FROZEN POTATO PRODUCTS INSTITUTE

October 21, 2020

Submitted Electronically

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Re.: Proposition 65 - Section 25505 Exposures to Listed Chemicals in Cooked or Heat Processed Foods

Dear Ms. Vela:

The Frozen Potato Products Institute (FPPI) is pleased to submit these comments to the California's Environmental Protection Agency Office of Environmental Health and Hazard Assessment (OEHHA) regarding its Notice of Proposed Rulemaking Adoption to Section 25505 Exposures to Listed Chemicals in Cooked or Heat Processed Foods pursuant to the Safe Drinking Water and Toxic Enforcement Act ("Proposition 65"). 1/ FPPI is the national trade association representing the producers and processors of frozen potato products, committed to representing their specific interests. The frozen potato products industry is committed to producing safe, wholesome, and nutritious products that consumers enjoy. Since acrylamide was discovered in foods about a decade ago, FPPI has made significant strides in better understanding acrylamide formation, developing effective acrylamide mitigation strategies, and educating Member Companies as well as end-users—both customers and consumers—about meaningful and practical acrylamide reduction strategies.

On August 4, 2020, OEHHA proposed to adopt a new regulation that would provide that intake of chemicals formed during cooking and heat processing of foods does not represent an exposure for the purposes of Proposition 65 if the concentrations are reduced to the lowest level currently feasible using appropriate quality control measures. In OEHHA's "Initial Statement of Reasons (ISOR)," the agency noted that the current proliferation of enforcement actions related to listed chemicals formed in food could result in businesses putting warnings on foods that do not require them, which is contrary to the statutory purpose of enabling consumers to make informed choices. The agency further stated the proposal was intended to (1)

1/ OEHHA, "Notice Of Proposed Rulemaking Adoption to Section 25505 Exposures to Listed Chemicals in Cooked or Heat Processed Foods," (Aug 4, 2020), *available at*: https://oehha.ca.gov/proposition-65/crnr/notice-proposed-rulemaking-adoption-section-25505-exposures-listed-chemicals?utm_source=Cooking+Chemical&utm_campaign=Proposition+65+-+Proposed+Maximum+Allowable+Dose+Levels+for+Chlorpyrifos&utm_medium=email (accessed on Sep 7, 2020).

reduce exposures to listed chemicals present in food due to the human activities of cooking or heat processing, (2) provide warnings for avoidable exposures to acrylamide, and (3) safeguard the effectiveness of those warnings. 2/ The proposal would establish maximum concentration levels for acrylamide in specific foods that are deemed by OEHHA to be the lowest levels currently feasible. Concentrations of the chemical at or below the level identified for the specified products would not require a warning.

FPPI supports OEHHA's efforts in addressing the unneeded, yet ubiquitous product warnings for low levels of acrylamide in food in California. Acrylamide is a substance that forms through a natural chemical reaction between sugars and asparagine, an amino acid, in plant-based foods. FDA monitors contaminant levels in foods, including acrylamide, and takes the position that consumers should not stop eating foods that are fried, roasted, or baked because of acrylamide. 3/ The consumers are recommended by the federal agency to adopt a healthy eating plan, consistent with the Dietary Guidelines for Americans (2015-2020), that emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products. As such, ubiquitous product warnings under Proposition 65 for acrylamide in plant-based foods also have the potential to lead to health detriments.

While FPPI applauds OEHHA's efforts in addressing the challenges the food industry is facing under Proposition 65, there are a number of issues with the proposal that we believe are contrary to the stated objectives, and we hope OEHHA can take into consideration in the final regulation. Specifically, we would like to ask the agency to explicitly acknowledge that the European Union (EU) acrylamide toolbox and FDA acrylamide guidance are appropriate examples of "quality control measures" under Subsection (a). To the extent a food manufacturer or producer can demonstrate it has implemented these "quality control measures," the acrylamide levels in the food products should be considered "lowest level currently feasible" and exempt from the warning requirements. We also do not view the so-called "reformulation levels" for acrylamide provided in legal settlements as equivalent to the "lowest levels currently feasible." These "reformulation levels" were negotiated between plaintiff's attorneys and individual companies and are not representative of the acrylamide levels found across the industry. Moreover, given the large variabilities in acrylamide levels among individual products, the use of "maximum unit concentration" levels will likely exacerbate, instead of reduce, the challenges the food industry is facing for the compliance of Proposition 65, and may further dilute the effectiveness of these warnings. We also recommend OEHHA specify the appropriate test method for acrylamide testing and the sampling plan in the final regulation for consistency.

Some aspects of the proposal also present unique challenges for FPPI members. Unlike any of the other foods identified in the proposal, acrylamide is mainly formed

2/ OEHHA, "Initial Statement of Reasons - Proposed Adoption Section 25505: Exposures to Listed Chemicals in Cooked or Heat Processed Foods," (Aug 7, 2020), *available at*: https://oehha.ca.gov/media/downloads/crnr/isor080720.pdf (accessed on Sep 7, 2020).

3/ FDA, "Acrylamide Questions and Answers," *available at*: https://www.fda.gov/food/chemicals/acrylamide-questions-and-answers (accessed on Sep 10, 2020).

during the final cooking step of frozen potato products (e.g., French fries), which predominantly happens at homes of the consumers. As such, manufacturers and producers of frozen potato products have very limited control over its formation. Generally speaking, the frying process (e.g., skillet or griddle preparation) would create more acrylamide than baking. By not explicitly recognizing the levels only apply to the cooked French fries when prepared following the labeled cook instruction (e.g., frying or baking) in the proposal, OEHHA risks putting our businesses in the impossible position of having to comply with a level they do not have control over.

As discussed in detail below, FPPI recommends several changes to the proposal. In addition to acrylamide, we also encourage OEHHA to consider establishing maximum limits for other chemicals such as furfuryl alcohol formed during cooking or heat processing in the proposal. FPPI thanks OEHHA for taking into consideration the following comments on its proposal, and generally supports the California Chamber of Commerce's submission.

The Frozen Potato Industry Has Already Implemented "Quality Control Measures"

FPPI members have already implemented various "quality control measures" in mitigating acrylamide formation since its discovery in food about a decade ago. These measures include, among other things:

- Lightened the finished color specification of frozen potato products and adjusted cooking instructions on product labels
- Incorporated asparaginase treatment
- Adopted new potato varieties with lower acrylamide forming potential

These measures are also consistent with guidance published by EU and US FDA on mitigating the formation of acrylamide such as "FoodDrinkEurope (2019) Acrylamide Toolbox 2019" and "US FDA (2016) Guidance for Industry: Acrylamide in Foods." To encourage the food industry to further mitigate acrylamide formation following established guidance, we would like to ask OEHHA to consider explicitly acknowledging that these two documents are appropriate examples of "quality control measures" under Subsection (a). Under Subsection (a), if the producer of food products can demonstrate it is following the EU toolbox or FDA guidance, acrylamide levels in any food products, even those not currently covered by Subsection (d) or any settlements from litigation, should be considered "lowest level currently feasible" and exempt from the warning requirements. FPPI members have already implemented "quality control measures" that are consistent with this guidance.

"Lowest Levels Currently Feasible" for Acrylamide in French Fries

The proposed Subsection (d) sets forth the maximum concentration levels for chemicals in foods that would not constitute an exposure that requires a warning

pursuant to Subsection (a). With two exceptions, 4/ 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. OEHHA reasoned 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.

Specifically, for "Potato products, French fried potatoes," OEHHA proposed to set the levels for acrylamide to be 280 ppb (Maximum Average Concentration) and 400ppb (Maximum Unit Concentration) based on two court-approved settlements. 5/ We have carefully reviewed these two settlements, and both refer to the 280 ppb and 400 ppb acrylamide levels as the "reformulation levels" that are in compliance with Proposition 65. Importantly, neither of the settlements discusses whether these levels are considered "lowest levels currently feasible" by the defendants or the plaintiffs. Rather, in one settlement, the defendant was explicitly offered the option of providing the warning, in the event the products cannot meet the "reformulation levels." Even OEHHA acknowledged in the ISOR the presumption that the reformulation level is currently feasible "may not always be the case." 6/

FPPI respectfully submits that neither the 280 ppb nor 400 ppb 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 our members. Instead, FPPI would like the agency to consider adopting the "benchmark level" established by the European Union (EU). In 2017, recognizing the hazard of acrylamide in foods, the EU adopted regulations to encourage the reductions by the food industry and set the benchmark levels with the goal of ensuring 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." As such, 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. We note OEHHA has also 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 EU is **500 ppb** and we urge the agency to consider adopting this level as the "lowest level currently feasible," just like what it proposed for wheat-based and non-wheat based bread categories, instead of the reformulation level in the settlements.

Only Maximum Average Concentration Levels Needed

Also in Subsection (d), OEHHA proposed to adopt, when available, two concentration levels from the consent decrees – the Maximum Average

4/ Wheat-based and non-wheat-based bread categories are based on benchmark levels established by the European Union.
5/ *CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-01412, Judg. No. J3851, Lamb Weston Holdings, Inc.]); *and CEH v. Lamb Weston Holdings, Inc., et al.* (Super. Ct. Alameda, 2018, No. RG 16838610 [AG No. 2016-00951; Judg. No. J3850, J.R. Simplot Company]).
6/ *See supra* note 2.

Concentration (i.e., average concentration measured in multiple items/individual packaging units) and the Maximum Unit Concentration (i.e., the maximum concentration measured in a single item/individual packaging unit). As discussed above, FPPI respectfully asks the agency to consider adopting the EU "benchmark levels," which are established by the EU as performance indicator for acrylamide mitigation, instead of the "reformulation levels" that were negotiated between private litigants and individual companies that are not representative of the acrylamide data across the industry and not considered feasible.

We also would like to note that by nature, the Maximum Average Concentration, which represents the "average" level, more accurately represents the actual intake of the listed chemicals from food consumption. Calculations of the concentration of a chemical in a food product for purposes of determining whether a warning is required should reflect an exposure that a consumer might reasonably receive from a product purchased at a specific time and place in California. As such, 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. This is especially the case when large variabilities in acrylamide are observed in individual product. The use of Maximum Unit Concentration, therefore, will likely exacerbate, instead of reducing, the challenges the food industry is facing with Proposition 65 compliance.

Testing Method and Sampling Plan

The current proposal is not specific about how the acrylamide levels should be measured and how the product samples should be taken for acrylamide determination. Lack of clarity can lead to incorrect determination whether the exposure is or is not subject to Proposition 65 warning requirements. We 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." 7/

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.

7/ *See* FDA, "Detection and Quantitation of Acrylamide in Foods," *available at*: https://www.fda.gov/food/chemicals/detection-and-quantitation-acrylamide-foods (accessed on Sep 10, 2020).

Chemicals Formation during Cooking of French Fries

Frozen potato manufacturers' and producers' main processing activities are usually limited to cutting, rinsing, freezing, and packaging frozen potato products. Frozen potato manufacturers provide cooking instructions designed to mitigate acrylamide formation—and work extensively to educate customers on proper cooking techniques—but ultimately have no direct control over the final acrylamide formation process. FPPI is concerned that the proposal, if left unchanged, can create a de-facto mandatory warning requirement for all frozen potato products. This is especially concerning when baking and frying can potentially produce vastly different levels of acrylamide. As such, it is important to measure the acrylamide levels in cooked French fries when prepared under the cook instructions provided on the label. FPPI respectfully asks OEHHA to modify the term "Potato products, French fried potatoes" under Subsection (d) by adding the term "(when prepared according to cook instructions)."

Furfuryl Alcohol, Another Chemical Formed during Cooking

Like acrylamide, furfuryl alcohol is another food contaminant which can form in thermally processed foods. Furfuryl alcohol can be unavoidable in these foods even after the food manufacturers have adopted appropriated quality control measures. Unlike acrylamide, as of today, there is no established OEHHA "safe harbor" level or NSRL for furfuryl alcohol. In the absence of an OEHHA "safe harbor," during Proposition 65 enforcement actions, a company will have to determine its own "safe harbor" level based on sound toxicology principles and self-assess whether its products, although containing furfuryl alcohol, present a potential exposure that falls within the "safe harbor" level and thus does not require a warning statement. This would make the compliance with Proposition 65 even more challenging. FPPI respectfully asks OEHHA to consider explicitly referring the chemical furfuryl alcohol in Section 25505 as another example of chemical formed during cooking or heat processing of food. 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 is exempt from Proposition 65 warning requirements.

Conclusion

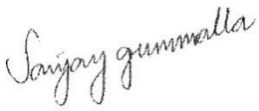
In summary, FPPI supports OEHHA's efforts in addressing the challenges the food industry is facing. As the national trade association for frozen potato product manufacturers and producers, FPPI's members face unique challenges in complying with the proposal as written. FPPI respectfully submits that OEHHA should adopt the EU "benchmark level" of **500 ppb** as the "lowest levels currently feasible" for acrylamide in French fries. We also encourage OEHHA to ensure that testing method and sampling plan is provided to ensure consistency and certainty in relying on the regulation for compliance. FPPI's members have limited control over the levels of acrylamide, which is mainly formed during the cooking process after products leave the manufacturer's control. As such, FPPI recommends the term "(when prepared according to cook instructions)" be added to Subsection (d) for the

French fries. FPPI also would like to request furfuryl alcohol be explicitly referenced in Section 25505 as another example of chemical formed during cooking or heat processing.

Thank you for your consideration and for this opportunity to provide comments.

Respectfully submitted,

Sincerely yours,



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