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Re.: P65 Warning Regulation - Article 6, Clear and Reasonable Warnings

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 pre-regulatory draft proposal to amend warning sign regulations 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.

FPPI thanks OEHHA for taking into consideration the following comments on its draft pre-regulatory proposal and generally supports the California Chamber of Commerce’s submission.

Background

The U.S. Food and Drug Administration (FDA) “has stated publicly that it is concerned that warning language for acrylamide in foods could confuse consumers; e.g., by creating unnecessary public alarm about the safety of the food supply and by diluting overall messages about healthy eating.” 2/ There remains significant uncertainty about the actual risks associated with acrylamide


through dietary sources based on overwhelming epidemiological evidence and recent reviews suggesting no safety concern. ³/⁴/⁵/⁶/

As many frozen potato products have the potential to form acrylamide when cooked, FPPI and our members are keenly focused on identifying ways to successfully reduce acrylamide formation. Since acrylamide was discovered in foods about a decade ago, the frozen potato products industry 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. Most recently, FPPI has prepared educational materials, including a video and poster (enclosed herein) for food service operators explaining proper frying temperature, proper frying time, and desired color for food service French fries. ⁷/ These materials are intended to reinforce FPPI Member Company recommendations that French fries be cooked at lower temperatures and to a lighter color to reduce acrylamide formation while still ensuring the fries are fully cooked.

We are proud of our successes so far, but we recognize that significant work remains to fully understand the effects of acrylamide consumption on public health and to develop even more robust mitigation strategies. FPPI provided detailed information and data about acrylamide reduction strategies in 2009 in response to the U.S. Food and Drug Administration’s (FDAs) Request for Comments and for Scientific Data and Information. ⁸/ Supplemental information was also provided in comments submitted in response to FDA’s recent draft guidance on acrylamide reductions. ⁹/ It should be noted that while many acrylamide mitigation strategies remain in the experimental phase, and others have shown mixed results under manufacturing conditions, both research and implementation efforts continue.  A promising mitigation strategy is the

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⁴/ Canadian Food Inspection Agency, Food Safety Action Plan 2010-2011 Targeted Surveys - Chemistry “The levels of acrylamide detected in foods in this survey were determined to be unlikely to pose a human health concern.”


development of genetically engineered potatoes with substantially less acrylamide formation potential.

**General Comments**

As stated in the Proposition 65 warnings reform summary fact sheet, the purpose of this pre-regulatory proposal is to “improve the quality of Proposition 65 warnings while providing both flexibility and certainty for businesses” so as to “reduce unnecessary litigation”. However, FPPI contends that the pre-regulatory proposal as written does little to improve the quality of the warnings and in fact renders the existing framework less flexible with increased ambiguity and uncertainty for businesses ultimately resulting in potentially increased litigation.

FPPI addresses a number of issues with the existing pre-regulatory draft proposal that we believe are contrary to the stated goals of the legislative revisions or not appropriate given earlier developments under Proposition 65. These aspects of the proposal should be deleted or significantly revised to more closely align the regulatory text with the Governor’s intent reflected in Proposition 65 legislative reform language. OEHHA’s pre-regulatory draft proposal would likely result in an increased number and frequency of warning labels, with substantially more unnecessary, redundant, and duplicative information through the web-based platform. Meanwhile, corresponding Proposition 65 litigation will likewise significantly rise due to the ambiguities, lack of clarity, and inconsistencies embedded throughout the current proposal.

FPPI provides further clarification for the following proposed sections -

- Proposed § 25603 Court-Approved Settlements;
- Proposed § 25604 Lead Agency Website;
- Proposed § 25605 Chemicals, Substances or Mixtures that must be Disclosed in Warnings;
- Proposed § 25606 Consumer Product and Food Warnings;
- Proposed § 25607.3 Food Exposure Warnings – Methods of Transmission for Food Products AND Proposed § 25607.4 Food Exposure Warnings – Content.

**Proposed § 25603 Court-Approved Settlements**

The draft regulatory language as written will inevitably lead to inequitable results that will undermine Proposition 65’s goals, erode public confidence, increase unnecessary Proposition 65 litigation, and disproportionately place increased burdens on businesses not involved in court-approved settlements. OEHHA proposes to exclude from the scope of coverage of its amended warning

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regulations “parties to court-approved settlements prescribing warning content and methods entered prior to January 1, 2015.” This provision would create inconsistent requirements and warnings and is contrary to the intent of many court-approved settlements, which contain “opt-in” provisions whereby similarly situated companies can elect to subject themselves to the terms of the settlement, including the warning requirements. FPPI believes that this provision should encompass not only parties to court-approved settlements but also ensure that the warning content and methods prescribed in those settlements extend to all relevant parties manufacturing similar products if they deem appropriate. Otherwise, inconsistent warning label requirements among similar products, areas, or chemicals would confuse consumers and unduly discriminate against those not previously subject to litigation, placing disproportionate burden on the latter in the marketplace and conferring an unfair competitive advantage to those in prior settlements.

OEHHA should aim to treat businesses that are equally positioned - except as to having entered into a prior Proposition 65 consent judgment - more equitably. Warnings specified in consent judgments for product-specific, area-specific or chemical-specific cases should be extended to apply to all relevant products, areas, or chemicals, respectively, if applicable.

Prior settlements should apply not only to those parties who have settled but to all relevant parties, as appropriate, and should be leveraged to establish clear precedent for the industry. An “opt-in” consent decree such as the one entered into by H.J. Heinz Company, L.P. as an option to satisfy the Proposition 65 warning labeling requirements should be afforded all frozen potato product manufacturers. 11/ Criteria for compliance should be equivalent for all companies competing within a food category. The ambiguity in the law itself necessitates further clarification and additional criteria beyond safe harbor levels. Requirements need to be more clearly defined. OEHHA should develop a Proposition 65 roadmap to assist companies generally, and food companies specifically, self-assess whether warning labeling requirements would be triggered in the first place.

**Proposed § 25604 Lead Agency Website**

Web-reporting and maintenance would require substantial OEHHA resources without providing more clarity to consumers or facilitating compliance.

The information being sought for web reporting is duplicative and redundant with the existing product label and required warning label in that:

- The route of exposure is self-evident based on product use;

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• Risk mitigation measures are accounted for by following the labeling instructions;
• The bar code is already on the product;
• Specific concentrations of chemicals in products would not be meaningful to the consumer, are not always consistent from product-to-product due to different processing techniques (e.g., acrylamide is highly dependent on the cooking process by the end user), and do not factor in natural occurrence.

Moreover, FDA has a dedicated webpage for acrylamide that should serve as the single authoritative reference source for consumers. 12/ OEHHA should direct consumers to FDA’s website to glean relevant information on acrylamide in foods.

Additionally, more information does not equate with better understanding and appreciation of relevance to public health among consumers. Context is extremely important for any disclosures, and in some cases, the Proposition 65 warning label may lead consumers to avoid foods that may contribute to a well-balanced healthy diet. Thus, more information in this case would contribute to increased consumer confusion and alarm rather than provide meaningful warnings.

**Proposed § 25605 Chemicals, Substances or Mixtures that must be Disclosed in Warnings**

Although listing chemical names and/or classes in the warning label may increase specificity, consumers may become unnecessarily alarmed and confused when they see particular chemicals listed. The unintended consequences of specifying chemicals in the Proposition 65 product warning label should be carefully evaluated and considered before implementing such a measure.

For acrylamide and Proposition 65 warning requirements for foods, much of the required information is already captured on FDA’s and OEHHA’s websites, rendering this level of rigor duplicative and unnecessary. 12/13/ Specifically listing acrylamide on a Proposition 65 warning label for foods is unnecessary and potentially misleading. There remains significant uncertainty about the actual risks associated with acrylamide through dietary sources based on overwhelming epidemiological evidence and recent reviews suggesting no safety concern. 3/4/5/6/

FPPI is currently undertaking a review of existing literature that suggests potatoes provide nutritional value and other beneficial attributes to consumers that would offset any potential risk from limited acrylamide exposure. In fact, 12/ http://www.fda.gov/food/foodborneillnesscontaminants/chemicalcontaminants/ucm2006782.htm
13/ http://oehha.ca.gov/prop65/acrylamide.html
the National Coffee Association continues to object to warning label requirements for coffee on the basis of its beneficial attributes that outweigh potential acrylamide concerns. ¹⁴/ Noteworthy is that acrylamide levels are highly dependent on the final cooking process employed by the end user as well. A number of mitigation strategies that could reduce acrylamide formation are currently being employed and tested. Acrylamide should be removed from the list of chemicals to be specifically identified.

Furthermore, the selection criteria for the twelve designated chemicals are not readily apparent. If chemicals are to be designated, a scientific risk-based relative ranking and prioritization scheme should be employed to identify and prioritize those chemicals contributing most to consumer exposure and health risk among Californians. The prioritization scheme should be subject to notice-and-comment rulemaking with the designated chemicals resulting from that process likewise subjected to notice-and-comment rulemaking. Additionally, a rationale must be provided to explain selecting twelve chemicals rather than five, four, or any other number. Both OEHHA’s Development and Reproductive Toxicant Identification Committee (DARTIC) and OEHHA’s Carcinogenic Identification Committee (CIC) should be consulted throughout this process.

According to the draft Initial Statement of Reasons (ISOR),¹⁵/ “The list of chemicals is not intended to be exhaustive and may be changed over time as the public becomes more familiar with the improved warning format.” The fact that the list of chemicals could change over time raises serious pragmatic concerns. This suggestion implies that a change in the list of chemicals would once again necessitate a change in product warning labels. Frequent product label changes are cost-prohibitive and do not meaningfully contribute to consumer understanding of chemical profiles associated with those products. In fact, consumers would likely become increasingly confused as the same product over time would bear different labels highlighting different chemicals despite no formulation changes.

**Proposed § 25606 Consumer Product and Food Warnings**

The responsibility to label cuts across the entire value chain and should be a shared responsibility, with the onus not solely placed on producers. In some cases, the producer may have a product that does not actually contain the Proposition 65 chemical. Acrylamide, for example, is formed predominantly during the cooking process, which is dependent on the end user. Foodservice establishments, depending on the cooking process (e.g., baking or frying), may have variable levels of acrylamide in the prepared food. Similarly, a retailer may sell a product that does not actually contain acrylamide, which is formed only after the consumer prepares the food. The complicated interaction among


all parties involved in the value chain underscores the inappropriateness of placing sole responsibility on one party.

Another consideration is the customer/supplier contractual agreement that details the required product specifications, potentially necessitating a Proposition 65 warning label due to different cooking/processing techniques.

**Proposed § 25607.3 Food Exposure Warnings – Methods of Transmission for Food Products**

**AND Proposed § 25607.4 Food Exposure Warnings – Content**

According to the Memorandum of Understanding between the California Department of Food and Agriculture (CDFA) and OEHHA, \(^{16}\) the MOU “serves as a mechanism for formalizing ... cooperation (between OEHHA and CDFA) concerning OEHHA’s implementation of Proposition 65 with respect to exposure to Proposition 65 listed chemicals in foods.” However, it is unclear whether OEHHA has consulted CDFA on the pre-regulatory draft proposal relative to food warnings. OEHHA should consult CDFA regarding the application of the warning statements to foods and should make publicly available the results of that consultation.

FPPI understands that food and beverage companies have previously suggested alternative systems of warnings in lieu of product labels and shelf signs as the latter are poor media for Proposition 65 warnings for foods. A potentially viable alternative for further consideration by OEHHA is to ensure that the Proposition 65 warning label directs consumers to FDA’s website to learn more about Proposition 65 requirements relative to specific chemicals that may be found in the packaged food as consumed. \(^{17}\) The latter proposal may positively increase transparency and understanding through appropriate consumer communication of food chemicals thereby contextualizing concerns associated with listed chemicals.

To avoid consumer confusion and alarm, the number of Proposition 65 warnings for foods should be limited. Additionally, for foods that are not adulterated, OEHHA’s proposal may be in conflict with other federal and state food safety and nutritional laws and policies. To date, FDA has not found acrylamide presence in food as a public health concern and has not required any warning labels. \(^{2/12}\)

As another example, any requirement that a Proposition 65 warning be placed on a meat or poultry product label would be preempted by the Federal Meat Inspection Act or the Poultry Products Inspection Act because the Proposition 65 warning statement is not identical to the federal labeling requirements. Thus,

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\(^{16}\) http://www.oehha.org/prop65/pdf/OEHHA_CDFA_MOU112513.pdf

\(^{17}\) An example citation on the warning label might be: "Please refer to: [www.fda.gov](http://www.fda.gov) for more information.”
all Proposition 65 warnings are inconsistent with federal law for meat and poultry products.

Beyond resolving the aforementioned conflicts, further clarification of OEHHA’s “naturally occurring” \(^{18}\) and “cooking” \(^{19}\) concepts through interpretive guidance materials for relevant chemical/food combinations may help reduce the ambiguity associated with these terms and ultimately minimize the number of frivolous lawsuits. Case in point, acrylamide concentration in French fries is highly dependent on the cooking process of frozen French fries by the end user. Thus, the labeling determination should be based on product content as sold and prepared following labeled cooking instructions, rather than subject to unforeseen uses by the end user.

**Continued Research Is Essential**

As mentioned, we are still in the very early stages of our understanding of acrylamide formation in food, how to manage its formation, and the broader implications that high-level presence poses for consumers. Although numerous strategies have been explored, many of the strategies tested have shown equivocal results, some have proven difficult to translate from the laboratory bench to the manufacturing facility floor, and some have been demonstrated to have unintended negative consequences on product acceptance or palatability. Much work remains, and continued research is essential to developing better acrylamide-mitigation strategies. FPPI encourages OEHHA to take steps to encourage and facilitate continued research and development in this area in coordination with both CDFA and FDA while reducing/eliminating risk of litigation.

Finally, to the extent it is going to try to improve the existing warning program with respect to its application to foods, OEHHA needs to recognize and take steps to give more practical and meaningful effect to the exceptions that were created in the existing regulations for application of the warning requirement to certain types of chemicals in foods when the chemicals are not being added to the foods by the party on whom the warning obligation would otherwise fall.

**Conclusion**

As leaders in the effort to understand and reduce acrylamide formation in frozen potato products, FPPI and its member companies continue to explore a number of potential approaches for reducing acrylamide formation. We believe that choosing appropriate strategies and continuing to research and experiment with new techniques, food manufacturers can meaningfully control and reduce acrylamide consumption. We encourage OEHHA to take note of industry efforts

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\(^{18}\) Title 27, California Code of Regulations ARTICLE 5. Extent of Exposure § 25501. Exposure to a Naturally Occurring Chemical in a Food

\(^{19}\) Title 27, California Code of Regulations ARTICLE 7. NO SIGNIFICANT RISK LEVELS § 25703. Quantitative Risk Assessment “(b) (1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination”
thus far and to ensure that court-approved settlements retain their intended effect and remain applicable to the broader frozen potato products industry. The outcome of the proposed rules as currently written is not likely to achieve the intent to improve quality of warning labels while providing flexibility and certainty among businesses, nor is it likely to reduce frivolous lawsuits. The contemplated rules substantially increase the complexity for compliance and the likelihood of disputes over subtleties in application of the rules. The proposed rules need to be either substantially revised and simplified or abandoned.

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

Respectfully submitted,

Maia M. Jack, Ph.D.
Director, Regulatory and International Affairs
Frozen Potato Products Institute

cc: The Honorable Richard Bloom, Chair,
    Assembly Budget Subcommittee No. 3
    The Honorable Jim Beall, Chair, Senate Budget Subcommittee No. 2
    George Alexeeff, Ph.D., OEHHA Director
    Karen Ross, CDFA Secretary
    Kristin Stauffacher, CalEPA Deputy Secretary for Legislative Affairs
    Dana Williamson, Office of the Governor
    Cliff Rechtschaffen, Office of the Governor
    Martha Guzman-Aceves, Office of the Governor

20/ Attorney General’s Office Acrylamide Agreement with KFC | Agreement with Potato Chip Manufacturers.
Know Your FRIES
Reduce Acrylamide!

REMEMBER!

- Keep fries frozen
- Cook in oil at 350°F/175°C or below
- Use a timer
- Check for color
- Follow the directions

For more information, please contact the Frozen Potato Products Institute at (703) 821-0770