feasible.” OEHHA also did not provide any analysis of how these levels compare to the NSRL for acrylamide. The whole

regulation should be withdrawn because the levels cannot be adopted under a uniform standard.

Response: The ISOR and the Addendum to the ISOR explain how OEHHA developed the levels for subsection (d)(4). The Addendum (pages 11 and 12) notes:

> 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.

The ISOR (pages 6-7) also explains:

> 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 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.

The ISOR (pages 11-12) further explains:

> 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 below which a Proposition 65 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.

The Addendum to the ISOR also expands on this process on pages 11-12. The Addendum explains why specific levels in settlements were used to set the levels in Section 25506(d)(4) for almonds, cookies, potato products and waffles, and why the European Union level was used to set the levels for bread, wheat and non-wheat. Specifically, see Addendum to the ISOR page 13 (almonds), pages 13-14 (bread), pages 13-14 (cookies), pages 15-16 (crackers), page 16 (potato and sweet potato products), and pages 16-17 (waffles).

There is no requirement that the proposed regulation be analyzed based on the NSRL for the chemical. The NSRL is an alternative defense for businesses as is set out in subsection (b).

OEHHA declines to withdraw the regulation.

No changes were made to the proposed regulation based on this comment but the Addendum to the ISOR provides further justification for the proposed levels in the regulation.

Comment 10 (CERT): The commenter alleges that this proposed regulation is the result of political pressure to exempt the food industry from Proposition 65. CERT asks OEHHA to withdraw the proposed regulation.

Response: OEHHA disagrees with the commenter, who provides no support for its allegations of political pressure. The proposed regulation does not exempt the food industry from Proposition 65. The ISOR explains the justification for the regulation as follows:

> 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.

(ISOR page 6.)

> 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.

(ISOR page 29.)

The proposed regulation is consistent with the purposes and intent of the law and is consistent with other regulations including the naturally occurring regulation in Section 25501 and the provision of Section 25703 that allows for alternative risk levels for chemicals formed in foods by cooking necessary to make the food palatable or to avoid microbial contamination.

It is also consistent with the case *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, where the court agreed that there are policy reasons for reducing the proliferation of warnings and providing consumers with meaningful warnings:

> Since one of the principal purposes of the statutes in question is to provide “clear and reasonable warning” of exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of meaninglessness if they were to be found on most or all food products. [14]

One of the goals of this regulation is to create avenues for businesses to be able to prove that they have reduced chemicals formed during cooking or heat processing to the lowest level feasible, thus eliminating the need for a warning.

OEHHA declines to withdraw the proposed regulation.

No changes were made to the proposed regulation based on this comment.

[14] *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 661.

Subsection (a) – Lowest level currently feasible using quality control measures

Relationship of "lowest level currently feasible" in subsection (a) to subsection (d)

Comment 11 (Anonymous #1): The commenter stated the proposed regulation is confusing. The commenter asked if a manufacturer employing "best practices" to produce the food item with the lowest feasible concentration would also have to test the item to confirm that the acrylamide level is below that in 25505(d); or whether a manufacturer could simply document that it used best practices. The commenter also asked if the manufacturer tests its food item and it is below the level in 25505(d), does it still have to employ "best manufacturing practices," and if so, how is the use of best manufacturing practices documented or enforced?

Response: OEHHA modified the original proposal to clarify that a business is not required to make any further showing of feasibility or compliance with good manufacturing practices to rely on the levels established in subsection (d).

The modified regulation states that the levels of acrylamide in subsection (d) are "deemed to comply with subsection (a)." A business that meets the levels in subsection (d) does not have to make any further showing of feasibility or compliance with the practices in subsection (a).

If the business tests its products and the concentrations of acrylamide are at or below the levels set out in subsection (d)(4) of the regulation, the business will not need to provide a warning or employ an additional defense. If testing determines that the concentrations of acrylamide are higher than the levels set out in subsection (d)(4), the business can reduce levels of acrylamide, provide a consumer warning, or if challenged, prove that they have reduced the level of acrylamide to the "lowest level currently feasible" as provided in proposed subsection (a).

As provided in subsection (b), a business may also rely on other provisions of the Proposition 65 regulations (in Articles 7 and 8) to establish that warnings are not required.

Where the business is a party to an existing settlement or judgment for a food product, under subsection (c), compliance with the settlement is all that is necessary.

Comment 12 (CalChamber/CB Coalition): The commenter stated that the second sentence of subsection (a) is confusing because it is attempting to explain how to apply subsection (d), not subsection (a). The sentence reads as follows: "If a person 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).” The Coalition proposes deleting the second sentence in subsection (a) as unnecessary and inserting a new subsection:

> “If the concentration level in a product type identified in subsection (d) exceeds the applicable level in subsection (d), then the applicable level in subsection (d) shall not be subtracted from the concentration level for purposes of determining the “level in question” as defined in Sections 25721(a) and 25821(a).”

Response: Based on this and other comments, in the first proposed modification, OEHHA amended the original proposal to remove the sentence that was causing confusion: “If a person 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).”

OEHHA considered the proposed language submitted by the commenter but found it to be unnecessary. As indicated in the first modification, a business that meets the levels in subsection (d) does not have to make any further showing of feasibility or compliance with the practices in subsection (a).

Comment 13 (CEH, Key Sciences): The commenters asked OEHHA to clarify the relationship between the baseline feasibility provision in Section 25505(a) and the proposed feasibility levels in Subsection 25505(d). CEH stated that ordinary Proposition 65 exposure principles should apply unless the level of the chemical has been reduced to the lowest level feasible irrespective of whether there is a specific feasibility level for that chemical in that food type under Subsection 25505(d). Key Sciences stated that it appears a defendant may only rely on the levels in subsection (d) if they have “utilized quality control measures that reduce the chemical to the lowest level currently feasible.” Key Sciences also noted that OEHHA should clarify what is meant be feasible.

Response: CEH is correct that ordinary Proposition 65 exposure principles apply unless the level of the chemical has been reduced to the lowest level currently feasible. In response to these and other comments, and to provide clarity, OEHHA revised the regulation in the first modification by removing the last sentence in subsection (a). This clarifies that a business is not required to make any further showing of technological feasibility or compliance with good manufacturing practices to rely on the levels established in subsection (d). In the second modification of text, subsection (d) was further modified to provide greater clarity: “The concentration levels for acrylamide in foods in this subsection are deemed to comply with subsection (a) if both the average

concentration and unit concentration are less than or equal to those listed in subsection (d)(4)."

Also, regarding "ordinary Proposition 65 exposure principles", as stated in the original ISOR (page 11):

> Subsection (b) provides that Section [25506] 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.

In the first modification, in subsection (b), the phrase "that is different from the concentrations provided in [subsection](d)"[15] was added for further clarification.

In the second modification to regulatory text, the term "lowest level currently feasible" was further clarified by indicating that it is achieved by utilizing the practices in the Codex 2009 Code of Practice, which the proposed regulation incorporates by reference.

Comment 14 (CalChamber/CB Coalition and ABA): The commenters asked OEHHA to clarify that the levels in subsection (d) do not preclude the use of alternative levels that comply with the requirements of subsection (a). Particularly for types of products that are not yet listed in subsection (d)(1) or products for which the level listed in subsection (d)(1) is not feasible due to certain attributes, it is important that companies have the flexibility to demonstrate that they have reduced the chemical to the lowest level currently feasible in compliance with subsection (a), independently of the levels in subsection (d)(1). The Coalition asked OEHHA to clarify that the levels set forth in subsection (d) are truly *safe harbor* concentration levels by adding the following sentence to the end of subsection(d):

[15] The word "subdivision" was changed to "subsection" in the second modification.

> "The concentration levels for foods in this subsection do not preclude the use of alternative levels that comply with the requirements of subsection (a)."

This clarification is consistent with the non-mandatory, safe harbor approach.

Response: In the first modification OEHHA modified the text of the regulation in subsections (a) and (b) in response to this and other comments. The phrase "that is different from the concentrations provided in subdivision (d)" was added for purposes of clarity. The modification is different than suggested by the commenters, but the result is the same. The modification is meant to provide clarity for businesses that they can demonstrate their products are at the lowest level feasible in several different ways under this and other regulations.

Comment 15 (IBA and NCA): Similar to the above comment, these commenters asked OEHHA to recognize that the values established in subsection (d) are a form of a safe harbor and do not preclude a manufacturer from demonstrating that a higher level of the substance in a specific product is the lowest level currently feasible and businesses therefore will have the option to rely on them or to make an evidentiary showing to establish the lowest level currently feasible given their specific food product and commercial situation.

IBA proposed the following highlighted language be added to subsection (a):

> "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. If a person has implemented quality control measures reducing the substance to the lowest levels currently feasible, the levels shall not be deemed an exposure regardless of any levels that may be established in subsection (d)."

Response: OEHHA made changes in the regulation to provide clarity on this point by modifying the original proposal as described in the Response to Comment 12.

This modification is in line with the original intent of the proposed regulation to provide different avenues for businesses to prove that no warning is needed for a given exposure. Further, subsection (b) makes it clear that other approaches to establish an alternative value than that in (d) are not precluded:

> 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.*

(ISOR page 11, emphasis added.)

Subsection (b) was further modified to provide greater clarity on this point in the first modification to the regulatory proposal.

Comment 16 (Diamond Foods, NCA, PTNPA and SNAC): The commenters asked that OEHHA recognize that when a commodity is not specifically included in subsection (d), the product will be deemed in compliance and exempt from the warning requirements when the manufacturer can demonstrate the product has been produced in a manner that reduces acrylamide levels to the lowest level currently feasible.

Response: Following the proposed language included in the second modification, if a food is listed in subdivision (d)(4) and meets the safe harbor levels for acrylamide in that section, then a business does not have to provide a warning. If a food is not included in the list of food in subdivision (d)(4), then according to subsection (a), a business does not need to warn if it can demonstrate that acrylamide has been lowered to the lowest level currently feasible by utilizing applicable practices recommended in the Codex 2009 Code of Practice.

Lowest level currently feasible

Comment 17 (IBA and ABA): The commenters asked OEHHA to recognize there are multiple variables that impact acrylamide formation. OEHHA should clarify that the ISOR discussion about determining the “lowest level currently feasible” is not meant to impose any particular definition of that term, adopt any other agency’s or organization’s definition, or imply that any of the examples cited necessarily apply to any particular

product or business, and that companies will be free to establish that they are at the lowest level currently feasible based on a case-by-case showing using evidence relevant to them and their particular product(s).

Some mitigation technologies are not available to all manufacturers, either because it is not feasible or cost-effective, not allowed (as for organic or non-GMO products), or adversely impacts the organoleptic properties of the product. The “lowest level currently feasible” will vary depending on the nature of the product and should consider the manufacturer’s proprietary baking or roasting process and the equipment that exists in the facility. Manufacturers should not be required to continually adopt new and evolving technologies or add novel ingredients that would not otherwise typically be included in such products. If a manufacturer can demonstrate it has utilized the available mitigation strategies to lower acrylamide levels to those currently feasible, the acrylamide levels for that specific good should not be deemed an exposure for purposes of Proposition 65.

Response: The regulation in subsection (a) provides an affirmative defense a business can use in an enforcement action. The burden of proof lies with the business relying on the defense. While subsection (d) establishes safe harbor concentration levels for acrylamide in certain foods, businesses are free to propose a different lowest level currently feasible given their specific food product and commercial situation. Subsection (a) provides each business a way to tailor its defense to show that the acrylamide level that it has achieved is the lowest level currently feasible. The second modification of text provides for this with a showing that the business has utilized applicable practices recommended in the Codex 2009 Code of Practice, which is incorporated by reference. Some methods for reducing the amount of acrylamide in products were included in the ISOR as examples.

Alternatively, a business could establish that a warning is not required using evidence, standards, risk assessment methodologies, principles, assumptions, or levels in Articles 7 and 8 of the Proposition 65 regulations pursuant to subsection (b).

Comment 18 (PTNPA): The commenter stated that current feasibility should be data-driven and product specific, however, when there is a level established for an ingredient that is used as an ingredient in another food product with no further heat processing that could enhance acrylamide levels (e.g., mixed nut and trail mix products), that established ingredient’s level should apply to the other food product.

Response: The commenter is requesting a change to the scope of the regulation. The levels for the food products identified in the regulation apply to the finished food product, not the individual ingredients of that product. Nonetheless, this does not preclude a

business from utilizing a level in subsection (d)(4) in making calculations to show that a product is at the “lowest level currently feasible” for purposes of subsection (a).

In this regard, the business may be interested in taking measurements of acrylamide in a packaged food product containing an ingredient in subdivision (d)(4). In the second modification, OEHHA specifically defines unit concentration, representative composite sample, and average concentration. Section 25506(d)(1) defines:

> A “representative composite sample” is made up of portions of the food in the same proportion as in the whole individual packaged unit, e.g., equivalent proportions of crust and crumb (the inner portion) in the sample as in the whole loaf of bread.

No changes were made to the proposed regulation based on this comment.

Comment 19 (Key Sciences): The commenter requested clarity on what the term “lowest level currently feasible” means, stating that OEHHA provides four methods of reducing acrylamide in food (ISOR page 10). The commenter questioned whether this is an exclusive or mandatory list of methods and requested that OEHHA provide clarity on how to evaluate whether an alleged violator has taken steps to reduce the acrylamide level to the lowest level currently feasible. The commenter proposed including language to account for advancements in science and technology. The commenter also stated that OEHHA should define what is feasible, that feasible is subjective to each manufacturer, and just because something is able to be done does not mean that is feasible for a particular manufacturer.

Response: This comment was submitted in response to the original proposal released in August 2020. In response to this and other comments, in the second modification, subsection (a) was modified to clarify that "lowest level currently feasible” means the “lowest level currently feasible by utilizing applicable practices recommended in Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009 (2009), hereby incorporated by reference.” The Codex 2009 Code of Practice specifies practices and methods for reducing acrylamide in food, applicable to different foods. What is a feasible level of acrylamide for each manufacturer and each food may depend on the applicable practices and the specific food.

Comment 20 (Sunsweet): The commenter asked OEHHA to define what is “feasible.” Just because something is expensive does not mean it’s not “feasible.” Without a definition or standard for what is “feasible” it could disincentivize manufacturers from taking available, albeit potentially expensive, steps to reduce acrylamide levels. Conversely, just because something is “able” to be done to reduce acrylamide levels, doesn’t mean it’s “feasible” for a particular manufacturer. A definition or guidance is

needed. Without a definition of “feasible”, enforcers will insist on the “cutting edge” of achievability when challenging acrylamide levels in generally healthy foods. The risk of over-warning with ubiquitous threats of cancer is not just a diluted message, but a potentially dangerous subconscious stress leading directly to a higher risk of cancer and lower defenses against all other health risks.

Response: This comment was submitted in response to the original proposal released in August 2020. In response to this and other comments, in the second modification, subsection (a) was modified to clarify what is meant by “lowest level currently feasible.” See Response to Comment 19.

OEHHA set the acrylamide concentrations in the proposed regulation for certain foods by relying on, with one exception for breads, court-approved settlements and other data including US FDA and EU data,[16] to determine the amounts of acrylamide for specific foods or food categories that are feasible. The businesses entering the settlements may or may not have relied on cutting edge technologies to reach achievable levels of acrylamide. The practices that were in place were the practices that the businesses used at the time of the settlement and OEHHA presumes for the purposes of this regulation that these concentrations are feasible and thus achievable by many businesses. Where that is not the case, a business will need to decide whether to provide a warning or rely on the defenses provided in subsections (a), (b), or other existing regulations.

Quality control measures

Comment 21 (Diamond Foods, FPPI, PTNPA and SNAC): The commenters asked that OEHHA acknowledge that the European Union (EU) acrylamide toolbox and U.S. Food and Drug Administration (FDA) acrylamide guidance are appropriate examples of “quality control measures” under subsection (a). If a manufacturer can demonstrate the implementation of quality control measures that reduce acrylamide levels to the lowest levels currently feasible, the manufacturer should be deemed in compliance and a warning should not be required. The manufacturer is in the best position to implement the mitigation measures that will limit acrylamide formation in its product(s).

If OEHHA agrees the feasibility standard should be “currently feasible”, the commenters question whether it is advisable to set levels in paragraph (d) in the final regulation. The levels established should be based on data demonstrating they are indeed the “lowest levels currently feasible” and are achievable by manufacturers across the industry.

[16] See ISOR pages 6-7, and Addendum to ISOR pages 11-17.

Response: This comment was submitted in response to the original proposal released in August 2020. OEHHA removed the term “quality control measures” in the second modification. If a manufacturer can demonstrate it used applicable practices in the Codex 2009 Code of Practice, which includes some common methods of acrylamide reduction like reducing cooking time and temperature, then the business can use this section as a defense.

In proposing this regulation (ISOR page 6)**,** OEHHA set specific concentration levels that rely on settlements entered in California courts by companies selling their products in the state. OEHHA set these concentration levels to further the statutory purpose of Proposition 65 to reduce exposures to listed chemicals present in food due to the human activities of cooking or heat processing, provide warnings for avoidable exposures to acrylamide, and safeguard the effectiveness of those warnings.

OEHHA was able to find numerous settlements between plaintiffs and defendants in California adopting commercially achievable acrylamide levels lower than the EU benchmark levels. For example, OEHHA found settlement levels that were lower than the EU levels for food groups, such as sandwich wafers cookies (or “wafers” by EU) and French-fried potatoes. As for bread, OEHHA did not find a California settlement that was below the EU benchmark level, and FDA measurements of levels in food indicated that the EU level was feasible. Therefore, OEHHA proposed the EU levels as the lowest feasible level for bread (ISOR pages 16-17).

Comment 22 (CEH): The commenter asks OEHHA to clarify what it means by “quality control measures.” Such measures should be broadly defined to include, for example, the use of altered crop growing or storage techniques to reduce the formation of listed chemicals and the use of enzymes like asparaginase. OEHHA could look to its naturally occurring regulation for guidance, as that provision only exempts exposures to chemicals to the extent their presence “was not avoidable by good agricultural or good manufacturing practices.” 27 Cal. Code Regs. § 25501(a)(4). OEHHA should clarify that any exposure exemption only applies to the extent the listed chemical is present due to the precipitating circumstance upon which the regulation is based. For naturally occurring chemicals, OEHHA’s existing regulations provide:

> A chemical is naturally occurring only to the extent the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, ‘exposure’ can only occur as to that portion of the chemical which resulted from such human activity. 27 Cal. Code Regs. § 25501(a)(3).

A similar provision should be added to Section 25505 to address any situations in which a chemical is present in foods due in part to cooking or other heat processing and due in part to other factors.

Response: This comment was submitted in response to the original proposal released in August 2020. OEHHA removed the term “quality control measures” in the second modification. See Response to Comment 21.

OEHHA declines to add a section similar in nature to that in Section 25501(a)(3). The scope of the regulation was narrowed from all listed chemicals formed in cooking to acrylamide in the second modification. Without human activity such as cooking or heat processing, acrylamide would not be formed in food. In the instance where a cooked food that contains acrylamide is added to another food, and either cooked again or not, the level of acrylamide in the final product is what is compared to the concentration levels established in subsection (d).

Comment 23 (AgCC): The commenter stated that cooking is a human activity that is required for many foods and will result in acrylamide or other potential chemicals being present. Good manufacturing and agricultural practices can minimize the formation of acrylamide in some specific cases, but there are a lot of other issues that influence the presence of acrylamide in foods. Changing the temperature, modifying baking times, or sourcing ingredients from growers that grow specific varieties may be options for some food groups, but others are limited by variety, cooking methodologies and food safety protocols that could prohibit the use of these outlined practices.

Response: This comment was submitted in response to the original proposal released in August 2020. In response to this and other comments, subsection (a) was modified to clarify that "lowest level currently feasible” means the “lowest level currently feasible by utilizing applicable practices recommended in Codex Alimentarius Code of Practice for the Reduction of Acrylamide in Foods CAC/RCP 67-2009 (2009), hereby incorporated by reference.” The Codex 2009 Code of Practice specifies practices for reducing acrylamide in different foods. What is a feasible level of acrylamide for each manufacturer and each food may depend on the applicable practices and the specific food. It is up to the individual business to determine whether or how to meet the concentrations in the proposed regulation, provide a warning, or take advantage of other provisions in the existing regulations identified in subsection (a) to show no warning is required.

Comment 24 (PTNPA and SNAC): The commenters urged OEHHA to recognize that when a manufacturer can demonstrate the implementation of quality control measures that reduce the listed substance formed during heat processing to the lowest levels

currently feasible, the manufacturer should be deemed in compliance. If appropriate "quality control measures" are taken, acrylamide levels in any nut products should be considered the "lowest level currently feasible" and exempt from the warning requirements regardless of any level that may be established in separate provisions of the final regulation. The commenters further encouraged OEHHA to recognize the "lowest level currently feasible" are examples of levels that could be achieved, that companies would be in a "safe harbor" if they meet those levels, and that alternative levels would be acceptable if the manufacturer could demonstrate they have implemented the mitigation strategies available and are producing products at the lowest level currently feasible for the product.

Response: This comment was submitted in response to the original proposal released in August 2020. OEHHA removed the term "quality control measures" in the second modification. See Response to Comment 21.

While the modified proposal removes reference to the undefined term, "quality control measures," it specifies that reductions can be achieved by utilizing practices recommended in the Codex 2009 Code of Practice. 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 (d) of the modified proposed regulation also establishes safe harbor levels for acrylamide in cooked and heat processed foods that are deemed by OEHHA to be the lowest levels currently feasible. Concentrations of acrylamide at or below the levels identified for the specified products would not require a warning (ISOR page 4).

Determinations whether a specific manufacturer complies with the Proposition 65 warning requirements in this regulation may be addressed through the Safe Use Determination process established in Section 25204 of the regulations.

Comment 25 (Key Sciences): The commenter notes that on page 8 of the ISOR, OEHHA states,

> "…[w]hen 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."

To incentivize food producers to reduce acrylamide levels, the ISOR should make it clear that a business should not be able to invoke the proposed regulation when that

business failed to use quality control measures to reduce the acrylamide level to the "lowest level currently feasible."

Response: The proposed regulation provides a complete defense for businesses that show that their product contains levels of acrylamide at or lower than the concentrations established in subsection (d). (ISOR pages 11-12.) It also provides a defense for businesses that use the applicable practices in the Codex 2009 Code of Practice to reduce the acrylamide level to the "lowest level currently feasible." See also Response to Comments 11, 26, 35, and 65. The proposed regulation will incentivize businesses to reduce acrylamide formed through cooking or heat processing to the concentrations established in the regulation, or to the lowest level currently feasible, to avoid the need to provide warnings for exposures to acrylamide in their food products. (ISOR page 28.)

Comment 26 (Key Sciences): The commenter states that OEHHA should provide clarity on how to evaluate whether an alleged violator has taken steps to reduce the acrylamide level to the "lowest level currently feasible." A list of factors provided by OEHHA would assist enforcers and the regulated community in determining to what extent a business can rely (or not rely) on the proposed acrylamide levels where the business may not have taken feasible steps to reduce acrylamide levels. For example, the language of the proposed regulation should identify factors such as:

a) What quality control measures they have been using to reduce the acrylamide levels,
b) When was the last time they evaluated their quality control measures designed to reduce acrylamide levels (it could be insufficient if the business has not reviewed their QC measures in a while and there are multiple recent processes that the business could have used to reduce acrylamide levels),
c) Has the business taken steps to reduce acrylamide – such as the examples given in the ISOR at p.10?

Response: This comment was submitted in response to the original proposal released in August 2020. OEHHA removed the term "quality control measures" in the second modification. See Response to Comment 21. In the second modification, subsection (a) was revised to incorporate the Codex 2009 Code of Practice, which provides guidance on how a business can achieve the "lowest level currently feasible" of acrylamide in its food product using an internationally accepted standard of practices. The incorporation of the Codex 2009 Code of Practice provides clarity regarding whether a business has taken steps to reduce acrylamide levels in a food. (See Addendum to the ISOR pages 5 and 6.)

The primary goal of this regulation is to encourage businesses to bring chemical levels down to the lowest level feasible, while at the same time avoiding a potential proliferation of warnings on many foods where the levels have already been reduced to the lowest levels currently feasible (ISOR page 29).

Holder of the food

Comment 27 (CEH): The commenter asks OEHHA to clarify who is a "holder of the food" for purposes of Section 25505(a), or simply eliminate that language as inherently ambiguous.

Response: This comment was submitted in response to the original proposal released in August 2020. Subsection (a) was modified in the second modification, the phrase "holder of the food" no longer appears in the regulation.

Subsection (b) – Alternative approaches to compliance

Comment 28 (AlmondAC): The commenter supported continuing a broader discussion related to a safe harbor alternative for almonds to ensure almonds can comply with food safety obligations without putting some processors in direct conflict with Proposition 65 warning requirements. The commenter appreciates the opportunity to explore the applicability of the cooking provision allowing for an alternative risk level, in terms of the application of a mandatory 4-log microbial reduction treatment.

Response: OEHHA is aware that almonds must comply with the USDA regulation mandating a 4-log microbial reduction treatment to reduce *Salmonella* contamination and that this treatment can lead to elevated acrylamide levels. The settlements that OEHHA based the proposed almond concentration levels on included products sold in California which likely had been 4-log treated. [17] Under subsection (b), where roasted almonds exceed the 225 ppb concentration level in this proposed regulation, a business can consider the application of the alternative risk level pursuant to Subsection 25703(b)(1) to determine if a warning is needed for a given product. A business can also utilize the defense in subsection (a) or provide a warning if the product is unable to meet the level set in subsection (d)(4).

OEHHA is open to discussions with any industry that would like to explore compliance with Proposition 65 warning requirements. OEHHA understands that some food products have specific processing requirements such as the 4-log microbial reduction treatment for almonds that can affect the levels of acrylamide in the final product.

[17] See ISOR page 14; Addendum to ISOR page 13.

OEHHA has the authority to modify the levels established in this regulation through the rulemaking process and may take that step in the future, depending on the evidence received, including new settlements.

No changes were made to the proposed regulation based on this comment.

Comment 29 (CEH): The commenter stated that the existing Alternative Significant Risk Level (ASRL) regulation already addresses exposures to listed chemicals formed by cooking food. Subsection 25703(b)(1) provides that a defendant is entitled to prove an alternative NSRL (i.e., a less stringent "ASRL") if "sound considerations of public health support an alternative level, as, for example: (1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination".

If OEHHA finds it necessary to promulgate additional regulations addressing exposures to listed chemicals formed by cooking food, OEHHA should ensure any new measures are consistent with this existing ASRL provision. Any new measure should:

1) place the burden on the defendant to prove the elements of any new defense,
2) tie the existence of any such defense to sound considerations of public health, and
3) limit the defense to necessary cooking (i.e., cooking "necessary to render the food palatable or to avoid microbiological contamination").

These limitations are important not only to maintain consistency with the existing ASRL defense, but also to ensure that any new regulation furthers the purpose of Proposition 65. OEHHA should not be discouraging warnings on foods unless there is a sound public health consideration for doing so. OEHHA should not discourage legitimate Proposition 65 warnings on foods that are a substantial contributor to non-Proposition 65 health impacts such as obesity or Type 2 diabetes.

Response: Subsection (b) harmonizes this regulation with Articles 7 and 8, including the alternative risk level provisions, and incorporates the other two points CEH mentions in its comments. Businesses still have the burden of showing a warning is not required, because the concentration is below the concentrations established in subsection (d), below the lowest level currently feasible per subsection (a), below a level using the methods in Articles 7 and 8 per subsection (b) or covered by a settlement per subsection (c).

The regulation differentiates between exposures to acrylamide in food that result from cooking or heat processing that cannot be feasibly avoided, and those that can be reduced by using the applicable practices outlined in the Codex 2009 Code of Practice. This approach incentivizes acrylamide reductions. Exposures to levels of acrylamide that could be feasibly avoided, on the other hand, are exposures that would require a warning, unless another exception applies. This ensures that individuals in California receive a warning about these higher, but avoidable, exposures (ISOR page 8), which is consistent with the purposes of Proposition 65.

No changes were made to the proposed regulation based on this comment.

Comment 30 (CalChamber/CB Coalition): The commenter stated that cooking and other heat processing of foods not only creates listed chemicals; it can also increase the concentration levels of listed chemicals that are present in the raw materials (e.g., through dehydration). The commenter suggests adding in subsection (a) the words "or its concentration increased by" after the words "created by" so that the first sentence of subsection (a) reads:

> "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, or its concentration increased 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."

A conforming change would also need to be made in subsection (b).

Response: OEHHA is aware that some raw ingredients will already contain acrylamide because they have been cooked or heat-processed prior to the additional cooking or heat processing in manufacturing the final product; however, the suggested language for the regulation does not provide additional clarity.

OEHHA amended subsection (b) in the first modification, to emphasize that the person who is otherwise responsible for an exposure to a listed chemical can utilize other methods from determining concentrations that do not require warning. Subsection (b), as amended, provides that:

> (b) Nothing in this section shall preclude a person ~~**in the course of doing business**~~ **otherwise responsible for an exposure to a listed chemical in a food** from using evidence, standards, risk assessment methodologies, principles, assumptions, or levels described in Articles 7 and 8 to establish an alternative

concentration for a listed chemical in a food that is created by cooking or other heat processing **that is different from the concentrations provided in subdivision (d)**.

This subsection was further modified in the second modification, but the changes do not impact the above response.

Subsection (c) – Existing court-ordered settlements and final judgments

No comments received were specifically directed at this subsection in the August 2020 regulatory proposal.

Subsection (d) – Safe harbor concentrations for acrylamide

Unit concentration levels

Comment 31 (CalChamber/CB Coalition, Diamond Foods, FPPI, IBA, PTNPA and SNAC): The commenters stated that OEHHA proposes to adopt, where available, two concentration levels from the consent decrees – the Maximum Average Concentration and the Maximum Unit Concentration. The Maximum Average Concentration, which represents the "average" level, more accurately represent the actual intake of the listed chemicals from food consumption by considering acrylamide levels from different batches. The "average concentration" in a finished food product must be measured based on test results on the food "in the form the product is sold to California consumers." It is inconsistent with this purpose to establish a Maximum Unit Concentration because an individual product is not necessarily representative of the products an actual California consumer would purchase or use.

The concept of "unit concentration" in subsection (d) has no basis in science, has the potential to create an impracticable standard and should be removed. The "unit concentration" level is derived from provisions in various consent judgments that were negotiated between private enforcers and defendant businesses. Variability in any given food type can be more than 3x from the lowest to highest, reflecting the natural variability of the raw materials and the cooking process that contributes to appetizing organoleptic qualities. The unit concentration levels could force manufacturers to adopt labeling even when implementing the mitigation strategies that are reducing acrylamide levels to the lowest level currently feasible. While a manufacturer may be able to control for acrylamide levels during the process, there will be outliers and regulatory compliance should not be based on outliers.

Response: The comment does not provide a suggested alternative to using unit concentration levels that have been established in several court settlements. The categories of “Maximum average concentration” and “Maximum unit concentration” are based on review of over 50 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. The levels provided in settlements are based on information shared during the litigation process between the parties regarding options for reducing acrylamide levels in specific products. Thus, in addition to analyzing relevant data for each of the specific food categories, OEHHA has adopted the units of measurement agreed upon in the court-approved settlements OEHHA reviewed and relied on for this regulation. When there is a maximum average concentration, and a maximum unit concentration, both must be complied with. The second modification of text clarifies this requirement.

Levels for maximum unit concentration are higher than the maximum average concentration because of concentration variations. Recognizing that acrylamide levels in actual products from the same manufacturers vary, the maximum unit concentration is an important parameter for quality control and set an upper limit of variations. The definitions provided in the second modification clarify how to measure “unit concentration” and “average concentration.”

OEHHA utilized data from the US FDA, the EU, and other published sources in addition to settlements. OEHHA uses levels from settlements, in addition to other data, 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 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 feasible.[18]

Comment 32 (Sunsweet): The commenter stated that the bifurcated tests of “maximum average concentration level” and “maximum unit concentration level” appear to be one of many tools developed by bounty hunters to distinguish same-product-different-manufacturer settlement agreements. Pertinent case law makes clear that chemical concentration should not be assessed on a per unit basis, but instead should be averaged across lots and over time using either a geometric or arithmetic mean. The commenter urges OEHHA to remove the maximum per unit concentration level. It is not

[18] See ISOR page 12; Addendum to ISOR page 7.

consistent with current Proposition 65 safe harbor limits, creates unnecessary complexity for any foods created with blended ingredients or ambiguous identities, and still does not fairly account for Nature's variability in annual tree crops.

Response: The settlement agreements provide categories for determining acrylamide levels in a broad range of products. A number of these agreements set maximum unit concentrations. Where OEHHA chose to adopt settlement levels, there was also supporting data to justify the levels adopted. See, e.g., Addendum to the ISOR page 13 (almonds), pages 14-15 (cookies), page 15 (crackers), page 16 (potato and sweet potato products). The second modification clarifies how to measure the unit concentration and average concentration.

Additionally, subsection (b) of the regulation allows a person to use evidence, standards, risk assessment methodologies, principles, assumptions, or levels described in Articles 7 and 8 to establish an alternative level for acrylamide in a food.

Reliance on settlements for establishing levels

Comment 33 (CalChamber/CB Coalition): The commenter stated that the principle of feasibility is rooted in many Proposition 65 consent judgments. The feasibility definitions and concepts incorporated into multiple consent judgments can provide the regulated community and the courts with additional guidance for implementing the proposed regulation on a case-by-case basis based on such factors as the nature of the product, availability of technologies and materials, and the size and role of the business involved.

Response: OEHHA acknowledges the comment and agrees that court-approved settlements can provide guidance in determining whether the chemical is at the "lowest level currently feasible."

No changes were made to the proposed regulation based on this comment.

Comment 34 (Sunsweet and Key Sciences): Sunsweet stated that consent judgments may include arbitrary subclassification of products for purposes of private settlements. Private enforcers use subclassifications to differentiate settlements among the same types of products (such as "from concentrate," "not from concentrate" and "organic"). The commenter asks that these subclassifications not be included in the regulation.

Key Sciences stated that OEHHA is treating the levels established in the selected court-approved settlements as identifying the lowest levels currently feasible even though OEHHA acknowledges that this may not always be the case. The "lowest level currently

feasible" should be supported by evidence (e.g., consumption estimates) and should not be an arbitrary number negotiated between the parties just to reach a settlement.

Response: In the original ISOR and in the Addendum to the ISOR, OEHHA stated the scientific basis for setting the levels of acrylamide for each of the listed foods in the regulation. The list of foods in subsection (d) is not exhaustive of the foods that contain acrylamide created by cooking or heat processing. The original proposal included the example referred to by Sunsweet – prune products. After reviewing this and other comments by Sunsweet**,** the concentration levels for prune juice were removed from the proposed regulation in order to have time to gather more information about this food product. Thus, prune juice was removed from the proposal in the first modification.

Court approval of a settlement means that the court has reviewed and applied the criteria in the statute[19] and there is a measure of feasibility to the level agreed upon[20]. Where a food industry defendant has agreed to a given concentration level in a court-approved settlement, OEHHA may reasonably presume that the level is "currently feasible" under Proposition 65. This may not always be the case, but it is presumed absent evidence demonstrating otherwise. OEHHA is treating the levels established in the selected court-approved settlements as identifying the lowest levels currently feasible and discusses each of the categories of food and the specific reasoning behind each of the levels in the ISOR and the Addendum to the ISOR. [21] Further, since the regulation is not mandatory, businesses can propose a different level in a defense to an enforcement action, per subsections (a) and (b)[22].

Comment 35 (AgCC, AlmondAC, CalChamber/CB Coalition, FPPI, IBA, PTNPA and SNAC): The commenters stated no single solution will fit all situations. Utilizing numbers derived from previous court-ordered settlements is a creative approach that demonstrates those numbers could potentially be feasible for those businesses participating in the settlement discussions. This approach, however, does not necessarily represent the "lowest level currently feasible", nor does it guarantee numbers that are achievable industry-wide across all manufacturers, products, and commodities in all situations. Some defendants may be interested in leaving the market segment, so they can afford to settle at lower numbers. Plaintiffs may also avail themselves of financial opportunities to settle early when filing 60-day notices. Not all

[19] Health and Safety Code section 25249.7(f)(4).

[20] See Addendum to ISOR pages 11-12.

[21] See ISOR page 12 for a general discussion, and pages 12-29 for specific discussions about each of the foods and food categories; see also Addendum to ISOR pages 11-12 for a general discussion, and pages 12-17 for specific discussions about each of the foods and food categories.

[22] See ISOR page 11.

plaintiffs/defendants have the consumer's interests at heart when entering settlement discussions. Flexibility is needed to determine that the level is achievable for any given product, any given business, and across the entire product category.

For example, AlmondAC stated the three primary settlements addressing roasted almonds used for the level established in the regulation were entered by large manufacturing companies who have the capacity to adjust processing lines and manufacturing parameters to meet the 225 parts per billion ("ppb") settlement level. The settlements did not consider industry or product-wide fluctuations, nor sufficiently describe the assumptions that were made (e.g., manufacturing processes or consumption levels). Each settlement reflects commercial considerations by the specific processor for the product produced at the time the action was brought against the company.

Others (FPPI, IBA, PTNPA and SNAC) stated that reformulation levels are not equivalent to the "lowest level currently feasible" but are negotiated levels and are not representative of the acrylamide levels found industry wide. Thus, these commenters recommend OEHHA specify the appropriate test method for acrylamide testing and a sampling plan in the final regulation for consistency. Those commenters further remark that OEHHA should base the lowest levels currently feasible on hard data rather than negotiated settlements.

Settlement levels may not be feasible for other businesses where a business has a proprietary technology or a supply of raw materials not available to others or where it tailors its food products to a subset of consumer preferences that is not representative of the entire product category (e.g., consumers who will accept higher prices or who prefer a certain flavor profile).

Response: The concentration levels specified in subsection (d) of the proposed regulation are not mandatory. They are safe harbor concentrations at or below which compliance with Proposition 65 is established. Where additional or different information on feasible levels is available, the regulation specifically allows for use of alternatives other than the proposed levels as a defense under subsection (a). Also, the business may establish alternative levels in an enforcement action under subsection (b). (ISOR page 11.)

OEHHA also recognizes that there are some circumstances where the concentration levels will not be feasible for a particular business or product. That business may need to provide a warning if it cannot establish a defensible alternative concentration level per subsections (a) or (b).

Further, in establishing the levels, OEHHA excluded any settlement that covered products that had been withdrawn from the California market by August 2020.

No changes were made to the proposed regulation based on this comment.

Comment 36 (AgCC): The commenter supports OEHHA's approach at this time for acrylamide because OEHHA has done a satisfactory job of attempting to mitigate some of the challenges businesses face by proposing this regulation. AgCC urges OEHHA to use more traditional, scientific approaches for safe harbor levels on a go-forward basis. Settlement numbers should only be considered on a limited case-by-case basis when other approaches seem unworkable.

Response: OEHHA acknowledges the comment. No further response is required.

No changes were made to the proposed regulation based on this comment.

Comment 37 (SMasri): The commenter stated that the proposed benchmark revised levels proposed in the regulation are nowhere near the "lowest feasible levels that can be achieved." The proposed rule sets feasible concentration levels based on court cases involving certain products and their manufacturers. This is an inadequate approach to determining acrylamide benchmarks, particularly given the impacts such benchmarks will have on public health in California. OEHHA should undertake an independent science-based assessment to better identify the lowest feasible levels that can be achieved for different cooked food products.

Response: Subdivision (d) sets forth concentration levels for acrylamide in foods that are deemed to comply with subsection (a).

OEHHA presumes that a company's agreement to such a level indicates that it is currently feasible to achieve the level.[23] The commenter incorrectly assumes that OEHHA only used settlement numbers to set the levels of acrylamide in food. The original ISOR and the Addendum to the ISOR sets out a specific explanation of the method used to establish the safe harbor levels for each food listed in the regulation. OEHHA started by gathering data for acrylamide in specific foods from the US FDA, the EU, and other published data sources, as well as looking at the target levels in regulations and Proposition 65 settlements[24] and evaluating that data to determine what level, if any, was appropriate for each specific food[25]. OEHHA did not use levels from

[23] See ISOR page 6.

[24] See Addendum to ISOR pages 11-12.

[25] See ISOR pages 12-29 and Addendum to ISOR pages 12-17, for specific discussions about each of the foods and food categories.

settlements where a product was taken off the market in California. In the food category of bread, OEHHA did not find a settlement for bread that has lower levels than those listed by the EU[26] so OEHHA did not use the higher levels set in settlements for breads. For further detail on the data and analyses leading to the proposed levels for bread see the Addendum to the ISOR.[27]

No changes were made to the proposed regulation based on this comment.

Comment 38 (AgCC): The commenter supports the concept of the "lowest level currently feasible." Acrylamide levels in certain foods can vary for several reasons. Asparagine levels in crops, for example, vary based on type of crop, year, commodity variety, and other issues surrounding the natural growing and life cycle in food. Flexibility is key. There are unknown considerations in specific settlements which may prohibit some food companies from being able to achieve the recommended numbers in the draft regulation. OEHHA should consider providing a more specific feasibility process to assist with those not able to achieve these thresholds.

Response: This comment was submitted in response to the original proposal released in August 2020. With the second modification, the proposed regulatory text was modified to clarify a manufacturer can prove that it has achieved the "lowest level currently feasible" by utilizing the practices recommended in the Codex 2009 Code of Practice. The Codex 2009 Code of Practice does not prescribe standard processes or analysis that businesses must follow because that is beyond the scope of the proposed regulation, but it does provide a guide for practices business can employ to reduce levels of acrylamide in their products. In subsection (b), the regulation also provides support for businesses to use other methods. Businesses may choose to rely on other provisions of the existing regulations, such as the safe harbor levels established in Sections 25705 or 25805, the alternative risk level described in Section 25703(b)(1), food intake calculations pursuant to Section 25721, or a combination of these, among other provisions, to show a warning is not required.[28]

No changes were made to the proposed regulation based on this comment.

Comment 39 (P&S): The commenter stated that consent judgments are a productive first step, but some may have unachievable acrylamide levels for a product category as currently defined in the proposed regulation because of various reasons. The proposed levels may not be achievable for all manufacturers of the same product, may not be

[26] See Addendum to the ISOR pages 13-14; ISOR page 17.

[27] See Addendum to the ISOR page 14.

[28] See ISOR page 11.

representative of other products within the same product category (e.g., animal crackers vs. iced animal cookies), and in some cases the reformulation levels were not intended to be practical because the manufacturer has determined the only feasible option was to settle and withdraw from the California market. The average ppb levels for each product category may be a more reliable and common-sense approach to establish safe harbor concentration levels in cases when the categories are sufficiently differentiated.

Response: The safe harbor acrylamide concentrations for specific food categories in subsection (d) are one method to determine if a warning is necessary. If a business cannot meet the safe harbor concentration levels established in subsection (d), it can provide a warning or take other actions such as those described in subsections (a) or (b). Meeting the levels in subsection (d) is one of multiple options.

US FDA survey data have shown wide variations of acrylamide levels for some products. For example, US FDA (2015)[29] reported that the levels of acrylamide in two samples of sweet potato chips were 260 and 8440 ppb. Establishing concentrations at the average of current measured levels in food products would likely not serve the purposes of the regulation, which is to encourage businesses to reduce acrylamide exposures where feasible and provide a warning where it is not. Consumers are then able to make informed choices about their exposures to this chemical.

OEHHA identified some settlements in which a company chose to withdraw their products from the California market; however, there were other settlements in the same food category that showed feasible levels for the companies agreeing to the settlement. OEHHA excluded any levels established in settlements in which a company agreed to leave the California market.

No changes were made to the proposed regulation based on this comment.

Comment 40 (FPPI and IBA): The commenters stated that OEHHA proposed levels for acrylamide for potato products and French fried potatoes based on two court-approved settlements. Neither the 280 ppb nor 400 ppb levels should be considered as “lowest levels currently feasible” levels for acrylamide in cooked French fries. These reformulation levels were negotiated between plaintiff’s attorneys and individual companies, and do not fairly represent the large variabilities in acrylamide levels observed by FPPI members.

The commenters asked OEHHA to consider adopting the “benchmark levels” established by the European Union (EU). The EU adopted regulations to encourage reductions by the food industry and set the benchmark levels with the goal of ensuring

[29] FDA (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.

the reduction of exposures. The “benchmark levels” are established at a level “as low as reasonably achievable with the application of all relevant mitigation measures.” The “benchmark levels” can serve as performance indicators to verify the effectiveness of the mitigation measures and are based on experience and occurrence for broad food categories. OEHHA adopted the EU “benchmark levels” for wheat-based and non-wheat-based bread categories. For French fries (ready-to-eat), the “benchmark level” established by the EU is 500 ppb. The commenters urge OEHHA to consider adopting this level as the “lowest level currently feasible”. Similarly, the EU established a “benchmark level” for cookies and wafers as 350 ppb and for crackers with the exception of potato-based crackers as 400 ppb. The commenters urge OEHHA to replace the proposed four categories for cookies and crackers with the two categories used by the EU and adopt the EU “benchmark levels”. The benchmark levels would be scientifically supported unlike the reformulation levels provided in settlements.

Response: OEHHA disagrees with the commenters’ argument that instead of using the reformulation levels provided in specific settlements to set safe harbor acrylamide concentration levels, the EU benchmark levels should be used for “Potato products, French fried potatoes”, “Cookies” (using the EU definition of the category, i.e., biscuits and wafers), and “Crackers” (using the EU definition of the category).

OEHHA also disagrees with the commenters’ assertion that the EU benchmark levels are more “scientifically supported” than reformulation levels provided in settlements. OEHHA looked at published data and settlements to set levels, which is overall a more comprehensive approach to setting safe harbor levels of acrylamide in food. EU benchmark levels are based on current occurrence data, and most are set at relatively high levels, while reformulation levels provided in settlements are based on information shared during the litigation process between the parties regarding options for reducing acrylamide levels in specific products. EU (2017)[30] states that the benchmark levels, “should be determined taking into account the most recent occurrence data from the Authority’s database, whereby it is assumed that within a broad food category, the level of acrylamide in 10% to 15% of the production with the highest levels can usually be lowered by applying good practices”.

The EU benchmarks for acrylamide are thus set at levels currently attained by approximately 85 to 90% of the EU products in each food category, and therefore are not necessarily reflective of the lowest levels technically feasible for a given food category in the US. Further, if the levels in the proposed regulation were set at the

[30] 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.

current levels found in foods, then would be no incentive to lower levels, even when it is feasible to do so.

In several instances, the EU benchmark levels for acrylamide are higher for a given food category than levels agreed upon in California settlements for the same or a similar food category.[31] Using settlements entered in California make the numbers more applicable to the California market.

No changes were made to the proposed regulation based on this comment.

Comment 41 (CalChamber/CB Coalition): The commenter stated that for some of the foods and food categories, the proposed concentration level is lower than some of the prior consent judgments for those products. The concentration levels must ensure fairness and be careful not to give a competitive advantage to companies that have consent judgments that incorporate more lenient concentration levels.

Response: OEHHA reviewed the settlements for each of the food categories. Both the business and plaintiff litigants also had the benefit of prior settlements when negotiating more current settlements. OEHHA believes that the more recent settlements are a better indicator of what is currently feasible.

No changes were made to the proposed regulation based on this comment.

Comment 42 (Key Sciences): The commenter posed numerous comments as questions. How were the proposed levels arrived at? If the proposed levels are not based on consumption estimates, they do not appear to be scientifically supportable. Was each consent judgment checked to see if the Court evaluated the appropriateness and scientific basis for each concentration level? If the consent judgment level is not based on current science, what if current data show higher consumption rates, and that level exceeds the MADL/NSRL?

Related to testing, high tests from a certain lot/batch should not be allowed to be averaged with low tests or non-detects from a different lot/batch to bring down the overall average. What happens if the average is less than the safe level for average results, but one lot of a product is higher than the single unit level? What happens if the acrylamide level in a product is above these proposed levels? Is there a presumption that if the chemical level exceeds the proposed level that a warning is required?

[31] See ISOR page 16; Addendum to ISOR page 11; see also 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 (originally cited in ISOR footnote 19).

Response: The ISOR and the Addendum to the ISOR address many of these questions[32]. The regulation uses the levels the court-approved settlements in each food category as the lowest feasible levels, except for bread. Separate consideration of food consumption data was not incorporated in the determination of the concentration level that was considered to be the lowest level currently feasible. One of the goals of this proposed regulation is to encourage businesses to reduce acrylamide levels in food where possible. Some level of acrylamide from cooking/heating food is unavoidable, but generally acrylamide can be lowered by optimizing certain practices.

If a food product meets the level in subsection (d) that is deemed to be the "lowest feasible", businesses are not required to provide a warning. These levels can incentivize businesses to lower levels of acrylamide in their products while still requiring warnings for higher exposures. As stated in the ISOR, "[u]biquitous warnings prevent consumers from distinguishing between products with very high concentrations of a listed chemical from those with considerably lower levels." (ISOR page 6.)

While science has driven the discovery of methods of mitigation and will continue to help us understand how to further reduce levels, not all scientific discoveries are immediately translated into manufacturing processes and are ready or feasible for businesses to adopt. Absent evidence to 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. (ISOR page 6-7.)

The commenter is concerned about the measurement in both the quality of the samples and the reliability of the results. The second modification to the regulatory text addresses these concerns by defining the makeup of the sample, specifying that the test must be performed using a "representative composite sample," defining "representative composite sample," and specifying more than one test, performed over a minimum number of days, with a specific minimum number of days in between tests. This allows for better quality samples, with less of a chance that they will be skewed one way or another. It also provides a check on the quality of the manufacturing process because the samples must be taken over a longer period of time, ensuring that the tests are performed using several different batches of raw materials. Additionally, the lab performing the test must be ISO/IEC 17025 accredited. This ensures that the lab is

[32] See ISOR pages 12-29.

accredited by a third party and using the latest quality standards for a chemical analysis lab ensuring quality and competency.

Sampling and testing methods

Comment 43 (ABA): The commenter requested clarification, as the consent judgments do in footnotes, that the level should be determined from samples of portions of the products that are not heels (end pieces of loaves) or other unrepresentative pieces (such as the disproportionately brown parts of the tops of buns or bagels). EU 2017/2158 provides for a consistent approach, stating that a "sample shall be representative for the sampled batch."

In addition, ABA believes that OEHHA intends to hold manufacturers responsible only for acrylamide levels in their products that exceed the safe harbor levels without further discretionary cooking or heat processing that may raise acrylamide levels. ABA requests OEHHA expressly state that the safe harbor levels for acrylamide in soft breads are to be applied as those products are packaged and sold and that any subsequent discretionary cooking or heat processing that may raise these products' acrylamide levels, including subsequent toasting, grilling, or frying by consumers or others further preparing or processing the finished products, is not the responsibility of the product's manufacturer.

Response: This comment was submitted in response to the original proposal released in August 2020. With the second modification, OEHHA set out a method for measurement. The modified text defines "unit concentration," "average concentration," "representative composite sample," and the qualifications of the lab that will test the food. Subsection (d)(1) states:

> A "representative composite sample" is made up of portions of the food in the same proportion as in the whole individual packaged unit, e.g., equivalent proportions of crust and crumb (the inner portion) in the sample as in the whole loaf of bread.

Thus, it would not be in accordance with the regulation "to sample disproportionately the brown parts of the tops of buns or bagels."

This proposal does not assume that every product is the same and should be subject to the same exact testing methods. The proposed methods for measurement and specific definitions in the regulation are designed to provide flexibility. For example, the definition of representative composite sample can be applied to a loaf of bread to ensure that the sample must contain a representative amount of crust and crumb as the

total loaf of bread, and also applied to a cookie in the form of a sample with a representative amount of the darker bottom part and the lighter inner part.

The safe harbor levels set out in the proposed regulation refer to levels of acrylamide determined after preparing the product as if prepared for consumption in accordance with the instructions on the packaging label of the product, which means it would be the levels after additional cooking or heating, if specified by the packaging. As an example, the ISOR cites this specific language in quoting the settlements relied upon for the levels in frozen waffles on page 29. If a consumer purchases soft bread that does not direct the customer to toast it, goes home, and toasts the bread, the manufacturer is not responsible for the acrylamide content that resulted from the toasting of the bread. A manufacturer also would not be responsible for the additional acrylamide that may be created where the consumer fails to follow the package directions.

OEHHA understands the commenter is making a request for additional language regarding a safe harbor for soft breads, and the final regulation text takes the concerns of the commenter into account. The example provided in the second modification should provide additional clarification for the regulated public.

Comment 44 (FPPI and SNAC): The commenters stated that the current proposal is not specific about how the acrylamide levels should be measured and how the product samples should be taken. Lack of clarity can lead to incorrect determinations. The commenters recommend incorporating the following as the testing method:

> "Compliance with the lowest levels currently feasible shall be determined by use of a test method equivalent to the Liquid Chromatography/Mass Spectrometry based analytical method published by FDA for the quantitative determination of acrylamide in foods."

To ensure the samples are representative, at least one sample each should be collected from five or more different lots of the particular product SKU. A production lot is defined as a 24-hour production period. 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 as outliers, and the mean and standard deviation recalculated using the remaining data points.

Response: This comment was submitted in response to the original proposal released in August 2020. In the second modification, OEHHA modified the proposed text to include specific methods for testing and provided the justification for the proposed changes in the Addendum to the ISOR. See Response to Comments 42 and 43 for more information.

OEHHA agrees that scientifically robust sampling and analytical methods should be followed in performing these sample analyses. Some examples of sampling methods from court-approved settlements were given for each food category in the ISOR (ISOR Section IV). The second modification includes the requirement that the laboratory used for testing is ISO/IEC accredited to ensure the quality of the testing and results. As noted in the Addendum to the ISOR (page 10), accreditation to the ISO/IEC 17025 standard is a widely used and acknowledged approach for ensuring laboratory competency for achieving reliable results. See also Response to Comment 42.

Other considerations in establishing safe harbor concentrations

Comment 45 (AgCC and Sunsweet): AgCC stated that within the context of feasibility OEHHA should also consider the nutritional content of certain foods. In some instances, acrylamide levels can be reduced using certain technologies, but in others, using these technologies could reduce the overall nutritional value of certain foods underscoring the need to build flexibility into the feasibility concept. Sunsweet stated that some form of prima facie standards must be established in advance of enforcement actions to limit arbitrary and unvalidated application. Any "lowest level currently feasible" standard should expressly exclude any requirement or demand that would or could reasonably be expected to sacrifice or reduce a food's traditional nutritional content or nutrient values.

Response: The commenters did not provide any evidence showing that reducing acrylamide levels would lead to the reduction of nutritional content. According to the market survey data conducted by US FDA, there are certain food products that are already below the proposed levels with no evidence showing that these products have reduced nutritional values. OEHHA considered the reformulation levels from the settlements to be the “lowest level currently feasible.” The regulation subsections (a), (b) and (c) provide other methods for determining concentrations that would not constitute exposures in the meaning of Section 25249.6 of Proposition 65. Businesses can use these as the basis for other regulatory defenses where appropriate.

No changes were made to the proposed regulation based on this comment.

Comment 46 (LGratt): The commenter questioned where the calculations are that show the concentration levels would have an impact in terms of human health risks. USDA provides food consumption data that can be used to estimate the distribution of the consumption of the cooked/processed foods in question. The commenter believes this regulatory concept will be a potential burden on the food preparation and restaurant industry leading to threats of legal proceedings like in the early days of Proposition 65 implementation.

Response: Listing information for acrylamide can be found on the Proposition 65 warnings website[33]. The proposed regulation will not add an additional burden for restaurants because the proposed regulation is not mandatory. In addition, there is a restaurant-specific safe harbor warning that has been in effect since August 30, 2016. The Proposition 65 warning for restaurants is as follows:

> **WARNING:** Certain foods and beverages sold or served here can expose you to chemicals including acrylamide in many fried or baked foods, and mercury in fish, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/restaurant

No changes were made to the proposed regulation based on this comment.

Comment 47 (CRC, Key Sciences, and Smasri): The commenters stated that the "feasible concentration levels" identified for various food products (cookies/sandwich wafers, crackers, potato chips, almonds, and wheat and non-wheat bread) were too high to be considered the "lowest feasible levels" achievable by manufacturers, but rather the levels are "easily achievable concentration levels".

Since acrylamide is a recognized carcinogen at levels well below those currently found in many cooked foods, and industry can feasibly reduce the acrylamide levels across many cooked foods, this proposed rule unnecessarily insulates industry from regulatory action at the expense of public health. OEHHA should look at consumption rates to determine safe harbor levels. It is incumbent upon OEHHA to revise the proposed rule to dramatically lower the "feasible concentration levels" to values empirically demonstrated to be the lowest feasible levels that can be achieved by manufacturers within each product category, or otherwise postpone its adoption until an independent science-based assessment can be undertaken to identify such benchmark levels more accurately.

CRC conducted product analyses of these various food products and reported results considerably lower than the proposed "feasible concentration levels". Key Sciences stated that if OEHHA moves forward with levels of acrylamide for the categories of products rather than establishing an NSRL or MADL, the level should reduce the overall contaminant load consumers ingest and should be a level that is attainable for those being regulated.

[33] https://www.p65warnings.ca.gov/fact-sheets/acrylamide.

CRC and Key Sciences report testing hundreds of products for acrylamide and shared their analyses in each proposed category of products. These results are discussed within comments on various product categories.

Response: OEHHA acknowledges the CRC and Key Sciences independent testing of products listed in the food product categories from the proposed regulation. According to the commenters, several commercially produced foods can contain much lower concentrations of acrylamide than the levels that are listed in the proposed regulation. OEHHA's approach to establishing safe harbor concentrations is explained in the ISOR and the Addendum to the ISOR.

The Addendum to the ISOR (page 11-12) explains:

> 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.

Certain amounts of acrylamide created in cooked, or heat processed foods are unavoidable. This is explained further in the ISOR on page 6:

> 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.

Having warnings for virtually all foods containing acrylamide does not further the statutory purpose of providing choices to consumers. The proposed regulation incentivizes businesses causing the high exposures to either lower their concentration levels or provide a warning. This will reduce overall exposures and allow consumers to

focus on the exposures likely to cause the most harm, without the warning fatigue that could occur with mass warnings on so many products. 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. (ISOR page 6.)

Data for each of the specific foods or food groups that have safe harbor levels set in subsection (d)(4) was carefully evaluated. The Addendum to the ISOR (page 13), for example, provides additional discussion of the selection of the level for roasted 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.[34]

No changes were made to the proposed regulation based on this comment.

Requests for additional food categories or chemicals

Comment 48 (AgCC, ABA and Coalition): AgCC believes the preliminary Foods/Food Groups Table is a good start; however, it would be beneficial to know why certain settlements or consent judgments were used and others were not. AgCC urges OEHHA to use caution when creating sub classifications for certain food groups. There are over 400 commodities in California, attempting to group them could present a lengthy list of legal and processing challenges. The commenters expressed hope that other chemicals that are the result of cooking or heating are included as well as concentration levels for other product categories.

[34] See Addendum to ISOR page 13.

The Coalition commented that OEHHA has looked to existing consent judgments in formulating the initial list of foods and levels in subsection (d), but it does not require that future safe harbor concentration levels be set using standards from consent judgments. OEHHA could set additional safe harbor concentration levels that evaluate feasibility based on the relevant data regarding the listed chemical concentration in the food or food category and could revise these levels based on new information.

Response: OEHHA acknowledges the commenters' suggestions for additions to the rulemaking. OEHHA declines to add concentration levels for the additional product categories or chemicals to the regulation in this rulemaking. OEHHA has the authority to modify the regulation to add additional categories and concentrations but plans to do so in subsequent rulemakings.

No changes were made to the proposed regulation based on this comment.

Comment 49 (FPPI): The commenter encourages OEHHA to consider establishing maximum limits for other chemicals such as furfuryl alcohol formed during cooking or heat processing. Furfuryl alcohol can be unavoidable in thermally processed foods even after the food manufacturers have adopted appropriate quality control measures. Unlike acrylamide, there is no established "safe harbor" level or NSRL for furfuryl alcohol. In the absence of a NSRL, during Proposition 65 enforcement actions, a company will have to determine its own "safe harbor" level. To the extent furfuryl alcohol is created by cooking or other heat processing and the manufacturers have utilized quality control measures that reduce the chemical to the lowest level currently feasible, the exposure should be exempt from Proposition 65 warning requirements.

Response: OEHHA acknowledges the commenter's suggestions for additions to the rulemaking. OEHHA declines to add concentration levels for the additional chemical to the regulation in this rulemaking. OEHHA has the authority to modify the regulation to add additional chemicals, food categories and concentrations and may do so in subsequent rulemakings.

No changes were made to the proposed regulation based on this comment.

Comment 50 (NCA): The commenter stated several 60-day notices have resulted in litigation against confectionary companies and to date, at least six of the cases have resulted in consent judgments. These settlements constitute a sufficient basis for OEHHA to establish a safe harbor level for the confections as part of this rulemaking based on the same rationale it applied to other foods for which it proposed such safe harbor levels.

Response: OEHHA acknowledges the commenter's suggestions for additions to the rulemaking. OEHHA declines to add concentration levels for the additional product categories to the regulation in this rulemaking. OEHHA has the authority to modify the

regulation to add additional categories and concentrations but plans to do so in subsequent rulemakings.

No changes were made to the proposed regulation based on this comment.

Comment 51 (Sunsweet and AgCC): Sunsweet commented that OEHHA has proposed concentration levels for many of the food products included on the Food Group list based on processor commitments made in recent court approved settlements, but OEHHA has also included some new average level categories for foods not originating from recent court approved settlements. The commenters request prunes be added as a food category to this list as "Processed Prunes," given that prune juice is already included, with a reasonably achievable maximum average concentration level of 100 ppb.

Response: OEHHA acknowledges the commenters' suggestions for additions to the rulemaking. OEHHA declines to add concentration levels for the processed prunes in this rulemaking. OEHHA has the authority to modify the regulation to add additional categories and concentrations and may do so in subsequent rulemakings.

No changes were made to the proposed regulation based on this comment.

Comment 52 (Masri): The commenter commends OEHHA for refusing to grant a regulatory exemption for roasted nuts and cocoa/chocolate based on insufficient scientific evidence to support the claim.

Response: OEHHA acknowledges the comment. No further response is required.

No changes were made to the proposed regulation based on this comment.

Comment 53 (SNAC): The commenter asks that OEHHA recognize that the regulation could be amended via petition in the future to establish new categories for acrylamide levels in products not currently listed or by creating "currently feasible" levels for other listed substances that form during the heat processing of foods. The petition should be supported by data, ideally generated by industry to capture the complexity of controlling the levels of the listed substance formed in their products and be based on appropriate "quality control measures" used for acrylamide mitigation.

If OEHHA concurs with this approach, the commenter would be prepared to engage with OEHHA in the future on the "lowest levels currently feasible" for snacks and listed substances that form during heat processing not currently covered by subsection (d). Alternatively, the commenter would like OEHHA to consider utilizing the existing Safe Use Determination (SUD) process to apply subsection (a) to a specific product and establish a numeric level. The SUD is a well-established process and in the past OEHHA has issued multiple SUDs on the levels of listed chemicals in food products that would not trigger the warning requirements under Proposition 65.

Response: OEHHA acknowledges the commenter's suggestions for future additions to the regulations and will consider these suggestions in future rulemakings.

No changes were made to the proposed regulation based on this comment.

Comment 54 (ABA): The commenter also requests that OEHHA include a concentration level for fried sweet goods such as donuts or hand pies. Acrylamide levels in fried sweet goods vary depending on time, temperature, equipment, and oil breakdown in the fryer. However, as a starting point ABA recommends OEHHA adopt the 100 ppb level for breads as the safe harbor level for all fried sweet goods.

Response: OEHHA declines to add a concentration level for sweet fried goods to the regulation in this rulemaking. OEHHA has the authority to modify the regulation to add additional categories and concentrations and may do so in subsequent rulemakings. This regulation is optional for businesses to use if they choose.

Comment 55 (Diamond Foods, NCA, PTNPA and SNAC): The commenters ask that OEHHA amend the regulations in the future to establish new product categories and new lowest levels currently feasible for their products. In addition, the commenters ask OEHHA to clarify that the "lowest level currently feasible" in future proceedings is to be based on the totality of evidence concerning a wide variety of factors and determined on a case-by case basis given the nature and characteristics of the food product and business involved, including its relative size and role in the chain of commerce. The flexibility would incentivize industries to collect data demonstrating effective mitigation measures and once the new levels are established, would provide transparency on the levels that do not trigger the Proposition 65 warning.

In instances when settlements are established for a new product category, the commenters urge OEHHA to recognize that any company marketing the same or similar product within the levels negotiated in the settlement is within a "safe harbor." If the product exceeds the levels found in the settlement, the company should be given the opportunity to demonstrate it has implemented mitigation strategies and has achieved the lowest levels currently feasible. If the company can make such a demonstration, OEHHA should recognize the levels are not an exposure for purposes of Proposition 65.

Response: OEHHA does not enforce Proposition 65 and does not make the determination that certain quality control methods fall within a specific safe harbor because the methods can vary widely depending on the product. (See ISOR food category specific suggestions for optimizing certain processes for reducing acrylamide content (pages 5-6)).

OEHHA can amend the regulation to add more categories as additional information becomes available so that there are more product categories where concentrations are established in subsection (d).

Automatically adopting any level established in future settlements would not be consistent with the regulation. The regulation is intended to provide all businesses with concentration levels they can apply to their products. Settlements levels can vary widely and OEHHA will still need to review them and provide for public notice and comment before those levels are included as safe-harbor levels.

Subsection (d)(1) – Concentrations of acrylamide in specific food groups

Almonds, roasted, roasted almond butter and chocolate covered almonds

Comment 56 (AlmondAC, CRC, Key Sciences): The two commenters spoke to the feasibility of achieving the proposed regulatory level for roasted almonds. AlmondAC stated that lightly roasted or blanched almonds may feasibly achieve the 225 ppb limit, but for other darker roasted almonds it may be infeasible and even unworkable for small businesses with limited economic resources. Smaller operations would either need to lower their production output or eliminate product lines, leaving them less competitive and economically disadvantaged. Manufacturers that cannot meet the levels in subsection (d) will need to pursue the provisions in subsection (a) demonstrating that despite good manufacturing practices, the manufacturer cannot achieve the levels in subsection (d).

Setting the level based on settlements that only a few large manufacturers can meet will put small-/medium-sized enterprises at a competitive disadvantage. The majority of the 7,600 almond growers and more than 100 processors have fewer than 500 employees. If a small company cannot achieve the 225 ppb level, it will be faced with a difficult and costly choice that might involve developing an alternative NSRL or adding a warning label to its product. Consumers could see the same product on the retail shelf – some with warnings, some without. This is likely to undermine confidence in the product with a warning, putting those companies at a competitive disadvantage to larger manufacturers.

OEHHA referred to Almond Board of California data showing that roasting almonds at or below 265 degrees will result in minimum acrylamide formation. This was based on a single 2011 lab study, not on commercial practices. It did not take into consideration regulatory requirements related to variations in almond pasteurization treatments. Roasting above 290 degrees is often needed to pasteurize almonds while chemical/fumigation is not allowed for organic production. The actions necessary to achieve a level below 225 ppb would be economically infeasible, technologically challenging, in conflict with regulations, and require significant up front and ongoing costs.

Key Sciences stated that its test results showed acrylamide levels in almonds non-detect as low as 20 ppb, which shows it is possible to formulate with little to no levels of acrylamide. The median level of acrylamide seen in this food group was 150 ppb. With a proposed maximum average concentration level of 225 ppb, 63% of almonds tested would be beneath the new regulated level.

Similarly, CRC stated that "for almonds, the feasible concentration level is set to 225 ppb. Meanwhile, over half of the almonds products we have sampled showed acrylamide levels below 50 ppb, in turn demonstrating the feasibility of almonds manufactures to apply best practices to ensure acrylamide levels below the 225 ppb benchmark. A feasible concentration level of 150 ppb would be more appropriate for this product category."

Response: OEHAA based the levels of acrylamide for almonds on two settlement agreements *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) and information from the US FDA and the Almond Board of California. OEHHA understands that there are different sized businesses that have different manufacturing processes. This may account for the difference in levels of acrylamide, but setting a non-mandatory, safe harbor concentration for this product category provides some guidance to businesses. The levels can be reevaluated in the future based on additional information.

OEHHA acknowledges the commenters' suggestions for changes to the rulemaking. This category of food was modified in the first modification to remove "roasted almond butter" for further review and possible inclusion in a future rulemaking. OEHHA has the authority to modify the regulation to add additional categories and concentrations but plans to do so in subsequent rulemakings.

Comment 57 (AlmondAC): The almond industry evaluated consumption levels of almonds based on shipments and analysis of CDC's National Health and Nutrition Examination Survey (NHANES) data. It was assumed 100% of the almonds consumed were roasted and contained some level of acrylamide, overestimating potential exposure. Estimates of daily per user supply and consumption of almonds, particularly in cereal, bars, bakery, and ingredients, is not likely to result in any consumer health implications nor trigger Proposition 65 warnings. Creating an impression that almonds are unhealthy directly conflicts with the message from key health and nutrition authorities, including the USDA and US FDA, and causes consumer confusion which is the result OEHHA is trying to avoid.

Response: As the commenter stated, “Subsection (b) provides that Section [22506] “*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*.” It further confirms that businesses may choose to rely on other provisions including *“…the alternative risk level described in Section 25703(b)(1) or food intake calculations pursuant to Section 25721, or a combination of these….to show a warning is not required*.”

Businesses are free to demonstrate compliance by any of the available options, e.g., utilizing the proposed levels for roasted almonds, or demonstrating that the average daily exposure from a food product is lower than the current NSRL for acrylamide. The proposed regulation does not label any of the covered food categories as “unhealthy,” but rather aims to avoid over warning for the products that have reduced acrylamide levels to the lowest feasible levels and incentivizes other businesses to do the same.

No changes were made to the proposed regulation based on this comment.

Comment 58 (WAPA): The commenter supported the establishment of a maximum level for acrylamide in roasted almonds and almond butters. However, the commenter expresses concern that there are limited data available and believes a more robust analysis would provide OEHHA the opportunity to expand its analysis and demonstrate a level that more accurately characterizes the acrylamide exposure from roasted almonds and almond butters under Proposition 65. The comments stated that it will be necessary to revise these numbers later as scientific data are developed that demonstrate a necessity to change the proposed level. According to OEHHA, the proposed levels are developed from the levels established in two court approved settlements. No background data were provided or are publicly available to determine how the levels were arrived at, or what almond products were the focus of the settlements. WAPA does not intend to undo or modify those settlements, only to ensure as more data become available, they have an opportunity to revisit and reconsider the proposed levels.

Response: OEHHA acknowledges the comment and has modified the regulation text. The reference to roasted almond butter was removed to provide more time for OEHHA to review any available information related to feasible levels for these foods.

Regarding the question from the commenter of “what almond products were the focus in the settlements,” the two settlements that the ISOR cites for the levels in roasted

almonds each give a clear definition of “product” or “products” in their “product description” section.[35]

Comment 59 (AlmondAC and Justin’s): The commenters stated OEHHA incorrectly assumed that almond butter is made from roasted almonds and that “there is no additional heating processes involved in making almond butter from roasted almonds…” There are multiple roasting stages for almond butter, depending on the use as a confectionary filling, spread, ingredient, etc. Roasting will vary from light to dark to achieve the flavor specification – resulting in varying acrylamide levels. Almond butter is typically produced using broken almonds and almond pieces that have a greater surface area and can lead to greater acrylamide formation. It is misleading to imply that it is universally feasible to produce almond butter that does not contain more than 225 ppb of acrylamide.

Neither settlement relied upon involved almond nut butter, which is produced with different almonds and through processes that maintain and apply heat differently than almonds used in other applications, leading to higher acrylamide formation. Settlements involving almonds are inappropriate for determining a presumptive acrylamide value for almond butter. If roasted almond butter is being produced, this necessarily means that there is significantly more surface area of the nut being exposed to heat, causing a faster, deeper, and longer Maillard reaction and hence greater acrylamide production than is the case with whole almonds. Using *Embry v. Frito Lay* and *Embry v. Hayden Valley Foods* settlements as an indicator of what is ‘feasible’ for almond butter is inappropriate.

In support of OEHHA’s assertion that achieving a 225 ppb maximum average acrylamide level for roasted almond butter is currently feasible, OEHHA referred to data collected by the US FDA as a follow-up to US FDA’s Total Diet Study. US FDA sampled only three brands (of the more than 55 brands and private label brands) of almond butter, each one twice, to represent the roasted almond butter industry. Two of the samples from one of the brands reported having acrylamide below US FDA’s detection level of 10 ppb. Based on existing science regarding acrylamide formation, it is unlikely a roasted almond butter could be produced with an acrylamide level as low as 10 ppb.

[35] For example, in *Embry v. Frito Lay, et al.* (Case Number HG 19021174, AG Notice No. 2019-01037; Judg. No. J4260), “Product” and “Products” were defined as “roasted almond products containing acrylamide that are manufactured, purchased, distributed, or sold by Frito-Lay and sold in California”. It did not name any specific product. *Embry v. Hayden Valley Foods* (Case Number RG 20052449, AG Notice No. 2020-01201; Stlmt. No. S8608) stated, “the products covered by this consent judgment include all roasted almond products that are manufactured and/or distributed for sale in California by Hayden Valley Foods, Defendant Releasees and Downstream Defendant Releasees.”

Nonetheless, OEHHA is using US FDA's data to establish an industry-wide production standard for roasted almond butter.

OEHHA identified several potential production or manufacturing changes that are used to reduce acrylamide in certain foods. None of them have been used on or are feasible for use with roasted almond butter. OEHHA's suggestion to shift crop varieties or agricultural practices is not feasible for almonds that are a perennial crop with roughly a 25-year crop production life.

Almonds used in almond butter are processed differently. Roasting is typically done at a lower temperature for longer periods of time influencing acrylamide formation. If the 225 ppb level is adopted, the reference to almond butter should be removed. The almond category should be Almonds, roasted, and chocolate-covered almonds.

Response: OEHHA acknowledges the commenter's request for clarification and has modified the text in the first modification. The reference to roasted almond butter was removed from the list of Food/Food groups: Almonds, roasted, ~~**roasted almond butter**~~, and chocolate-covered almonds. This is to provide more time for OEHHA to review any available information related to feasible levels for this product category.

In the second modification, OEHHA further clarified the category of Almonds, by inserting "specifically" to make clear the category includes specially these items only, "roasted almonds" and "chocolate-covered roasted almonds."

Comment 60 (NCA): The commenter stated there are two consent judgments that apply the same 225 ppb level for chocolate covered almond products to almonds with non-chocolate confectionary coatings (as well as to almonds with non-confectionary coatings). https://oag.ca.gov/system/files/prop65/settlements/2019-01271S8756.pdf; https://oag.ca.gov/system/files/prop65/settlements/2019-01941S8557.pdf. Two other consent judgments have extended the same 225 ppb threshold to confections composed of chocolate and walnuts and to chocolate confections with other inclusions that undergo cooking or heat processing, including peanuts in various forms, wafers, and toasted rice. *See* https://oag.ca.gov/system/files/prop65/settlements/2019-01243S8783.pdf; https://oag.ca.gov/system/files/prop65/settlements/2019-01312S8459.pdf. NCA requests OEHHA clarify that the proposed 225 ppb safe harbor level for acrylamide in almonds apply to ***all*** chocolate confections containing almonds as an ingredient, including forms other than whole nuts (i.e., "chocolate almond products" as several prior consent judgments specify). The commenter requests that OEHHA expand the safe harbor category to include almonds covered with confectionary coatings other than chocolate that also undergo cooking or heat processing, such as caramel or toffee. Because several of the consent judgments recently approved by the

Alameda County Superior Court extend the 225 ppb average acrylamide level beyond chocolate almond products, NCA requests OEHHA adopt an additional subsection (d) safe harbor level for chocolate containing inclusions other than almonds that have undergone cooking or heat processing (such as walnuts, peanuts, raisins, wafers, caramel, toffee, toasted rice, etc.).

Response: OEHHA acknowledges the commenters' suggestions for additions to the rulemaking. OEHHA declines to add concentration levels for the additional product categories to the regulation in this rulemaking. OEHHA has the authority to modify the regulation to add additional categories and concentrations. Any such modifications would be the subject of subsequent rulemakings.

No changes were made to the proposed regulation based on this comment.

Bread

Comment 61 (ABA, CRC, Key Sciences): The commenters support using the average concentration rather than the "unit concentration" concept in subsection (d). OEHHA should conform its proposed safe harbor levels for acrylamide in soft bread products to those in the Proposition 65 consent judgments. OEHHA should also make its proposed 100 ppb average acrylamide level for soft breads applicable to both wheat and non-wheat-based products. There is no reason to distinguish among these product types, as wheat-and non-wheat-based breads substitute for one another in the diet, based on consumer preferences. Having a single level for bread would benefit the baking industry and consumers by having a consistent approach and avoiding potential ambiguities around the product categories.

Alternatively, ABA stated that safe harbor levels for soft bread are not currently feasible for certain types of breads, such as some potato-based breads, gluten-free breads that contain potato starch, flavored baked goods, traditionally sweeter breads, and baked goods with inclusions (e.g., cookies with nuts or chocolate that provide additional acrylamide). The proposed rule implicitly recognizes this by providing significantly higher levels proposed for other potato products compared with breads. Similarly, the safe harbor levels for potato-based breads and breads containing potato starch should be higher than the 100 ppb level for other types of breads.

On the other hand, CRC states that wheat, non-wheat bread, and waffles have been shown by US FDA to have substantially lower average acrylamide concentrations compared to the proposed benchmark levels. Given the similar median levels, and the overall dataset, Key Sciences sees no reason to differentiate between wheat and non-wheat-based breads. Key Sciences recommends all breads be subject to a 50 ppb limit.

They report that test results showed acrylamide levels in non-wheat-based breads non-detect as low as 10 ppb, which shows it is possible to formulate with little to no levels of acrylamide. The median level of acrylamide seen in this food group was 20 ppb. With a proposed maximum average concentration level of 100 ppb, 97% of non-wheat-based breads would be beneath the new regulated level. They state that the benchmark acrylamide concentrations identified in prior court cases should serve as a guide to OEHHA, but not the basis for the final rule.

Response: The proposed regulation includes both maximum average concentration and maximum unit concentration where appropriate. With two exceptions (wheat-based and non-wheat-based bread categories), the concentration 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. As specified in the ISOR, EU (2017) establishes two separate levels for wheat-based and non-wheat-based breads, and OEHHA is adopting these two levels separately for each bread group.

OEHHA notes the comment that the proposed levels for the two groups of bread may not be feasible for certain types of bread, such as potato-based bread. Businesses have several options to show a warning is not required, and the levels established in subsection (d) is just one option. As stated in the ISOR (page 11),

> [T]he 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.

No changes were made to the proposed regulation based on this comment.

Comment 62 (ABA): The commenter stated that extensive research documents the protective effects of grain-based foods against cancer and other chronic diseases. A recent meta-analysis by Dr. Glenn Gaesser demonstrated that despite the formation of acrylamide in such products, grain-based foods, on the whole, reduce the risk of cancer. The commenter presented some of the findings from Dr. Gaesser's research to the FDA, which they believe would also benefit the continuing collaboration with OEHHA to promote healthy balanced nutrition for Californian consumers.

Response: The proposed regulation makes no judgment about the benefits of specific foods; it only sets safe harbor concentrations for certain food categories to help businesses determine when a warning may be required.

The purported dietary benefits of certain foods containing acrylamide are outside the scope of this rulemaking. Nonetheless, OEHHA notes that information about the benefits of eating a balanced, high-fiber diet are readily available, OEHHA also notes that not all grain-based foods contain whole grains. Further, numerous whole grain foods will not contain acrylamide at levels that require a warning.

Additionally, work by Dr. Gaesser[36] does not necessarily support the commenter's contentions. The commenter provides no indication of the cooking or food preparation techniques for the foods underpinning Dr. Gaesser's research. The paper reports that whole grains were associated with reductions in cancer risk. However, although the paper's author concluded that the data on refined grains was inconclusive, cancer risks for all studies tabulated were elevated, including one meta-analysis of 19 studies showing a 63% increase in gastric cancer risk in the top exposure group.

No changes were made to the proposed regulation based on this comment.

Cookies categories

Comment 63 (ABA and IBA): The commenters requested further clarification of the cookie product categories in subsection (d)(1) and more guidance on what products are covered within the category of baked goods. Cookies are broken into three subcategories (animal/animal crackers, thin and crispy, sandwich wafers). It is unclear, however, how some of the most common types of cookies - such as a classic chocolate chip cookie (81-168 ppb, according to March 2004 FDA data) or a sugar cookie (29-70 ppb, according to March 2004 FDA data) - would be classified under the proposed subsection (d)(1). ABA stated that cookie categories would benefit from more specific details and differentiation.

The commenters stated that the category for thin and crispy cookies seems to be the catch all for any thin cookie, regardless of the cookie's formulation (e.g., peanut butter cookies or almond butter cookies which have higher acrylamide levels). If OEHHA maintains this category, it should be limited to the specific cookies covered by the consent decrees: that is, ginger snaps, gingerbread cookies, graham crackers, and double chocolate thins.

[36] Gaesser GA (2020), *Whole Grains, Refined Grains, and Cancer Risk: A Systematic Review of Meta-Analyses of Observational Studies*, 12 Nutrients 3756. Available at https://www.mdpi.com/2072-6643/12/12/3756.

The proposed values for the “Cookies, sandwich wafer” category are based on two settlements involving particular types of thin wafers sandwiched with cream filling filed by the same private litigant. IBA questions whether these two settlements initiated by the same litigant would be representative of the lowest currently feasible acrylamide levels achievable by other sandwich wafer cookies on the market. The settlements involved wafer cookies with cream fillings, and unlike many other wafer products, are not coated with chocolate or nuts and may have other fillings. If OEHHA maintains this category, IBA urges OEHHA to revise the name of the category to “Cookies, uncoated sandwich wafers with cream fillings” to avoid any confusion over the scope of the category.

IBA urges OEHHA to combine the three cookie categories into two categories, “Cookies and Wafers,” and “Crackers with the exception of potato-based crackers”. If OEHHA rejects this approach and maintains the existing categories, IBA urges OEHHA to significantly narrow the products that would be covered by each of the existing categories. The product category descriptions are very confusing. Three of the product categories have used the same descriptor term “cookies”, yet the differences are not apparent based on their names. IBA members have difficulty classifying their particular baked goods under these three proposed product categories for cookies. There is no rationale or acrylamide data provided in the ISOR to explain why the cookies are separated into these three separate categories with very different acrylamide levels considered as “lowest levels currently feasible.” The classification appears to be based entirely on the cookies covered by specific settlements.

Response: The commenter is correct that the specific products and categories in the court-approved settlement agreements are used in the proposed regulation. The “cookies, animal and animal crackers (sweet)” categories are specific to animal-shaped hard cookies and animal crackers (ISOR page 18). The “cookies, thin and crispy” category covers all thin and crispy cookies, including but not limited to ginger snaps, gingerbread cookies, graham crackers, biscuit cookies, or double chocolate thins (ISOR page 19-20). The “cookies, sandwich wafers” category covers wafer cookies that are made from thin biscuit cookies sandwiched with cream filling (ISOR page 21). The Addendum to the ISOR also explains that the categories of cookies are specific to those listed on the chart and that they are taken from specific settlements.[37]

In the examples that the commenter provides, if a classic chocolate chip cookie or sugar cookie is thin and crispy, along the lines of a ginger snap, graham cracker, or biscuit, then it could fall within that category. If the cookie was not like a ginger snap, graham cracker, or biscuit, then it would not fit in this category. A thin chocolate chip cookie

[37] See Addendum to ISOR pages 14-15.

would not fit the category of sweet animal cracker or cookie, or a cream filled wafer cookie. A business can also use other regulations to determine whether the product needs a warning.

OEHHA will consider amending the regulation to add more categories as more information and resources are available.

No changes were made to the proposed regulation based on this comment.

Comment 64 (P&S): The commenter stated the proposed regulation distinguishes between cookies and crackers within three separate categories: (1) Cookies, animal and animal crackers (sweet); (2) Cookies, thin and crispy; and (3) Cookies, sandwich wafers. The first category, animal crackers and iced animal cookies, can have higher acrylamide concentration levels when cooked because of varying dough mass, the differing baking process, whether the cookies are 'gluten-free', and the amount of icing used. Animal crackers may be feasibly manufactured with maximum average concentration levels of 75 to 100 ppb. Animal cookies, a product with greater dough mass, are more likely to have a higher acrylamide concentration. Gluten-free animal cookies may feasibly achieve acrylamide levels of 100 to 125 ppb. Animal cookies which are not gluten-free, are lightly iced, have a greater dough mass, and have higher acrylamide concentration levels in the range of 281 to 350 ppb. The higher acrylamide concentration levels are present even when using quality control measures to reduce the level of acrylamide to the lowest level currently feasible. This issue is compounded by the lack of consent judgments on this issue, or those entered into by companies intending to remove the product from the California market.

To consider the differentiation of serving size, dough mass, enrobing and content, as well as feasibility, the commenter requests that the category "Cookies, thin and crispy" include animal cookies and animal cookies partially iced with concentrations levels of 281 to 350 ppb, or a separate category be established for animal cookies and animal cookies partially iced with the 281 to 350 ppb levels. These products are baked under a completely different process and have a different dough mass than crackers, enrobed cookies, or gluten-free cookies, and cannot be feasibly manufactured with acrylamide concentration levels below 281 to 350 ppb.

Response: The categories mentioned by the commenter, (1) Cookies, animal and animal crackers (sweet); (2) Cookies, thin and crispy; and (3) Cookies, sandwich wafers were generated from the settlements that were available at the time the regulation was developed. OEHHA did not use any settlement levels to set the limits in this regulation where a product has been removed from the California market. OEHHA may amend the regulation to add more categories as additional information becomes available.

No changes were made to the proposed regulation based on this comment.

Comments 65 (SNava): The commenter makes gluten-free cookies made predominantly with almond flour and almonds. The commenter stated the safe harbor limit is too low because of the quantity of almonds used in their recipe. Small companies are consistently being sued by private enforcers from whom the businesses need better protection. Their business is limited in the extent to which they can minimize acrylamide levels that are naturally occurring in almonds and baking. The commenter recommended adding more specific examples and setting higher safe harbor levels.

Response: OEHHA understands that small businesses may have limited resources available to modify processes that can create acrylamide in their products and will consider adopting additional levels in future rulemakings.

It should be noted that the acrylamide concentrations set out in this proposed regulation apply to the whole food product as sold. There is no need for a business to aggregate the concentration of acrylamide that may be in flour or almonds. Instead, the business can rely on the concentrations established in the regulation if the concentration of acrylamide in the food product as sold, such as a cookie, are at or below the established level.

The product categories in subsection (d) are limited to the product categories that were covered by court-approved settlements. The categories for cookies in the current proposal are animal cookies and crackers (sweet), thin and crispy cookies, and sandwich wafers cookies. If the gluten-free cookies made by the commenter do not fit into one of these categories, the commenter can use other provisions of the regulations to determine whether a warning is required for their products. For example, the business could utilize the defense in subsection (a), consider the existing safe harbor levels established in Sections 25705 or 25805, consider the alternative risk level process described in Section 25703(b)(1), use food intake calculations described in Section 25721, or a combination of these, among other provisions in the regulations to determine whether a warning is required. (ISOR page 11.) There are regulations that establish safe harbor warning methods and content for chemicals in foods in Sections 25607.1 and 25607.2.

It is beyond the scope of this rulemaking to provide specific enforcement relief to small businesses.

No changes were made to the proposed regulation based on this comment.

Comment 66 (Key Sciences, CRC): Manufacturers have readily demonstrated their ability to produce products with much lower acrylamide levels. In CRC's product analyses, roughly half the cookie products tested show acrylamide levels below the

proposed benchmark. Similarly, according to the ISOR (page 21), “acrylamide levels in two wafer cookies samples reported in 2015 [by the FDA] were 50 and 80 ppb”. Thus, OEHHA is proposing a feasible concentration level that does not incentivize manufacturers to make improvements in food production that would be readily within their abilities.

The test results showed acrylamide levels in animal cookies as low as 4 ppb, which shows it is possible to formulate with little to no levels of acrylamide. The median level of acrylamide seen in this food group was 112 ppb. With a proposed maximum average concentration level of 75 ppb, 43% of animal cookies would be covered by the new regulation.

Response: OEHHA appreciates the information regarding tested levels of acrylamide in some products and may consider it in future rulemakings. The concentrations established in the proposed regulations are based on published data and levels established in settlements of enforcement actions in California. For example, the level for animal cookies was based on seven settlements that were approved by the court. These settlements all set the level at 75 ppb. (ISOR pages 18-19.) See also Response to Comment 47.

No changes were made to the proposed regulation based on this comment.

Cookies, sandwich wafers

Comment 67 (SGF, CRC): The commenter requested that the proposed maximum average concentration level of 115 ppb for the category “Cookies, sandwich wafers” be revised to 280 ppb. Both of the Consent Judgments identified by OEHHA in this category ultimately will permit products to be sold without a warning with up to 280 ppb of acrylamide because they may be automatically adjusted to the 280 ppb level allowed by the Mondelēz Global LLC consent judgment.

CRC reported test results showing acrylamide levels in sandwich wafers at non-detect as low as 20 ppb, which shows it is possible to formulate these cookies with little to no acrylamide. The median level of acrylamide seen in this food group was 42 ppb. With a proposed maximum average concentration level of 115 ppb, 100% of sandwich wafers tested would fall below the proposed regulation. This limit does not help consumers and the commenter recommends dropping the limit for this product category.

Response: The level of 115 ppb set for “cookies – sandwich wafers” comes from two different court approved settlements for sandwich wafer cookies[38], which set the level of

[38] *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).

acrylamide in these products at 115 ppb. The settlements are also consistent with US FDA data[39]. The settlement identified by the commenter, *Embry v. Mondelez Global LLC, et al.* (Super. Ct. Alameda, 2019, No. HG 19023388 [AG No. 2019-00852 and AG No. 2019-00514; Judg. No. J4318, Mondelez Global, LLC]), includes two different products, which fall into two separate product types: thin and crispy cookies and sandwich wafers. That settlement set the level of acrylamide at 280 ppb for two products, and it is higher than 115 ppb, the lowest feasible level. The settlement is applicable to the parties in the specific lawsuit but is not controlling on OEHHA in a regulatory action. The levels set in subsection (d) are non-mandatory, safe harbor concentrations. Businesses can use other regulatory provisions appropriate to the situation or provide a warning for the product. The regulation is not intended to eliminate all warnings.

No changes were made to the proposed regulation based on this comment.

Crackers, savory, including crispbread

Comment 68 (IBA, CRC, Key Sciences): The proposed product category for "Crackers, savory, including crispbread" is based on two settlements for saltine crackers and crispbread; however, it would cover all savory crackers such as cheese crackers, nut-based crackers, and a multitude of other cracker products. Based on the limited number of consent decrees and the breadth of the category, it seems implausible that 350 ppb would be the lowest level currently feasible for the multitude of crackers covered. IBA urged OEHHA to adopt the EU levels for all crackers because the industry has clarity on the products that are included and there are sufficient data to support the level as the lowest currently feasible. If OEHHA maintains the product category, the commenter urged OEHHA to limit the scope to saltines and crispbread because those are the products covered by the consent decrees.

Alternatively, CRC reports that the testing of crackers showed over half of the products fell below the proposed benchmark, with nearly a third falling below 200 ppb. US FDA reporting reaffirms that "the average level of acrylamide in crackers was 233 ppb" across 41 samples in 2011 and 97 ppb across 50 samples in 2015. According to Key Sciences, test results showed acrylamide was not detected in crackers at non-detection limits as low as 20 ppb, which shows it is possible to formulate with little to no levels of acrylamide. The median level of acrylamide seen in this food group was 75 ppb. With a proposed maximum unit concentration level of 490 ppb, 82% of crackers would fall below the new regulation. Key Sciences recommends that OEHHA differentiate between types of crackers. Without differentiation, the commenter recommends the

[39] See ISOR page 21.

maximum level be drastically reduced. With more than 50% of the cracker category yielding results below 75 ppb, 490 ppb is too high.

Response: For savory crackers, the ISOR states that "this group covers all savory crackers, such as saltine crackers and crispbread". (ISOR page 22.) Saltine crackers and crispbread are two examples for savory crackers. The maximum average concentration of 350 ppb and the maximum unit concentration of 490 ppb for crackers are based on two settlements that cover a variety of multigrain or gluten-free crackers. (ISOR page 22.) 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 the *Van Patten v. Dare Foods, Inc., et al.* settlement (Case No. 37-2019-00053698-CU-PO-CTL, AG No. 2019-01267) on multigrain crackers. (ISOR page 22). OEHHA declines to use the EU benchmark level (400 ppb) for the EU category "Crackers with the exception of potato based crackers" because this level is higher than the maximum average level identified in the settlements (350 ppb).

In the second modification, OEHHA clarified that this category is "Crackers, specifically savory crackers, including crispbread." The Addendum to the ISOR explains on page 15, "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."

IBA is incorrect that the safe harbor concentration applies to savory crackers other than the crackers described in the relevant settlement documents that the concentration is based on. The second settlement[40] covers several gluten-free crackers including Milton's Gluten-Free Crispy Sea Salt Baked Crackers. Milton's Gluten-free Cheddar Cheese Baked Crackers, Milton's Gluten free Everything Baked Crackers, Milton's Gluten-Free Multi-Grain Baked Crackers, Milton's Gluten-Free Baked Crackers in Other Flavors to be introduced in the future. The proposed level is not limited to these specific brands but is limited to the specified types of products.

Potato products, French fried potatoes

Comment 69 (FPPI): The commenter stated that unlike other foods identified in the proposal, acrylamide is mainly formed during the final cooking step of frozen potato products (e.g., French fries), which predominantly happens at the homes of consumers. As such, manufacturers and producers of frozen potato products have very limited

[40] *Van Patten v. Dare Foods, Inc., et al.* (Case No. 37-2019-00053698-CU-PO-CTL, AG No. 2019-01267). Consent judgment was entered by the Superior Court of San Diego County on June 9, 2020.

control over its formation. By not explicitly recognizing the levels only apply to the cooked French fries when prepared following the labeled cooking instructions, OEHHA risks putting their businesses in the impossible position of having to comply with a level they do not have control over. Frozen potato manufacturers provide cooking instructions designed to mitigate acrylamide formation in their products but ultimately have no direct control over the final acrylamide formation process. Baking and frying can potentially produce vastly different levels of acrylamide. It is important to measure the acrylamide levels in cooked French fries when prepared under the cooking instructions provided on the label. The commenter asks to modify the phrase "Potato products, French fried potatoes" under subsection (d) by adding the phrase (when prepared according to cooking instructions).

Response: OEHHA acknowledges the comment and suggested language. As the commenter points out, manufacturers and producers cannot control the behavior of individual consumers. The settlements that OEHHA relied on to set the level for the category, Potato products,[41] assumed that consumers follow the guidance on product packaging for foods that need to be prepared. Many of the judgments for products that require food to be cooked to be consumed, like frozen hashbrowns[42] and waffles, provide sampling and testing methodology that includes following the cooking instructions on the package label. From *Embry v. Sprouts Farmers Market, et al.* settlement (Case No. RG 19011780, AG No. 2020-01096; Stlmt. No. S8556), "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."

The burden of proving that the concentration level in a product prepared according to package instructions is at or below the established concentration level is on the business.

No changes were made to the proposed regulation based on this comment.

Comment 70 (Key Sciences): The commenter stated its results showed that acrylamide was not detected in French fried potatoes at non-detection limits as low as 30 ppb, which shows it is possible to formulate with little to no levels of acrylamide. The median level of acrylamide seen in this food group was 85 ppb. With a proposed maximum unit concentration level of 280 ppb, 100% of French-fried potatoes would fall

[41] This category was modified in the second modification to combine all potato and sweet potato products into one category.

[42] 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]).

below the new regulation. The commenter believes 85 ppb is a feasible level for French fried potatoes, and therefore a level of 280 ppb accomplishes no benefit for consumers.

Response: As noted in the ISOR (page 23) levels of acrylamide in some French-fried potatoes measured by US FDA exceeded the maximum unit concentration and average level being proposed by a considerable amount. The apparent difference of acrylamide levels from French-fried potatoes tested by the US FDA and data from Key Sciences demonstrates the difficulty of arriving at a representatively feasible level using testing data. Testing data can be informative but suffer from limited sample size and selection of food products brands and lots, and the results can vary due to different analytical methods and protocols.

No changes were made to the proposed regulation based on this comment.

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

Comment 71 (SNAC): The commenter requested that OEHHA reconsider grouping potato and sweet potato products together into one category. Potato and sweet potato are very different and unrelated, botanically. Sweet potatoes generally contain more sugar than potatoes, and, as such, have the potential to form more acrylamide during the Maillard reaction. Given the differences in the raw materials, acrylamide levels in snack foods made from potatoes and sweet potatoes will differ. If OEHHA establishes a category for potato chips, SNAC urges OEHHA to limit the category to “potato chips” and omit sweet potato chips from the category. All the data submitted in SNAC’s comment are for potato chips, which further supports the need to remove sweet potato chips from the category.

Response: Potato and sweet potato products are grouped in the regulation because the settlements OEHHA relied on for the proposed levels set the same numbers for potato and sweet potato products. More than 20 settlements and US FDA data were used to set the levels in this category.[43] Some settlements covered both potato and sweet potato products. While it is possible that the levels of acrylamide formed in cooked potato products differ between potato products and sweet potato products, there is also variability within potato products or within sweet potato products because of the variety of the potato/sweet potato, storage conditions, cooking methods, and other factors. The data available to OEHHA do not show whether variations in concentrations are caused by differences between the two crops or are caused by other variables.

No changes were made to the proposed regulation based on this comment.

[43] See ISOR pages 27-28; Addendum to ISOR page 16.

Comment 72 (Key Sciences): Hash browns and potato puffs test results showed acrylamide was not detected in hash browns/potato puffs at non-detection limits as low as 20 ppb which shows it is possible to formulate with little to no levels of acrylamide. The median level of acrylamide seen in this food group was 35 ppb. With a proposed maximum unit concentration level of 350 ppb, 100% of hash browns/potato puffs would fall below the new regulation. Key Sciences observed variability within this sub-category that may warrant a level higher than the median observed in their data. The commenter urged OEHHA to reconsider this proposed level.

Response: As explained in the ISOR on page 25-26, according to US FDA data, the average level of acrylamide in various potato products was 369 ppb[44]. The 350 ppb maximum average concentration level and the 490 ppb maximum unit concentration level were established using over 20 court-approved settlements for this category (ISOR page 24; Addendum page 16).

No changes were made to the proposed regulation based on this comment.

Potato or sweet potato products, sliced chips

Comment 73 (SNAC, Key Sciences, CRC): SNAC stated that data from its members suggest that approximately 85 percent of the potato chips in the market today would exceed the proposed maximum average level for acrylamide of 281 ppb, and 71 percent of the potato chips would exceed the proposed maximum unit level of 350 ppb. A more appropriate number based on extensive data points would be the 750 ppb level established by the EU for potato chips. OEHHA has already adopted the EU "benchmark levels" for wheat-based and non-wheat-based bread categories in the current proposal, and SNAC asks OEHHA to do the same here to be consistent.

Alternatively, OEHHA could base the level on the data submitted by the commenter demonstrating the mean level of acrylamide in potato chips marketed in the United States is 509 ppb. The adoption of 509 ppb would require the reformulation and additional work for 38 percent of the potato chip products analyzed which is a percentage much higher than the 10-15 percent used by the EU when developing its "benchmark levels." Taking the industry data into consideration is consistent with OEHHA's approach in the ISOR for the product category "Almonds, roasted, roasted almond butter, and chocolate-covered almonds." OEHHA noted levels reported for almonds by the Almond Board of California are on average lower than the proposed feasible level, indicating feasibility. SNAC asks OEHHA to use the same common-sense

[44] 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.

approach for potato chips and adopt the 509 ppb industry mean as the “lowest level currently feasible.”

An alternative perspective was provided by Key Sciences who stated test results showed acrylamide levels in sliced chips as low as 177 ppb. The median level of acrylamide seen in this food group was 380 ppb. With a proposed maximum unit concentration level of 490 ppb, 69% of sliced chips would fall below the new regulation. In this case, even the median level of 380 ppb is quite high relative to the other categories discussed in the proposed regulation. The commenter proposes working together with industry leaders to lower the level to between the lowest observed point in their data (177 ppb), and the median (380 ppb), which fifty percent of products already fall beneath. Further, CRC stated that over half of the potato chip products they sampled this year had acrylamide levels below 150 ppb. Meanwhile, the currently proposed benchmark is nearly twice as high. A benchmark of 281 ppb does not adequately inform consumers when in fact many low-acrylamide-containing potato chip options exist on the market. A feasible concentration level in the range of 150-200 ppb would be much more reasonable as it would be readily achievable by industry and would more appropriately inform consumers.

Response: The proposed levels for the category of “potato or sweet potato products, sliced chips,” was based on over 10 court-approved settlements[45], all of which set the same levels for sliced chips: 281 ppb maximum average concentration and 350 ppb maximum unit concentration. OEHHA’s regulation establishes the lowest levels of acrylamide that are feasible for each category of food; the number comes from either the EU benchmark levels or court-approved settlements, whichever is the lowest. The

[45] *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]).

settlements, which were all entered in 2018 or 2019, provide the most recent information that the 281 ppb maximum average concentration and 350 ppb maximum unit concentration are feasible levels for chips sold in the California market. The commenter suggests that since the parties were not contemplating a lowest level feasible, but thinking about a reformulation level during settlement negotiations, this should mean that the levels should be set higher to match what the industry practice was at the time. The idea that the parties understood that their products could be manufactured in a way that produced the levels agreed to in the myriad of settlements in this product category provides proof that the industry can feasibly achieve these levels.

No changes were made to the proposed regulation based on this comment.

Prune juice, 100% (not from concentrate); Prune juice, made with concentrate

Comment 74 (Sunsweet): The commenter believes prunes and prune juice are uniquely situated to be considered for complete exemption of acrylamide warnings in a manner afforded by OEHHA to coffee. If prune juice is not entirely exempted based on its well-documented health benefits, then a maximum average concentration of 450 ppb should be established in the regulation for the single category of “Prune Juice” that complies with the FDA standard of identity. A 450 ppb level for a subclassification of prune juice has already been accepted by California as not requiring a cancer warning label and which does not require use of enzymes. The level is based on test data collected over various annual crops and a diverse mix of standard and experimental processes pursued in efforts to minimize formation of acrylamide or to reduce heat levels or cook times while maintaining the integrity, nutritional value and pasteurized safety of prune products offered to consumers.

Many types of prune juice are offered to California consumers. Sunsweet views most prune juice distinctions as branding or marketing claims since the standard of identity and nutritional content labels are generally identical. The familiar caramelized flavor of quality prune juice is a direct result of the standard Maillard reaction that is accompanied by the formation of acrylamide from cooking. Relying on arbitrary prune juice marketing classifications is inappropriate both for the industry and California consumers and suggests that a single level be applied for all prune juice manufacturers without regard to what proprietary enzymes are applied, what brand or manufacturing equipment is used, or what label classification or claim is made. Science-based reports are made publicly available to demonstrate why certain processes are entitled to be granted different concentration levels as a matter of law, and the technology is reasonably accessible to all participants.

Tunnel drying currently remains the only commercially feasible method of reliably producing high quality prunes. The initial heating for dehydration facilitates acrylamide formation within the intact fruit, with high variability influenced by internal prune sugars, fruit size, and day-to-day ambient temperature and humidity. Throughout the dehydration and rehydration processes there is no known opportunity to introduce any enzyme or otherwise affect the asparagine or acrylamide formation within each intact fruit.

Response: After reviewing this comment**,** OEHHA removed the concentration levels for prune juice from the proposed regulation at this time to gather more information about this food product.

Waffles

Comment 75 (Key Sciences): The test results showed acrylamide levels in waffles as low as 22 ppb. The median level of acrylamide seen in this food group was 60 ppb. With a proposed maximum unit concentration level of 280 ppb, 95% of waffles would fall below the new regulation. The commenter recommended 60 ppb as the revised proposed level.

Response: The level for waffles of all flavors and sizes was determined based on the court-approved settlement in *Embry v. Sprouts Farmers Market, et al.* (Case No. RG 19011780, AG No. 2020-01096; Stlmt. No. S8556). This is the only settlement in this specific category. This settlement was the most reliable information to use for setting the level in the currently proposed regulation and this level has also been used in two subsequent settlements for this food group[46].

No changes were made to the proposed regulation based on this comment.

Miscellaneous Comments

Comment 76 (SMasri): OEHHA said that "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." This reasoning presupposes that an individual's diet is committed to specific product categories and that the purpose of Proposition 65 should be to guide the consumer to the least harmful products within that category. Under this assumption, the proliferation of Proposition 65 warnings could indeed lead to consumer confusion. However, this assumption is incomplete as it does not consider the real possibility that consumers may choose to reduce their consumption of certain food categories altogether over time, due to the abundance of Proposition 65 warnings on many products within that category.

Response: Proposition 65 is a right-to-know law that is intended to help Californians make informed choices about the products that they use. OEHHA does not presume that the individual's diet is committed to specific product categories. As noted in the ISOR (page 6) and modified in the Addendum to ISOR (pages 3-4), the problems this 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 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. The regulation

[46] See Addendum to ISOR pages 16-17.

achieves these objectives by incentivizing food manufacturers and producers to reduce acrylamide formed through cooking or heat processing to the lowest level currently feasible, while continuing to require warnings for acrylamide in food when present at levels above the lowest levels currently feasible.

No changes were made to the proposed regulation based on this comment.

Comment 77 (SMasri): The commenter stated that the intent of Proposition 65 is not to warn consumers against only the highest-risk products in a high-risk category, but rather to warn the consumer against high-risk products altogether. If a particular food category such as toasted ready-to-eat cereal or fried chips happens to be dominated by products that pose an elevated cancer or reproductive risk, resulting in a proliferation of Proposition 65 warnings across the entire food category, the effect of this abundance of warnings should not be simplified to mean “confusion” that is without value to the public. Proposition 65 in such cases serves the important function of alerting consumers that an entire food category constitutes an elevated health risk, much like the public has come to understand that the entire cigarette category poses a cancer risk. Those wishing to avoid the elevated cancer risk posed by the entire cigarette product category can choose to do so, thanks to the warnings universally applied across the entire product category. In the context of acrylamide exposure in cooked foods, consumers have the right to know which foods pose an elevated cancer risk, even if that means the proliferation of warnings across an entire food category, allowing them the information needed to make healthier food purchases.

Response: This comment oversimplifies the products and chemical at issue. Cigarettes are a uniform group of products with the same active ingredients that makes warnings more effective. The proposed regulation addresses the potential ubiquity of warnings across all food categories covered by the proposal. It strikes a balance between too many warnings for unavoidable exposures to chemicals in cooked or heat processed foods and incentivizing businesses to reduce exposures.

No changes were made to the proposed regulation based on this comment.

Comment 78 (PTNPA): The commenter stated that nut and seed products have been the subject of over 130 notices of violation which creates uncertainty for their businesses and the potential for a proliferation of Proposition 65 warnings for unavoidable chemicals formed by cooking and heat processing. Each case, whether resolved through settlement or by judgment after trial, increases the likelihood that inconsistent warnings will appear on thousands of food products sold throughout California.

Response: The concentration levels established in subsection (d) are intended to cut down on consumer confusion and provide target levels for the food categories identified, many of which may contain nuts and seeds. Where a given product or food category is not included in subsection (d), subsection (a) provides options for businesses to determine whether a warning is needed for their products. Other regulations adopted in Article 6 provide warning methods and content so that businesses can provide consistent warnings deemed "clear and reasonable" for purposes of Proposition 65. Note that the proposed regulation does not cover any nut or seed products other than roasted almonds in subsection (d).

No changes were made to the proposed regulation based on this comment.

Comment 79 (Sunsweet): The commenter considers this regulation as an experiment to see if naturally occurring chemicals in foods can be treated more rationally than the current enforcement business model permits. The commenter is hopeful that a regulation of this kind can establish more clarity and certainty of action and response and offer future guidance for other foods or products where similar issues may arise.

Response: OEHHA notes that acrylamide is not naturally occurring in the context of Proposition 65. (See Title 27, CCR section 25501.) The regulation is intended to promote public health and provide clarity for businesses that may cause exposures to acrylamide in their products.

No changes were made to the proposed regulation based on this comment.

Comment 80 (CERT): The commenter stated that in subsection (d) OEHHA proposes that "maximum average concentration levels" of acrylamide ranging from 50 to 350 ppb for different foods or food groups "are deemed to comply with subsection (a)". The range exceeds the No Significant Risk Level (NSRL) for acrylamide 250-fold up to 1,750-fold. Exposing Californians to such high levels of acrylamide requires entities doing so to provide a prior cancer warning rather than exempt them.

Response: The regulation provides feasible target levels for reducing exposures to acrylamide from specific food groups and establishes that a warning is not required when acrylamide levels are at the lowest level currently feasible. In the proposed regulation, OEHHA is adopting concentration levels deemed to be the lowest level currently feasible for certain cooked and heat processed foods. Some businesses may not be able to achieve the levels that are set out in subsection (d) and will need to decide whether to provide a warning, or whether warning is not required pursuant to subsections (a) or (b). Since acrylamide only occurs when a food is cooked or heat processed, the wide variety of foods affected require levels to be set by food category to

ensure that acrylamide levels are at the lowest levels currently feasible to reduce levels of acrylamide as much as possible.

As stated in the ISOR on page 31,

> 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.

See also Addendum to ISOR pages 5-6.

No changes were made to the proposed regulation based on this comment.

Outside the Scope of the Proposed Rulemaking

Comment 81 (Anonymous #2): The commenter stated that if exemptions are allowed for cooked or heat processed foods, which people ingest, it highlights the political nature of Proposition 65 as opposed to protecting the people of California. If food items become exempt, why regulate cosmetics or personal care products? Those are applied topically with moderate chance of penetration into the skin. How is ingestion safer than topical application?

Response: This comment falls outside the scope of the regulation. The proposed regulation does not provide an exemption for cooked, or heat processed food. The regulation specifically establishes maximum concentration levels for acrylamide in foods that are produced by cooking or heat processing that are deemed by OEHHA to be the lowest levels currently feasible.

OEHHA did not decide that ingestion is “safer” than topical application of listed chemicals. Proposition 65 requires businesses with 10 or more employees that expose people to chemicals on the Proposition 65 list to provide a clear and reasonable warning prior to that exposure. “Exposure” includes contact with a substance through swallowing, breathing, or touching the skin or eyes. Other regulatory provisions help businesses determine when warnings are needed for listed chemicals applied to the skin.

No changes were made to the proposed regulation based on this comment.

Comment 82 (Sunsweet): The commenter believes that the opportunity to validate mitigation measures should be available to any manufacturer through OEHHA or another expedited process prior to the filing of any enforcement action against it. The commenter assumes that when a manufacturer can demonstrate the implementation of quality control measures through either sourcing or manufacturing processes that reduce the acrylamide levels to the "lowest levels currently feasible," the manufacturer will be deemed in compliance such that cancer warnings will not be required, and a certificate to that effect from OEHHA would be available to the manufacturer for the benefit of the entire downstream and upstream supply chain being threatened with litigation.

Response: This comment is outside of the scope of the current rulemaking. OEHHA notes that the manufacturing practices that are included in the Codex 2009 Code of Practice are in essence validated as practices that a manufacturer can use to show they have a food product with an acrylamide level that is the lowest level currently feasible. The Codex 2009 Code of Practice is incorporated by reference into subdivision (a) of the proposed regulation.

Comment 83 (SSujimoto): The commenter posed several comments as questions. How are retailers supposed to manage a chemical that is produced by cooking? Acrylamide may affect thousands of food items. Can one sign at the door and one at each register be used? Lawsuits will be huge. It will be difficult to manage signs on every single item and the number of signs would not fit on shelves.

Response: These questions are beyond the scope of the current rulemaking. Existing regulations can help businesses to determine when and how to provide a warning. In general, retailers are only required to pass on warnings that are provided by upstream manufacturers, importer, or producers. (Title 27, CCR section 25600.2, Responsibility to Provide Warnings.)

No changes were made to the proposed regulation based on this comment.

Comment 84 (Sunsweet): The commenter suggests OEHHA require that any regulatory finding or motion to approve a consent judgment includes either (a) an explanation of what process was used to reduce acrylamide formation and thereby support the reasonable expectation of maintaining a level below the settlement-specific safe harbor amount, or (b) a non-technical description of production and/or food product facts that support a "lowest level currently feasible" manufacturing process (without regard to future variability of specific product concentration measurements since a specific concentration level is then not relevant to the settlement). The process can continue to be relied upon as long as it continues to minimize any increases in

acrylamide formation wherever feasible. This type of settlement informs other manufacturers of possible steps to minimize acrylamide for the benefit of all, and creates new standards of rationality, credibility and testability of any one-off settlements that might establish differing reformulation levels for acrylamide concentrations. In effect, the “reward” of an exemption from the original NSRL requires a sharing of information helpful to consumers, manufacturers and OEHHA.

Response: This suggestion is outside the scope of this proposal. The Attorney General’s Office is responsible for oversight of settlements.

No changes were made to the proposed regulation based on this comment.

Summary of and Response to Comments to the First Modification of Proposed Regulation – April 2021

The following organizations submitted written comments on the first modification during the April 16, 2021, to May 7, 2021, comment period:

Almond Alliance of California (AlmondAC)

Center for Environmental Health (CEH)

SNAC International (SNAC)

The comments are summarized and responded to below. As described above, changes have been made to the substance and numbering of the final proposed regulation. When a commenter referred to Section 25505 or used verbiage from the original proposal, such as “listed chemical,” that language is maintained in the summary of the comment. Where applicable, responses to comment acknowledge the subsequent modifications.

Subsections (a) and (b)

Comment 85 (SNAC): SNAC fully supports the proposed changes. OEHHA has modified the language in subsections (a) and (b) in such a way that food manufacturers would have the flexibility to use evidence, standards, risk assessment methodologies, principles, assumptions, or levels described in Articles 7 and 8 of the Proposition 65 regulations to establish an alternative concentration for a listed chemical that is different from those specified in the table in subsection (d).

Response: OEHHA acknowledges the comment.

No changes were made to the proposed regulation based on this comment.

Comment 86 (CEH): CEH commented that in OEHHA's ISOR, OEHHA explained that "if a business sells products with [listed chemical] 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." OEHHA now proposes to delete the requirement and appears to be saying that even if a company takes no steps at all to reduce the levels of listed chemicals in its cooked food products, it should be able to subtract the numeric concentration levels in subsection (d) from any consequent exposure calculation. It is possible that an entity could take this approach even for food types that lack a numerical feasibility level. This is ill-advised and contrary to Proposition 65. As CEH stated in its initial comments, allowing feasibility-based exceptions to the warning requirement for knowing and intentional exposures to listed chemicals is not permitted by statute. This situation is not analogous to OEHHA's naturally occurring regulation (Section 25501) because exposures to listed chemicals that form through cooking are "deliberately added or put into the environment by human activity."

CEH commented that either a food manufacturing company has reduced the level of the listed chemical to the lowest level currently feasible or it has not. If it has not, then it should not benefit from the exemption. To allow the amounts listed in subsection (d) to be used as an "offset" against any exposure analysis essentially credits companies that have taken no measures to reduce listed chemicals in their products. Rewarding such a lack of effort is unjustified, contrary to Proposition 65 and would allow companies to expose consumers to higher levels of toxic chemicals without a warning than would otherwise be permissible irrespective of whether they have taken any efforts to reduce those exposures.

Response: If a business sells a product that has levels of acrylamide that are below the listed concentrations in subsection (d)(4), it does not need to provide a warning. As noted previously, through the proposed regulation, OEHHA is attempting to limit the proliferation of warnings, and reducing consumer confusion, while at the same time incentivizing the reduction of acrylamide in food products where feasible. This furthers the purposes of the statute. OEHHA did not intend, and nothing in the regulation supports the idea, that the concentration level in subsection (d)(4) can be subtracted from the total concentration in the food. If it does not, the business must provide a warning or use another defense as provided for in subsections (a), (b) and (c).

No changes were made to the proposed regulation based on this comment.

Subsection (d)(1)

Comment 87 (AlmondAC): AlmondAC appreciates the removal of roasted almond butter from the food group “almonds, roasted, and chocolate-covered almonds”. In removing roasted almond butter, OEHHA further understands that chemicals are unavoidably created by cooking or heat processing, and many require special treatment under the regulations.

Response: OEHHA acknowledges the comment, without agreeing or disagreeing with the assertion.

No changes were made to the proposed regulation based on this comment.

Comment 88 (AlmondAC): AlmondAC commented that using settlements as a basis for “feasibility” is a unique approach, but it assumes that the settlement is feasible *across all manufacturers, products, and commodities in all situations* which is not the case. AlmondAC elaborated on this and stated its belief that there will be numerous situations where manufacturers will not be able to meet the 225 ppb level given the USDA food safety regulatory requirements.

Response: Similar comments were raised on the August 2020 rulemaking. However, these comments are not within the scope of the modification to the proposed rulemaking. Comments on the proposed rulemaking regarding the technical feasibility of reaching the 225 ppb level for roasted almonds are summarized and responded to above. See Responses to Comments 28, 56, and 57. OEHHA modified the almond category to make the products clearer.

No other changes were made to the proposed regulation based on this comment.

Comment 89 (CEH): CEH indicated that it found it unclear why OEHHA is proposing to remove the levels for all prune juice products. A review of the public comments submitted to OEHHA reveals only one set of comments, submitted by Sunsweet Growers, Inc., on this subject, and the comments contain no evidence that would facially support the removal. CEH was the private enforcer in the three court-approved prune juice consent judgments identified as the basis for these levels (See ISOR page 28 and Response to Comment 74) and can discern no reason why Sunsweet or other prune juice manufacturers would be categorically unable to comply with the reformulation standards to which three other major producers have already been subject for several years. OEHHA noted earlier in its ISOR (at p. 29) that prune juice levels in the initial proposed regulation are generally consistent with acrylamide levels reported in prune juice products by the US FDA as early as 2005.

CEH believes that if OEHHA is going to codify reformulation levels from earlier settlements as presumptive of those levels that are presently the lowest feasible,

OEHHA should be consistent for any public interest settlements involving food types where the subject entities actively manufacture such products, as is the case with prune juice.

Response: OEHHA needs more time and information about the classification of prune juice and the processing of the fruit used to make the juice. The categories in the proposed regulation were based on the categories used in settlements regarding prune juice, but the comments state that these categories are used for marketing purposes, rather than for classification based on manufacturing process differences between the products. As such, OEHHA needs to do further review and will possibly include prune juice products in a future rulemaking.

No changes were made to the proposed regulation based on this comment.

Comment 90 (SNAC): SNAC encouraged OEHHA to provide further guidance in the final regulation or the FSOR on the type of quality control measures that are available to reduce listed substances that form during processing to the lowest levels currently feasible. SNAC urged OEHHA to recognize the EU acrylamide toolbox (i.e., the commercial application tools) and FDA acrylamide guidance as examples of quality control measures that can be considered appropriate examples of “quality control measures” under subsection (a). To the extent a manufacturer can demonstrate it implemented appropriate “quality control measures” and has lowered a substance to the “lowest level currently feasible,” the manufacturer should be exempt from the warning requirements regardless of whether OEHHA has established a different level for the listed substance in the specific commodity in the regulation.

Response: A variety of quality control measures such as storage and lower temperature cooking were provided in the ISOR for each category of foods identified in the proposed regulation.

OEHHA acknowledges the resources listed in the comment and notes that those resources, as well as additional resources, are also included in the ISOR. (ISOR pages 8 - 10). OEHHA also acknowledges that as science and the food industry change and make advancements, some practices will change, which may in turn require changes to the listed concentration levels and food in the regulation.

In response to this and other comments, in the second modification, OEHHA incorporated the Codex 2009 Code of Practice by reference. The Addendum to the ISOR explains on pages 5-6:

> 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 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).

Summary of and Response to Comments to the Second Modification of Proposed Regulation – October 2022

The following organizations submitted written comments on the second modification during the October 6, 2022, to October 22, 2022, comment period:

Almond Alliance of California (AlmondAC)

American Bakers Association (ABA)

Azteca Milling, L.P. (Azteca)

California Chamber of Commerce and Consumer Brands Association on behalf of 17 organizations (CalChamber/CB Coalition-2)[47]

Center for Environmental Health (CEH)

National Confectioners Association (NCA)

The comments are summarized and responded to below. As described above, changes have been made to the substance and numbering of the final proposed regulation. The

[47] Comment submitted on behalf of: Agricultural Council of California, Almond Alliance, American Bakers Association, American Chemistry Council, American Frozen Food Institute, Asian Food Trade Association, California Restaurant Association, California Manufacturers and Technology Association, California Attractions and Parks Association, CA Automatic Vendors Council, Can Manufacturers Institute, Frozen Potato Products Institute, National Confectioners Association, NAMA, Peanut and Tree Nut Processors Association, SNAC International, and The Food Industry Association.

comments and responses in this section refer to the modified regulation text from the second modification, and current numbering of Section 25506.

General Comments

Support for the Regulation

Comment 91 (ABA, CalChamber/CB Coalition-2, and NCA): The CalChamber/CB Coalition-2 stated their continued support for the adoption of the regulation. They also state that the proposal is "a workable regulation exempting exposures to listed chemicals arising from cooking or heat processing of foods that have been reduced to the lowest level feasible." The regulation provides businesses with a compliance roadmap and discourages private enforcers from filing lawsuits for unavoidable exposures. NCA supports the adoption of the regulation and agrees with the comments submitted by CalChamber (i.e., the CalChamber/CB Coalition). Despite requesting further modifications to the proposal (see comments 93 and 94), ABA states that the concentration levels in the proposed regulation are an important step forward to provide guidance to baking companies.

Response: OEHHA acknowledges the supporting comments.

No changes were made to the proposed regulation based on these comments.

Narrowed Scope of Regulation to Acrylamide

Comment 92 (AlmondAC, ABA, CalChamber/CB Coalition-2, and NCA): AlmondAC stated that their members "favor a broader approach to addressing all chemicals that are unavoidably created during the heating of foods." They stated that narrowing the scope of the proposal to specifically address acrylamide formation is an acceptable first step to addresses OAL's March 2022 decision to disapprove the earlier version of the proposed regulation. ABA stated, "Though this draft makes several improvements over prior versions, it also substantially reduces the utility of this exemption by limiting it to only one chemical—acrylamide—despite the fact that many Proposition 65 listed chemicals can be formed by cooking or heat processing." ABA commented that since acrylamide is created by the Maillard reaction, and the Maillard reaction can also result in the formation of furfuryl alcohol, furans, and 4-MEI (4-methylimidazole), the regulation "should expand the exemption to cover at least these three additional Proposition 65 constituents." Cal Chamber/CB Coalition expressed disappointment that OEHHA narrowed the scope of the proposed regulation to focus only on acrylamide. NCA urged expansion of subsection (a) to cover furfuryl alcohol. ABA suggests that the proposed

regulation creates a framework that could be applied to other Proposition 65 listed chemicals formed during cooking.

Response: OEHHA has determined that at this time the regulation should specifically address acrylamide exposures from food. The explanation for narrowing the regulation to acrylamide is provided in the Addendum to the ISOR on pages 5–6. This does not preclude OEHHA from proposing regulations in the future to include additional chemicals.

No changes were made to the proposed regulation based on these comments.

Subsection (a)

Codex 2009 Code of Practice

Comment 93 (ABA): ABA stated that "while referencing the Codex Standard can help bring clarity and certainty to businesses," complying with the Codex Standard is "infeasible" and "particularly challenging for smaller bakers." It explained that "many small bakers … do not have the resources nor the capability to use the methods recommended by Codex" and that "the standard unfairly discriminates against small businesses." ABA "encourages OEHHA to adopt a more flexible approach where businesses can comply with the 'lowest level currently feasible' through adopting Codex's recommendations, but alternatively can comply by adopting other reasonable and commercially appropriate methods."

Response: The commenter expresses concern about "small bakers" but does not define that term. Proposition 65 exempts businesses with fewer than 10 employees.[48] To the extent that the commenter considers "small bakers" to be those with fewer than 10 employees, Proposition 65's warning requirements would not apply to them.

To the extent the commenter considers "small bakers" to include those with ten or more employees, the commenter does not share the reasons it believes that they lack the resources and capability needed to comply with the Codex 2009 Code of Practice. Nor does the commenter discuss any shortcomings of any specific Codex 2009 Code of Practice approach. The omission of such information from the comment limits OEHHA's ability to respond.

Practices in the Codex 2009 Code of Practice can be used by both large and small bakers, and include adjusting temperature, cooking times, fermentation time, and

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

selection of the type of flour and other raw materials. The Codex practices are 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 commenter recommends that OEHHA broaden the regulation to allow businesses to choose between complying with the Codex 2009 Code of Practice and complying "by adopting other reasonable and commercially appropriate methods", without speaking to what those may be and how they are not included in Codex. An alternative formulated in this manner lacks specificity and clarity and OEHHA declines to adopt it.

Moreover, the proposed regulation provides additional flexibility. In subsection 25506(b), the regulation expressly supports the use other methods in Articles 7 and 8 to establish a warning is not required for an exposure to acrylamide in foods. A business may also establish a warning is not required where the acrylamide levels are less than the concentration levels set out in subsection (d), or where the business is party to an existing settlement per subsection (c).

No changes were made to the proposed regulation based on this comment.

Comment 94 (ABA): ABA commented that **"**OEHHA should similarly clarify that 'lowest level currently feasible' does not require the use of enzymes to reduce acrylamide formation. The Codex Standard mentions that addition of the enzyme asparaginase has been shown to reduce asparagine and thus acrylamide levels in potato products. ABA requests that OEHHA clarify that use of such enzymes is not required given the significant variability that enzymes can introduce and the challenges they present for organic, gluten free, and flavored products."

Response: The Codex 2009 Code of Practice does not require the use of the enzyme asparaginase. Codex 2009 Code of Practice recognizes that the enzyme asparaginase may assist in reducing acrylamide levels. The Codex 2009 Code of Practice recognizes numerous other methods that may also assist in reducing acrylamide levels that do not include adding the enzyme asparaginase.

The regulation does not require the use of any specific practice described in the Codex 2009 Code of Practice, including the use of enzymes to reduce acrylamide formation. The Codex 2009 Code of Practice guidance is referenced to identify specific approaches businesses may use to reduce acrylamide concentrations in their products and thereby establish the safe harbor defense. Also, as noted in the Response to Comment 93 above, there are other alternative provisions of the regulations that can be also used as a defense to an enforcement action.

No changes were made to the proposed regulation based on this comment.

Comment 95 (CEH): CEH commented that the inclusion of the Codex "is vague because 'applicable practices' within the entirety of this document provides insufficient guidance as to whether any given manufacturer has taken the requisite steps to avail itself of the regulation." Further, the commenter asked, "How does one know which 'practices' in the 'Codex' are even 'applicable' to any given food product?"

Response: The burden of establishing the defense provided by the regulation is on the business asserting it. If the business uses subsection (a) as a defense, the burden is on the business to demonstrate that it applied the guidance in the Codex 2009 Code of Practice to reduce the levels of acrylamide in its products to the lowest level currently feasible for that business. This would include identifying the methods used and why they are applicable to the product at issue.

No changes were made to the proposed regulation based on this comment.

Comment 96 (CEH): CEH commented that the Codex 2009 Code of Practice appears to incorporate considerations into its acrylamide reduction recommendations that are not permissible under Proposition 65. The commenter explains that the Codex provides that "[m]easures aimed at reducing levels of acrylamide cannot be taken in isolation from other considerations," and then gives as an example that "[p]recautions should be taken to avoid detrimental changes to the organoleptic properties of the final product." The commenter states, "For 'junk food' products such as deep-fried potato chips, this would appear to allow a food manufacturer to claim that 'feasibility' constraints preclude further reductions simply because its chips (which no one believes are healthy to consume) would be marginally less tasty or aesthetically appealing as a result."

CEH reiterates the comment from October 2020, that this approach is inconsistent with the existing Alternative Significant Risk Level ("ASRL") regulation at 27 Cal. Code Regs. § 25703(b)(1), which requires an independent finding that "sound considerations of public health" support the alternate level. OEHHA should thus (1) place the onus on the defendant to prove the elements of any new defense, (2) tie the existence of any such defense to sound considerations of public health, and (3) limit the defense to "necessary" cooking (as the ASRL regulation does).

Response: The commenter indicates that the approach is inconsistent with Section 25703(b), which provides in relevant part:

> (b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one

excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level, as, for example:

(1) where chemicals in food are produced by cooking *necessary to render the food palatable* or to avoid microbiological contamination. . ..

(Emphasis added.)

Where the Codex 2009 Code of Practice recognizes precautions should be taken to avoid detrimental changes to the organoleptic properties of the final product, Section 25703(b)(1) takes into account palatability as a consideration regarding an alternative risk level. Both recognize the importance of palatability in food, while at the same time the importance of reducing risk.

OEHHA acknowledges the difference between “cooking to render food palatable” and avoiding “detrimental changes to the organoleptic properties of the final product”. Nonetheless, while subsection (a) of the proposed regulation provides an affirmative defense a business can use in an enforcement action, the burden of proof lies with the business relying on the defense.

Furthermore, as pointed out in Response to Comment 29 on the original proposal, subsection (b) harmonizes this regulation with Articles 7 and 8, including the alternative risk level provisions of 25703(b). This defense is available to businesses in addition to or instead of the defenses outlined in subsection (a) that incorporates the 2009 Codex Code of Practice by reference. See Response to Comment 29 for a response to the original comment.

No changes were made to the proposed regulation based on this comment.

Comment 97 (CEH): The commenter stated that a document from 2009 cannot reflect current practices and technologies. The commenter suggests that if the Codex 2009 Code of Practice is used, the regulation should clarify that any further recommendations set forth in later editions to that document should be implemented.

Response: The Codex 2009 Code of Practice is a practical approach to reducing acrylamide formation in foods utilizing an internationally accepted standard of practice; it operates under the aegis of the United Nations and the Code of Practice is published by the Food and Agriculture Organization of the United Nations. The Codex Alimentarius Commission revises the standards as necessary to “ensure that they are consistent with

and reflect current scientific knowledge and other relevant information."[49] OEHHA does not expect the Codex Alimentarius Commission to revise the Codex 2009 Code of Practice often. New techniques and technological advancements that could assist a business to reduce acrylamide in its food product are likely to fall within the 2009 Code of Practice. If and when the Codex Alimentarius Commission revises the Codex 2009 Code of Practice or a relevant new technique or technology becomes generally available, OEHHA will consider revisiting the regulation.

No changes were made to the proposed regulation based on this comment.

Lowest Level Currently Feasible

Comment 98 (ABA): ABA asked that OEHHA amend its proposal to acknowledge that "lowest level currently feasible" reflects the reductions in acrylamide that are feasible given supply chain challenges. Supply chain issues that started during the Covid-19 pandemic will likely continue, and "and other seasonal complications can present continued difficulties." ABA explained that substitutions may impact acrylamide content in a way that is difficult for bakers to predict based on existing manufacturing processes and formulations. The commenter suggested that OEHHA modify its proposal to make clear that "lowest level currently feasible" is "sufficiently flexible to account for supply chain challenges and accompanying ingredient modifications, so long as all other commercially feasible methods of acrylamide reduction are otherwise applied."

Response: Pursuant to subsection (a), businesses can show they have reduced the level of acrylamide in their products to the lowest level currently feasible by utilizing the practices outlined in the Codex 2009 Code of Practice, such as modifying raw ingredients. A business that does not have access to a material because of significant supply shortages may not feasibly be able to utilize a particular method in the Codex 2009 Code of Practice but can utilize other practices in the Codex 2009 Code of Practice for reducing acrylamide. The burden of proof lies with the business relying on the defense. Additionally, see Response to Comment 93 for a discussion regarding regulatory flexibility.

No changes were made to the proposed regulation based on this comment.

Subsection (c)

[49] The Codex Alimentarius Commission (2022). "About Codex Alimentarius: General Principles of the Codex Alimentarius: Revision of Codex Standards." Webpage content current as of 10/27/2022. Available from: https://www.fao.org/fao-who-codexalimentarius/about-codex/en/.

Comment 99 (CalChamber/CB Coalition-2): The commenters stated that subsection (c) could be read to automatically modify some consent judgments and to preclude a court from modifying its prior consent judgment to conform to the levels set forth in subsection (d). The commenter proposed revised text as follows:

> "(c) Nothing in this section shall ~~apply to parties to~~ modify the terms of 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 acrylamide in a specific product that is covered in the settlement or judgment, ~~that is different from the concentrations provided in subsection(d)~~ but nothing in this section shall preclude a court from modifying its prior order or judgment."

Response: The proposed regulation expressly does not apply to parties to an existing settlement, and thus does not modify an existing settlement or judgment entered prior to the effective date of the proposed regulation. It also expressly does not limit a court's authority to modify those settlements or judgments if it chooses to do so. The suggested modifications to the proposed regulation would not add clarity to that provision, and they would eliminate an important element of the regulation – that it applies prospectively to limit the parties' ability to set reformulation levels that exceed those that have been determined to be feasible under the proposed regulation. Therefore, OEHHA declines to make the suggested changes.

No changes were made to the proposed regulation based on these comments.

Subsection (d)

Comment 100 (ABA): ABA comments that they interpret subsection (d) to mean that manufacturers are responsible only for acrylamide levels in their products that exceed the safe harbor levels without further discretionary cooking or heat processing by the consumer. ABA requests OEHHA to confirm that "the safe harbor levels for acrylamide in soft breads are to be applied as those products are packaged and sold." ABA "asks that OEHHA clarify that any subsequent discretionary cooking or heat processing that may raise these products' acrylamide levels, including subsequent toasting, grilling or frying by consumers or others further preparing or processing the finished products, is not the responsibility of the product's manufacturer."

Response: A manufacturer can be responsible for the acrylamide created in a product that is prepared by a consumer according to the package directions, but a manufacturer is not responsible for other actions taken by a consumer that are not consistent with or

specified by the package directions. The commenter describes those subsequent actions correctly as “discretionary” on the part of the consumer. For example, if a consumer purchases soft bread, goes home, and heavily toasts the bread, the manufacturer is not responsible for the acrylamide content in the finished toast. A manufacturer also would not be responsible for the additional acrylamide that may be created where the consumer fails to follow the package directions.

No changes were made to the proposed regulation based on this comment.

Subsection (d)(1)

Comment 101 (ABA): The commenter explained: “OEHHA’s proposed rule imposes maximum unit concentrations for savory crackers, potato or sweet potato products, and certain cookie categories, in addition to maximum average concentrations. The industry standard practice is to use composite sampling over multiple batches or production runs. Indeed, this is the sampling method FDA uses to determine compliance with its nutrition regulations. Requiring manufacturers to meet specified limits for a single unit pulled from a single batch compounds the variability inherent in the manufacturing process and heightens the risk that a single unit fails to meet the threshold. It is not a science-based approach to find that a company is out of compliance based on an outlier.”

Response: The commenter discusses the concept of composite sampling only in the context of determining maximum average concentrations, without acknowledging that composite sampling is also to be employed in determining maximum unit concentrations, as has been done in the proposed regulation in subsection (d)(1). Specifically, Section 25506(d)(1) states that “the unit concentration is based on a *representative composite sample taken* from the individual packaged unit” (emphasis added).

The proposed regulation adopts maximum average concentrations for all the foods/food groups specified in subsection (d)(4) and only adopts a maximum unit level where it has been used in a settlement specific to that food. The commenter does not provide supporting documentation for the concept that the “industry” does not utilize single-unit maximum safe harbor levels.

Several of the settlements that OEHHA consulted set a maximum unit concentration for covered products, and OEHHA has included those maximum unit concentrations in the relevant food categories (cookies, animal and animal crackers (sweet); cookies, thin and crispy; crackers, specifically savory crackers, including crispbread; and potato or

sweet potato products).[50] For example, as stated in the discussion about crackers in the ISOR on page 22, "The *CEH v. FoodShouldTasteGood, Inc., et al.* settlement states the following regarding determination of the average level and the unit level: …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."

No changes were made to the proposed regulation based on this comment.

Subsection (d)(2)

Comment 102 (CalChamber/CB Coalition-2): The commenters suggested changes to subsection (d)(2) of the proposed regulation, which currently provides that "[t]he 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."

The commenters stated that many foods are not produced on a regular basis, including foods that are produced in infrequent batches, foods that are seasonal, and foods that are produced during a short period of time based on freshly harvested produce or limited shelf-life. The commenters stated that it is not clear how the "no less than 10-day intervals" element or the 60-day duration element of subsection (d)(2) could be applied to these foods. The commenters recommend that OEHHA revise subsection (d)(2) to account for these situations, as follows. (The commenters' proposed additional language is shown in underline and their proposed deletion of existing language is shown in ~~strikeout~~.)

> "In this subsection, 'average concentration' refers to the average of unit concentrations measured. The average concentration is determined by adding together the unit concentrations from 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.~~ and then dividing this by the total number of samples. The samples will be randomly selected from as many different lots (as that term is defined in 21 Code of Federal Regulations section 101.9(g)(1)) as possible that span production dates of at least 60 days or the entire production period if it is shorter than 60 days."

[50] See Section 25506.

The commenters suggested that introducing the term “lot” as defined in 21 CFR section 101.9(g)(1) would provide clarity for those food manufacturers who are familiar with this term. The commenters state the suggested changes would require samples to be taken over a period of at least 60 days for those products with production periods of 60 days or longer, while at the same time allowing sampling to span the entire production period for the product if it is shorter than 60 days.

The commenters stated that their proposal is consistent with OEHHA’s intent in proposing subsection (d)(2), and their suggested changes would ensure that in the limited circumstances they describe, samples would still be randomly selected and taken over a sufficient period to account for variability in ingredients and cooking conditions so that the level of acrylamide in the food product is accurately measured.

Response: The commenters suggest changes to the testing frequency for establishing a product’s acrylamide concentration is less than the level adopted in subsection (d)(4) for cases when foods are not produced on a regular basis and introduce an additional element of random selection from as many different lots as possible. The proposed regulation includes a definition of “average concentration” that includes sampling over “no less than 60 days with no less than 10-day intervals between sampling.” See Addendum to the ISOR page 9.

OEHHA declines to make the requested change for a number of reasons. First, introducing the notion of random selection from as many different lots as possible introduces lack of specificity to the regulation and leaves the number of samples to be taken indeterminate. Second, the proposal introduces the term “lot”. In a pre-regulatory effort in 2015 to modify Section 25821, challenges were raised to the use of the term. Finally, for the hypothetical described in the comment, the responsible business has options. For example, it can provide a strong defense under subsection (a) if it has sampled over a shorter period but because of infeasibility given a shorter production period is unable to make the 60-day requirement. It would establish this defense using the presumed feasible levels adopted in subsection (d)(4). Thus, in the hypothetical described by the commenters, the business could still establish that the concentration of acrylamide in its products has been reduced to the lowest level currently feasible by utilizing applicable practices recommended in Codex 2009 Code of Practice. Alternatively, the business could rely on subsection (b). See Response to Comments 11, 26, 35 and 65 above.

Since businesses described in the commenters’ hypothetical have other options for establishing a defense under Section 25506, and because the proposal introduces

ambiguity with the indeterminate sampling and challenges with the use of the term “lot”, OEHHA declines to further modify subsection (d)(1).

No changes to the proposed regulation were made based on these comments.

Outside of the Scope of the Proposed Modifications

Levels in Section (d)(4)

Comment 103 (AlmondAC): The Almond Alliance reiterates their prior comments that the level of 225 ppb set for almonds “were product - and manufacturer-specific, and are not feasible across all manufacturers, products, and commodities in all situations.”

Response: This comment is outside the scope of the second modification to the regulation, which did not change the level of acrylamide for almonds. This comment was raised earlier in the rulemaking process and was responded to in Responses to Comments 28, 56, 57, and 88.

No changes were made to the proposed regulation based on this comment.

Comment 104 (AlmondAC): The commenter acknowledged that OEHHA removed almond butter from subsection (d)(4).

Response: OEHHA acknowledges the comment. No further response is required.

No changes were made to the proposed regulation based on this comment.

Comment 105 (AlmondAC): The commenter requested an opportunity to engage with OEHHA to provide data on almond consumption levels in the US.

Response: This comment is outside of the scope of the current rulemaking. OEHHA is open to discussions with any party that would like to discuss Proposition 65 warning requirements as applied to specific consumer products.

No changes were made to the proposed regulation based on this comment.

Comment 106 (ABA): ABA requested that OEHHA’s proposed maximum average concentration of 50 ppb safe harbor level for wheat-based bread should be revised to 100 ppb and that the level should be the same for wheat-based and non-wheat based breads.

Response: This comment is outside the scope of the second modification. The comment was also raised earlier in the rulemaking process. See Responses to Comment 61.

No changes were made to the proposed regulation based on this comment.

Comment 107 (ABA): ABA recommended that OEHHA clarify the product categories for baked goods— particularly the cookie categories. ABA requested clarification of how a "classic chocolate chip cookie (81-168 ppb, according to March 2004 FDA data) or a sugar cookie (29-70 ppb, according to March 2004 FDA data) would be classified under the proposed subsection (d)(4)." ABA requested, in line with the OAL disapproval decision, more specific details and differentiation in the cookie categories.

Response: The proposed regulation did not change the categories of cookies, but it reformatted the table to add clarity. The proposed levels do not cover all types of cookies. See further discussion in the Addendum to the ISOR page 14 and in the ISOR on pages 19-21. In regard to ABA's specific questions, if the chocolate chip cookie is thin and crispy, then it would fall into the thin and crispy category, but if it is thick or soft, it would not fall within this category. The settlements relied on to establish the safe harbor levels include very specific product descriptions the commenter can consider in evaluating whether their product falls into a particular category. See also Response to Comment 63.

No changes were made to the proposed regulation based on this comment.

Foods Not in Subsection (d)(4)

Comment 108 (ABA, and NCA): NCA urged expansion of the 225 ppb for acrylamide in chocolate-covered roasted almonds to apply to other chocolate-covered nuts, and other non-chocolate confections, including toffee and caramels, which are heat processed or which contain heat processed inclusions such as nuts, wafers, dried fruits, or toasted rice. ABA also requested that OEHHA expand its chocolate-covered almonds category to include other chocolate-covered foods based on consent judgments recently approved by the Alameda County Superior Court that extend the 225 ppb maximum average acrylamide level beyond chocolate-covered roasted almonds to chocolate products containing other cooked or heat-processed foods, such as tree nuts, raisins, wafers, caramel, toffee, and toasted rice.

Response: This comment is outside the scope of the second proposed modification. OEHHA will consider adding food groups and levels in future rulemakings.

No changes were made to the proposed regulation based on these comments.

Comment 109 (ABA): ABA also requested that OEHHA include a concentration level for fried sweet goods such as donuts or hand pies. ABA recommended that OEHHA adopt the 100 ppb level for breads as the safe harbor level for all fried sweet goods.

Response: This comment is outside of the scope of the second proposed modification. OEHHA will consider adding food groups and levels in future rulemakings.

No changes were made to the proposed regulation based on this comment.

Comment 110 (Azteca): Azteca Milling stated the food industry would benefit from the inclusion of a specific category for Tortilla Fried and Baked Products in the Foods/Food Group of the proposed regulations, with a Maximum Average Concentration of 281 ppb and a Maximum Unit Concentration of 300 ppb.

Response: This comment is outside of the scope of the second proposed modification. OEHHA will consider adding food groups and levels in future regulatory actions.

No changes were made to the proposed regulation based on this comment.

Comment 111 (Azteca): Azteca Milling seeks confirmation that tortilla-related fried and baked products (tortilla chips, tostadas, and taco shells) would be covered by the Cookie, Thin and Crispy category of the Foods/Food Group table located at Section 25506(d)(4).

Response: Tortilla chips, tostadas, and taco shells are not covered by the Cookie, Thin and Crispy category, and are not covered in subsection (d)(4). See ISOR pages 19-21 and Addendum to the ISOR pages 14 and 15.

OEHHA will consider adding food groups and levels in future rulemakings.

No changes were made to the proposed regulation based on this comment.

Expand to Other Chemicals

Comment 112 (ABA): ABA encouraged OEHHA to use this framework to issue similar rulemakings for furfuryl alcohol, furans, 4-MEI and other listed chemicals that may be formed through cooking or heat processing.

Response: This suggestion is outside the scope of changes in the second modification, but OEHHA acknowledges the commenter's suggestions and can consider additional future rulemakings to address other chemicals formed in cooking.

No changes were made to the proposed regulation based on these comments.

Miscellaneous

Comment 113 (CEH): CEH commented that, “OEHHA’s proposal continues to impermissibly link together two unrelated issues: an exposure to a listed chemical and a company’s ability to reduce that exposure.” Consumers in California need to know whether the food they choose will expose them to listed chemicals regardless of whether a business has taken steps to reduce the presence of the chemical.

Response: This comment is outside the scope of the proposed second modification to the regulation. The general concept of the consumer’s right to know is addressed above. See Response to Comments 4 and 86. The commenter made a similar comment earlier in the rulemaking process. See Response to Comment 8.

No changes were made to the proposed regulation based on this comment.

Comment 114 (CEH): CEH suggested that OEHHA address enforcement activities more directly by, for example, banning out-of-court settlements and bolstering mechanisms to ensure Proposition 65 plaintiffs and their attorneys are acting in the public interest.

Response: This suggestion is outside the scope of the proposed second modification. In addition, OEHHA does not enforce Proposition 65 and does not have the authority to ban out-of-court settlements.

No changes were made to the proposed regulation based on this comment.

Local Mandate Determination

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

Alternatives Determination

In accordance with Government Code section 11346.9(a)(4), OEHHA has considered available alternatives, including those suggested by public commenters,[51] to determine whether any alternative would be more effective in carrying out the purpose of the regulations. OEHHA has determined that no alternative it considered or that was otherwise identified and brought to its attention would be more effective in carrying out the purpose of the proposed regulation, would be as effective and less burdensome to affected private persons than the proposed regulation, nor would be both more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. OEHHA considered taking no action but finds that taking no action is inconsistent with the intent of the Act and its implementing regulations.

Alternatives that Would Lessen the Adverse Economic Impact on Small Business Determination

There were no alternatives proposed that would lessen any adverse economic impact on small businesses as defined in Government Code Section 11342.610 that were rejected by OEHHA.

The proposed regulatory amendments do not affect small businesses as defined in Government Code Section 11342.610. Proposition 65, by its terms, does not apply to small businesses with less than 10 employees. Further, this regulatory action does not require any business to meet any specific concentration level or adopt specific practices Instead, the proposed regulation provides non-mandatory, safe harbor levels for exposures to acrylamide.

Non-duplication Statement

Proposition 65 is a California law that has no federal or state counterpart. OEHHA has determined that the regulation does not duplicate and will not conflict with federal law or regulations. OEHHA has further determined that the regulation does not serve the same purpose as a state or federal statute or another regulation.

[51] Specific responses to proposed alternatives are provided in the summary/response sections of this FSOR.