



OEHHA Proposes New Safe Harbor Levels for Acrylamide in Prepared Foods

OEHHA, CHEMICALS OF INTEREST, PROPOSITION 65

By ROGER PEARSON, LANA BECKETT, August 21, 2020

The Office of Environmental Health Hazard Assessment (OEHHA) is **proposing new safe harbor levels for acrylamide**¹⁾ for several prepared foodstuffs under Proposition 65. Manufacturers of the covered foods who demonstrate their products are below the limits will be able to sell them in California without a Product 65 cancer warning.

The OEHHA proposal is a response to increasing private party enforcement actions alleging failure to warn of acrylamide in various manufactured food products. There have been over 800 60-day notices filed concerning the chemical in food products with 702 filed since 2017.

OEHHA is proposing to adopt a new section to its Prop. 65 implementation regulations [**Title 27 California Code of Regulations, Section 25505**²⁾]. That section first provides that a warning is not required if the manufacturer, distributor, other purveyor of a covered product has first reduced acrylamide levels in the product to the "lowest level currently feasible" utilizing "quality control measures" [subsection (a)]. It then establishes acrylamide concentration levels for classes of common food products. If the manufacturer (or other purveyor) can show that a representative sample of its product meets the acrylamide concentration level for its class, the manufacturer will be deemed to meet the feasibility standard [subsection (d)]. OEHHA used the settlement in **CEH v. FoodShouldTasteGood**³⁾ as an example of how the parties defined "unit level" as the representative composite sample taken from the individual unit being tested.

The proposed regulation also makes clear that if a purveyor elects not to meet the proposed concentration level for its class it can establish its own alternate level using the standards set forth in the regulations [subsection (b)]. Finally, the regulation provides that it does not apply to parties subject to a concentration standard established pursuant to a court-ordered settlement or judgment [subsection (c)].

Required Concentration Levels

For each food group listed the regulation provides a "maximum concentration level" in parts-per-billion. These concentration levels were based on settlements in Prop. 65 cases. The product in question must meet this level using a representative sample of the product. In addition products in some categories must also meet a "maximum unit concentration level" where the product is packaged into individual units. The listed concentration levels for classes are as follows:

- Almonds, roasted, roasted almond butter, and chocolate-covered almonds—225 maximum concentration level; no unit level. OEHHA based these levels on court case settlements:

- **Embry v. Frito-Lay⁴⁾**

- **Embry v. Hayden Valley Foods⁵⁾**

Bread, nonwheat-based products including loaves, rolls, buns, baguettes—100 maximum concentration level; no unit level. OEHHA base these levels on 2017 European Union regulations setting benchmark levels. Bread, wheat-based products including loaves, buns, and baguettes—50 maximum concentration level; no unit level. OEHHA base these levels on 2017 European Union regulations setting benchmark levels. Cookies, animal and animal crackers (sweet)—75 maximum concentration level; 100 unit level. OEHHA base these levels on the following court case settlements:

- **CEH v. Fantasy Cookie, Bay Valley Foods settlement⁶⁾**

- **CEH v. Fantasy Cookie, Pure's Food Specialties settlement⁷⁾**

- **CEH v. Fantasy Cookie, Panos Brands settlement⁸⁾**

- **CEH v. Fantasy Cookie⁹⁾**

- **CEH v. Biscomerica, Pagasa settlement¹⁰⁾**

- **CEH v. Biscomerica¹¹⁾**

Cookies, thin and crispy—281 maximum concentration level; 300 unit level. OEHHA base these levels on a number of court settlements. Below is an example of three:

- **CEH v. Enjoy Life Natural Brands, Kellogg and Murray Biscuit settlement¹²⁾**

- **Embry v. Mondelez Global¹³⁾**

- **CEH v. Enjoy Life Natural Brands, LLC¹⁴⁾** , Mary's Gone Crackers settlement

Cookies, sandwich wafers—115 maximum concentration level; no unit level. OEHHA base these levels on two court settlements. Below is one of the cases:

- **Embry v. Colombina USA¹⁵⁾**

Crackers, savory, including crispbread,—350 maximum concentration level; 490 unit level. OEHHA base these levels on two court settlements. Below is one of the cases:

- **Van Patten v. Dare Foods Inc.¹⁶⁾**

Potato products, French fried potatoes—280 maximum concentration level; 400 unit level. OEHHA base these levels on three court settlements:

- **CEH v. Lamb Weston Holdings¹⁷⁾**

- **CEH v. Lamb Weston Holdings¹⁸⁾** , J.R. Simplot settlement

- **CEH v. Snikiddy, Inventure Foods settlement¹⁹⁾**

- Potato or sweet potato products, not otherwise specified, such as hash browns and potato puffs—350 maximum concentration level; 490 unit level. OEHHA base these levels on 20 court approved settlements. Below are four of the settlements:

- **CEH v. FoodShouldTasteGood²⁰⁾** , Live Better Brands settlement

- **CEH v. FoodShouldTasteGood²¹⁾** , FGF Brands settlement

- **CEH v. Snack Innovations, Warnock Food Products settlement²²⁾**

- **CEH v. Think Food Group, Nugget settlement²³⁾**

Potato or sweet potato products, sliced chips—281 maximum concentration level; 350 unit level. OEHHA base these levels on 10 court settlements. Below are three of the settlements:

- **CEH v. Snikiddy, Dieffenbach's Potato Chips settlement²⁴⁾**

- **CEH v. Think Food Group, Nugget settlement²⁶⁾ 25)**

- **CEH v. Snack Innovations, Warnock Food Products settlement²⁸⁾ 27)**

Prune juice, 100 percent Prune juice (not from concentrate)—no maximum concentration level; 250 unit level. OEHHA base these levels on three court approved settlements.

Prune juice, made with concentrate—no maximum concentration level; 150 unit level.

OEHHA base these levels on three court settlements:

- **CEH v. Mrs. Gooch's Natural Food Markets, Cliffstar settlement²⁹⁾**

- **CEH v. Mrs. Gooch's Natural Food Markets, Lassonde Pappas and Company settlement³⁰⁾**

- **CEH v. Mrs. Gooch's Natural Food Markets, Smucker Natural Foods settlement³¹⁾**

Waffles—280 maximum concentration level; no unit level. OEHHA base these levels on one court approved settlement:

- **Embry v. Sprouts Farmers Market Inc.³²⁾**

Basis for the Proposal

Acrylamide in these products and other food products (e.g. brewed coffee) is created during the cooking process through a reaction known as the Maillard reaction (named for its discoverer). Thus,

OEHHA deems the existence of acrylamide in cooked products to be unintentionally added and not within the normal purview of Proposition 65, which attempts to discourage chemicals that are deliberately added by human activity. OEHHA analogizes acrylamide in cooked foods to the agency's exemption for "naturally occurring" chemicals. That exemption is qualified by the requirement that anyone claiming it reduce the exempt chemical's presence to the extent feasible through best manufacturing processes and other actions.

Using the naturally occurring model the proposed regulation applies only if the manufacturer reduces the acrylamide level in its product to the extent feasible utilizing good quality control practices. These practices are not further prescribed in the regulation. So long as the finished product meets the acrylamide content levels specified its manufacturer can take advantage of the regulation. However, in its Initial Statement of Reasons supporting its proposal, OEHHA notes that such best practices include:

- Agricultural practices, such as the type and timing of fertilizer use;
- Selection, storage conditions, and handling of ingredients, such as management of storage temperatures after harvest;
- Cooking duration and temperature.

The Initial Statement describes the agency's basis for selecting the limits specified for each class of foods. For the most part these are based on limits required under consent decrees or other judicially approval of settlements. The agency reasons that those limits have been agreed to by at least one manufacturer of the class of products as feasibly achievable.

The regulation does not specify the methodology for measuring the limits (sample size, sampling procedures, etc.). So long as the manufacturer uses valid methodology then it does matter how it meets the limits. However, the Initial Statement describes the methodology that was agreed upon in each of the settlements on which the limits are based; if the settlement prescribed such procedures.

Comments

Comments on the proposal may be submitted in writing or electronically through Tuesday, October 6.

Resources for this article

1. proposing new safe harbor levels for acrylamide

<https://oehha.ca.gov/proposition-65/crn/notice-proposed-rulemaking-adoption-section-25505-exposures-listed-chemicals>

2. Title 27 California Code of Regulations, Section 25505

<https://prop65clearinghouse.com/documents/63988>

3. CEH v. FoodShouldTasteGood

<https://prop65clearinghouse.com/cases/3890>

4. Embry v. Frito-Lay

<https://prop65clearinghouse.com/cases/5653>

5. Embry v. Hayden Valley Foods

<https://prop65clearinghouse.com/cases/6406>

6. CEH v. Fantasy Cookie, Bay Valley Foods settlement

<https://prop65clearinghouse.com/documents/63989>

7. CEH v. Fantasy Cookie, Pure's Food Specialties settlement

<https://prop65clearinghouse.com/documents/63990>

8. CEH v. Fantasy Cookie, Panos Brands settlement

<https://prop65clearinghouse.com/documents/63991>

9. CEH v. Fantasy Cookie

<https://prop65clearinghouse.com/documents/63992>

10. CEH v. Biscomerica, Pagasa settlement

<https://prop65clearinghouse.com/documents/63993>

11. CEH v. Biscomerica

<https://prop65clearinghouse.com/documents/63994>

12. CEH v. Enjoy Life Natural Brands, Kellogg and Murray Biscuit settlement

<https://prop65clearinghouse.com/documents/63995>

13. Embry v. Mondelez Global

<https://prop65clearinghouse.com/documents/63996>

14. CEH v. Enjoy Life Natural Brands, LLC

<https://prop65clearinghouse.com/cases/4521>

15. Embry v. Colombina USA

<https://prop65clearinghouse.com/documents/63997>

16. Van Patten v. Dare Foods Inc.

<https://prop65clearinghouse.com/cases/6044>

17. CEH v. Lamb Weston Holdings

<https://prop65clearinghouse.com/documents/63998>

18. CEH v. Lamb Weston Holdings, J.R. Simplot settlement

<https://prop65clearinghouse.com/documents/63999>

19. CEH v. Snikiddy, Inventure Foods settlement

<https://prop65clearinghouse.com/documents/64000>

20. CEH v. FoodShouldTasteGood, Live Better Brands settlement

<https://prop65clearinghouse.com/documents/64001>

21. CEH v. FoodShouldTasteGood, FGF Brands settlement

<https://prop65clearinghouse.com/documents/64002>

22. CEH v. Snack Innovations, Warnock Food Products settlement

<https://prop65clearinghouse.com/documents/64003>

23. CEH v. Think Food Group, Nugget settlement

<https://prop65clearinghouse.com/documents/64004>

24. CEH v. Snikiddy, Dieffenbach's Potato Chips settlement

<https://prop65clearinghouse.com/documents/64005>

25. CEH v. Think Food Group, Nugget settlement

<https://prop65clearinghouse.com/documents/64004>

26. CEH v. Snack Innovations, Warnock Food Products settlement

<https://prop65clearinghouse.com/documents/64003>

27. CEH v. Mrs. Gooch's Natural Food Markets, Cliffstar settlement

<https://prop65clearinghouse.com/documents/64006>

28. CEH v. Mrs. Gooch's Natural Food Markets, Lassonde Pappas and Company settlement

<https://prop65clearinghouse.com/documents/64007>

29. CEH v. Mrs. Gooch's Natural Food Markets, Smucker Natural Foods settlement

<https://prop65clearinghouse.com/documents/64008>

30. Embry v. Sprouts Farmers Market Inc.

<https://prop65clearinghouse.com/cases/6335>