



April 08, 2015

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**Re.: Prop 65 - Clear and Reasonable Warning Regulations**

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 to Article 6 in Title 27 of the California Code of Regulations pursuant to the Safe Drinking Water and Toxic Enforcement Act ("Proposition 65"). <sup>1/</sup> 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 May 7, 2013, Governor Brown proposed reforms to Proposition 65. The Administration announced it will revamp Proposition 65 by ending frivolous "shake-down" lawsuits, improving how the public is warned about dangerous chemicals and strengthening the scientific basis for warning levels. <sup>2/</sup> According to OEHHA's January 16, 2015 Initial Statement of Reasons for the proposed revision to the Proposition 65 warning regulation ("ISOR"), the proposed regulations are intended to implement the Administration's vision concerning improving the quality of the warnings being given while providing compliance assistance to businesses subject

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<sup>1/</sup> January 16 (2015) Notice for Title 27, Proposed Repeal of Article 6 and Adoption of New Article 6 ([http://oehha.ca.gov/prop65/CRNR\\_notices/WarningWeb/pdf/NPR\\_Article6Jan2015.pdf](http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/NPR_Article6Jan2015.pdf)); Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1986. (<http://www.oehha.org/prop65/law/P65law72003.html>)

<sup>2/</sup> May 7 (2013) Press Release, Governor Brown Proposes to Reform Proposition 65 (<http://www.gov.ca.gov/news.php?id=18026>)

to the warning requirements. 3/

FPPI addresses a number of issues with the proposed rules that we believe are contrary to the stated objectives. Specifically, the “12 chemicals” that are required to be named on the warning labels are arbitrarily selected with no apparent scientific basis. This alone will likely exacerbate, instead of reduce, the problem of consumer confusion over the Prop 65 warning. Moreover, by not explicitly recognizing all previous court-approved warning statements as meeting the “clear and reasonable” requirement in the proposed rules, OEHHA risks putting businesses in the impossible position of having to choose between two different warning statements without clear guidance.

Some aspects of the proposed rules also present unique challenges for FPPI members. Unlike any of the other “12 chemicals” identified in the proposed rules, acrylamide is a naturally-occurring substance mainly formed during the cooking process. Very low levels of acrylamide have probably been present in foods including fried potatoes, bakery products, breakfast cereals, and coffee for decades. Despite of its recent discovery in food by Swedish scientist in 2002, most studies today show no clear association between the acrylamide dietary intake and an increase in human cancer. As such, there is no sound scientific basis to put acrylamide on the “12 chemicals” list when other, more potent, chemicals are not.

Moreover, because acrylamide is mainly formed during the final cooking step, manufacturers and producers of frozen potato products have very limited control over its formation. By unfairly placing the primary burden of the product warning requirement on the frozen potato manufacturers and producers, OEHHA is creating a regulatory scheme that is not only ineffective but also becomes a de-facto mandatory warning requirement for all frozen potato products sold in California. With no real control over how the frozen potato products are prepared prior to consumption, frozen potato manufacturers and producer will be pressured under the proposed rules to provide prophylactic warning requirements for all frozen potato products sold in California, even when the acrylamide levels of the final cooked products do not trigger Prop 65 warning requirements. This will not only discourage California consumers from selecting potassium and fiber-rich potato products, but also open up new frontiers for “shake-down” lawsuits.

As discussed in detail below, FPPI recommends several changes to the proposed rules and additions to the Final Statement of Reasons to make them align more with the stated objectives of providing more meaningful warning to consumers and reducing frivolous “shake down” lawsuits. FPPI also recommends changes or additions that will provide further clarifications for businesses subject to the warning requirements. Clear and unambiguous guidance from OEHHA is essential in reducing frivolous lawsuits because OEHHA itself does not enforce Prop 65 and is not involved in private litigations. FPPI thanks OEHHA for taking into consideration the following comments on its proposed rules and also generally supports the California Chamber of Commerce’s submission.

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3/ Initial Statement of Reasons for Proposed Repeal of Article 6 and Adoption of New Article 6 ([http://oehha.ca.gov/prop65/CRNR\\_notices/WarningWeb/pdf/Article6\\_ISOR.pdf](http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/pdf/Article6_ISOR.pdf))

## **Proposed § 25600.2 Responsibility to Provide Product Warnings**

The proposed § 25600.2 would unfairly place the primary responsibility for providing the warning for food products such as frozen potato products with the manufacturer, producer, packager, importer, or distributor. If left unchanged, the proposed provision has the potential for discouraging California consumers from eating potassium and fiber-rich potato products. The proposed provision also overlooks the complexities of the food supply chain.

According to OEHHA's ISOR, one of the main objectives of the proposed rules is to put the primary responsibility for providing product warnings on the manufacturer, producer, packager, importer, or distributor because they are usually "in a much better position than the retailer to determine whether and for what a warning is required." <sup>4/</sup> FPPI respectfully submits that this is not the case for frozen potato manufacturers and producers. Unlike most of the chemicals currently listed on the Prop 65 list, acrylamide is a natural by-product of the cooking process and is formed when reducing sugars such as glucose or fructose react with the amino acid asparagine. The levels of acrylamide in foods are mainly determined by factors such as the amount of reducing sugar and asparagine in raw foods, cooking temperature, the length of the cooking, and moisture content. <sup>5/</sup> The U.S. Food and Drug Administration (FDA) also acknowledges that "final cooking conditions are the major factor in determining final acrylamide levels". <sup>6/</sup> Indeed, the most effective intervention thus far identified by FPPI members to mitigate acrylamide formation is lowering the cooking temperature, which is a step ultimately controlled by the final user or consumer, not the manufacturer.

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. The contractual agreements between the manufacturers or producer and their customers (e.g., retailers) usually dictate the product specifications and processing conditions. As such, the responsibility to provide warnings for frozen potato products should cut across the entire value chain and should be a shared responsibility, with the burden not placed solely on the manufacturers or producers.

FPPI is concerned that the proposed provision, if left unchanged, can create a de-facto mandatory warning requirement for all frozen potato products. A blanket warning is not only ineffective in mitigating acrylamide exposure but also has the unintended consequence of discouraging Californian consumers from eating

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<sup>4/</sup> See *id.*

<sup>5/</sup> Virk-Baker, Mandeep K., et al. "Dietary acrylamide and human cancer: a systematic review of literature." *Nutrition and cancer* 66.5 (2014): 774-790.

<sup>6/</sup> FDA, Draft Guidance for Industry: Acrylamide in Foods (November, 2013)

(<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm374524.htm>)

potassium and fiber-rich potato products. According to the 2015 Dietary Guidelines Advisory Committee Scientific Report, potatoes are the most commonly consumed single vegetable and make up about 80 percent of all starchy vegetable consumption. <sup>7/</sup> They account for 25 percent of all vegetable consumption and are a good source of both potassium and fiber, especially among children and adolescents 2 to 19 years old. <sup>8/</sup> FPPI respectfully asks OEHHA to address these unique concerns of food manufacturers and producers in the final rule or the Final Statement of Reasons.

The proposed § 25600.2 is also too prescriptive and overlooks the complexities of the food supply chain. For example, under the proposed rule, a frozen potato manufacturer might be considered as not complying with the regulation if a written notice of the warning is passed along to a distributor who later fails to deliver the warning notice to a retailer or its agent. This is particularly concerning for FPPI members because acrylamide is mainly formed during food preparation over which the manufacturers have limited control once the products leave the warehouse. FPPI asks OEHHA to insert “or any immediate customer or recipient” to § 25600.2 (b) right after “or by providing a written notice directly to the authorized agent for a retailer who is subject to section 25249.6 of the Act,” to clarify that a manufacturer or producer will satisfy the product warning requirement by sending the written notice to the next business through the supply chain.

### **Proposed § 25602 Chemicals Included in the Text of a Warning**

OEHHA provides no sound scientific basis for the selection of the “12 chemicals” in the proposed § 25602. By arbitrarily including the naturally-occurring acrylamide, OEHHA will only exacerbate the consumer confusion over the product warning and open up new avenues for frivolous lawsuits. OEHHA should remove this provision in its entirety or, at a minimum, remove acrylamide from the list.

According to OEHHA’s ISOR, when selecting the “12 chemicals” to be included in Section 25602, OEHHA considered the following criteria: <sup>9/</sup>

- Widespread prevalence of the listed chemicals in products and/or locations beyond those that are covered by specific warning language in Section 25608;
- Potential for significant exposure to the listed chemical through human interactions with products, including food, or at locations frequented by the public;
- Recent Proposition 65 enforcement activity;
- Recognizability of the chemical name among the general public;
- The general availability of additional authoritative information and resources for the public on the toxicity and exposure to the chemical, doses of concern, and ways to prevent or reduce exposure.

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<sup>7/</sup> The Report is available at <http://tinyurl.com/nt9qf4c>.

<sup>8/</sup> See *id.*

<sup>9/</sup> See *supra* note 3.

FPPI respectfully submits that the above criteria are arbitrary in nature and asks OEHHA to reevaluate whether it is necessary to create a special list for “12 chemicals” in the proposed rule. Notably, in the ISOR, OEHHA states that it selects the “12 chemicals” that can be identified with simplified chemical names by the public over chemicals with longer and more technical names. As there is no apparent correlation between the length of a chemical’s name with its toxicity potency or human exposure, such criteria offer little, if any, meaningful information to the consumers. Moreover, the fact that OEHHA uses recent Prop 65 enforcement activities as one of the selection criteria contradicts its stated objective of reducing frivolous lawsuits. OEHHA noted in the ISOR that one of the reasons why acrylamide is listed on the “12 chemicals” list is that during the past 5 years, there has been 17 60-day notices filed regarding exposures to acrylamide. <sup>10/</sup> By explicitly requiring acrylamide be identified on product labels based on recent enforcement activities and creating a “dirty dozen” list of chemicals, OEHHA practically invites more lawyer-manufactured lawsuits targeting products with these substances.

Also notably missing from the above criteria is any sound scientific basis in selecting these “12 chemicals.” Although listing chemical names and/or classes in the warning label may increase specificity, consumers may become unnecessarily alarmed and infer, incorrectly, that any or all of these “12 chemicals” pose greater health risks to the public than other Prop 65 listed chemicals not included in Section 25602. If OEHHA nonetheless decides to designate 12 chemicals in the final rule, scientific risk-based criteria that focus on the toxicity potency and human exposure, instead of the current criteria, should be employed to identify and prioritize chemicals that require specific identification in warnings.

The inclusion of acrylamide as one of the “12 chemicals” is particularly concerning to FPPI members and offers little meaningful information to California consumers. Among the “12 chemicals,” acrylamide is the only substance formed in food as a consequence of the final cooking process, an inevitable part of making the food palatable and safe to eat. There remains significant uncertainty about the actual risks associated with acrylamide exposure through dietary sources. Human have been safely consuming foods such as fried potatoes, bakery products, breakfast cereals, and coffees that contain very low levels of acrylamide for decades. Overwhelming epidemiological evidence and recent reviews also suggest there is either no human risk associated with acrylamide intake or there is not enough evidence to conclude that the current dietary exposure to acrylamide presents any

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<sup>10/</sup> See *id.*

human safety concern. 11/ 12/ 13/ 14/ FPPI respectfully submits that acrylamide should be removed from the list of chemicals to be specifically identified regardless of what selection criteria OEHHA is going to use.

During the public hearing for the proposed rules on March 27, 2015, OEHHA noted that the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant (DART) Identification Committee are currently reviewing the list of “12 chemicals.” FPPI respectfully asks the OEHHA not to publish the final “12 chemicals” until these two committees finish their review and the public has a chance to review and comment on their findings. FPPI is particularly interested in how the two committees compare the “12 chemicals” with the other more than eight hundred chemicals also listed on Prop 65 in terms of the history of use, natural occurrence, toxicity potency, and human exposure levels.

### **Proposed § 25608.1 Food Exposure Warnings - Methods of Transmission**

The proposed § 25608.1(b) fails to provide clear guidance on what triggers a non-English warning requirement.

The current proposed § 25608.1(b), read plainly, seems to require multi-language warning when there is even only a single non-English word in any label, labeling, or sign about a food. From a practical perspective, given the universal presence of non-English words in our culture and the diversity of California consumers, it is challenging for food manufacturers and retailers to keep track of the use of every non-English word. Moreover, not all the non-English words are used to attract non-English speakers that warrant a multi-language warning. For example, the French word “baguette” is commonly used by bakeries and commonly understood by consumers to refer to the French stick breads. Imposing a Prop 65 warning label in French merely because the word “baguette” is used does not advance the agency’s goal of better informing the consumers. Once implemented, FPPI is concerned that this provision will essentially become a requirement that imposes a multi-language warning for all food products. FPPI respectfully asks OEHHA to consider providing clearer guidance in the final rule on the use of non-English language that warrants a multi-language warning.

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11/ Lipworth L, Sonderman JS, Tarone RE, and McLaughlin JK. Review of epidemiologic studies of dietary acrylamide intake and the risk of cancer. *Eur J Cancer Prev.* 2012 Jul; 21(4): 375-86 (“the collective evidence suggests that a high level of dietary acrylamide intake is not a risk factor for breast, endometrial, or ovarian cancers, which have generated particular interest because of a conjectured hormonal mechanism of acrylamide.”)

12/ 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.”

13/ International Food Information Council Acrylamide Resources (2014) ([http://www.foodinsight.org/Resources/Detail.aspx?topic=Acrylamide\\_Resources](http://www.foodinsight.org/Resources/Detail.aspx?topic=Acrylamide_Resources)) (“Recent media coverage of acrylamide has raised consumer questions, as studies of laboratory animals indicate that very high doses of acrylamide increase the incidence of cancer in certain laboratory studies. However, numerous studies of low levels of dietary acrylamide in humans have not drawn such conclusions.”)

14/ See *supra* note 5 (“A majority of the studies reported no statistically significant association between dietary acrylamide intake and various cancers, and few studies reported increased risk for renal, endometrial, and ovarian cancers; however, the exposure assessment has been inadequate leading to potential misclassification or underestimation of exposure. Future studies with improved dietary acrylamide exposure assessment are encouraged.”)

Moreover, the proposed provision further supports our position that the responsibility to provide warnings should cut across the entire value chain and should be a shared responsibility. As product manufacturers and producers do not have real control over product shelf signs, the responsibility of providing multi-language warning should not be placed on manufacturers or producers. FPPI urges OEHHA to confirm that the label of a packaged food product or a warning sign provided by the food manufacturer or producer would not need to provide a multilingual warning on account of foreign language information provided by another party, such as a the retailer.

### **Proposed § 25600 General**

By failing to explicitly state that all previous court-approved warning statements and other appropriate statements meet the “clear and reasonable” requirement, the proposed § 25600 will inevitably lead to inequitable results that will undermine the stated objectives.

According to OEHHA’s ISOR, the agency recognizes that businesses who are parties to a settlement or judgment must comply with the provisions of the court’s order, regardless of the “safe harbor” provided by the proposed regulations. However, by failing to explicitly state that all the previous court-approved warning statements also meet the “clear and reasonable” requirement, the proposed regulation will leave the industry in limbo and likely increase the frivolous litigations.

For example, statements such as the following are provided for in consent decrees: 15/

“WARNING: Brownd potatoes contain acrylamide, a chemical identified under California’s Proposition 65 as causing cancer. It is not added to the potato but is formed from cooking. The U.S. FDA encourages people to continue to eat a wide variety of foods and has not advised people to stop eating baked or fried potatoes. For more information see [www.fda.gov](http://www.fda.gov).”

We are concerned individuals could take the position that this and similar warnings provided for in consent agreements are not explicitly authorized by or are somehow materially different than the warnings provided for in accordance with the proposed § 25600 (d). By not explicitly noting those warnings called for in court-approved settlements already in existence are considered as “clear and reasonable,” OEHHA puts businesses in the impossible position of having to choose between two different warning statements without clear guidance, risking further lawsuits or contempt proceedings.

Moreover, as the proposed rules are intended to serve as “safe harbor” for businesses to establish “clear and reasonable” warning requirements, OEHHA should also acknowledge the use of other appropriate statements that use different languages can nonetheless meet the requirement. As such, FPPI respectfully asks

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15/ Consent Judgment as to H.J. Heinz Company, L.P. July 22, 2008  
([http://oag.ca.gov/system/files/attachments/press\\_releases/n1595\\_heinz\\_entered\\_cj.pdf](http://oag.ca.gov/system/files/attachments/press_releases/n1595_heinz_entered_cj.pdf)).

OEHHA to consider inserting a new § 25600 (f) to the proposed regulation that states:

“(f) The foregoing does not prevent other appropriate warning statements, including those provided for in court-approved settlements, from being considered “clear and reasonable.””

FPPI also believes that this provision should apply not only to those parties who have settled but to all relevant parties, as 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.

### **Conclusion**

FPPI applauds OEHHA’s efforts in updating these regulations that were originally adopted over 25 years ago. As the national trade association for frozen potato product manufacturers and producers, FPPI’s members face unique challenges in complying with the proposed Prop 65 regulations. 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. FPPI also respectfully submits that OEHHA should not establish a list of “12 chemicals” with no sound scientific basis, and if such list were to be established, acrylamide should not be included on the list. We also encourage OEHHA to ensure that other appropriate warning statements, including those court-approved settlements, can still be considered “clear and reasonable.”

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

Respectfully submitted,



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Frozen Potato Products Institute

cc: The Honorable Richard Bloom, Chair,  
Assembly Budget Subcommittee No. 3  
The Honorable Lois Wolk, Chair, Senate Budget Subcommittee No. 2  
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