Comments on Proposal to Amend Title 22, California Code of Regulations, Section 12705 to Add a New Subsection Providing an Alternative Risk Level for the Chemical Acrylamide in Breads and Cereals.

Submitted to
Office of Environmental Health Hazard Assessment, California Department of Environmental Protection, State of California

By
Barbara J. Petersen, Ph.D., E^{X}ponent, Inc.

On behalf of
The Industry Acrylamide Coalition

Agricultural Council of California
American Bakers Association
American Frozen Foods Institute
American Institute of Baking
American Soybean Association
Baking Association of Canada
California Chamber of Commerce
California Farm Bureau Federation
California Grocers Association
California Hotel and Lodging Association
California League of Food Processors
California Manufacturers and Technology Association
California Restaurant Association
California Retailers Association
Food Products Association
Frozen Potato Products Institute
Grocery Manufacturers Association
Independent Bakers Association
Institute of Shortening and Edible Oils
National Confectioners Association
National Oilseed Processors Association
National Potato Council
National Restaurant Association
North American Millers' Association
Snack Food Association
Tortilla Industry Association
Western Growers Association
Wheat Foods Council

The Office of Environmental Health Hazard Assessment (OEHHA) is proposing to amend Title 22, California Code of Regulations, section 12705 to add a new subsection providing an alternative risk level (ARL) for the chemical acrylamide in breads and cereals. The Industry Acrylamide Coalition (The Coalition) has reviewed the proposal and strongly objects to the concept of an ARL as currently proposed, i.e. an ARL based on the possible nutritional benefits of a single nutrient. The Coalition also believes that the inconsistencies and limitations in the underlying methods and data that were used in reaching the proposed ARL are of sufficient magnitude that the proposal is not scientifically defensible.

The Coalition recommends that OEHHA further consider its proposal. The Coalition's comments on the ARL are summarized below. The first set of comments addresses the broad topic of whether OEHHA can and should define ARLs for subsets of foods. The remaining comments identify problems with the methods and handling of data that were used by OEHHA in its decision making process for the currently proposed ARL.

I. The Coalition believes that all foods contain beneficial components and that sound consideration of public health warrants that OEHHA define an ARL that recognizes that acrylamide formed solely due to cooking and processing does not present undue risks to consumers.

In layman's terms, OEHHA is proposing an ARL that would allow consumers to be exposed to higher amounts of acrylamide from foods that meet a single nutritional characteristic, e.g. dietary fiber. The scientific basis for this selection is weak and not justifiable. In proposing an ARL, OEHHA has not defined nutritional criteria that would justify an ARL for fiber or for any other nutrient. The result is that some foods with greater nutritional benefit will not be subject to an ARL while others with minimal nutritional value, including minimal dietary fiber, will be subject to an ARL. Further, the proposed approach of trading a nutritional benefit for the perceived risks of acrylamide will mislead consumers about health benefits since many other nutrients and minerals that are critical to good nutritional status may be contained in many other foods containing acrylamide. The ARL should clearly recognize that all foods contain beneficial components and that there is inadequate information to justify arbitrarily designating some foods as "good" foods and other foods as "bad" foods based on the existing information about possible effects of acrylamide and possible benefits of selected components of foods. The nutrition community has always advocated the consideration of the total diet in evaluating nutrition and not individual foods.
There is no existing methodology that would allow any scientifically defensible method to balance the nutritional benefits of foods versus possible risks due to acrylamide in those foods. The approach proposed by OEHHA is at best arbitrary and at worst based on inconsistent exposure and risk assessment methods and inadequate consideration of the wide variety of benefits provided by foods. The OEHHA assessments rely on incomplete, incorrect and missing data. The critical data do not exist to fully define nutritional benefits of certain food components or risks due to acrylamide. In fact, FDA has undertaken significant (and expensive) new research

because it identified critical data gaps in its preliminary evaluation of acrylamide. The Coalition believes, as does FDA, that at the present time any ARL that is defined for subsets of foods would be arbitrary and based on inadequate information. The proposal to develop an ARL based on a single nutritional benefit certainly represents potential for much harm. Of particular concern is the potential disruption of nutritional status by using the provisions of Proposition 65 to provide nutritional and dietary guidance to consumers. Proposition 65 has never been used to establish nutrition policy and The Coalition strongly objects to its use for this purpose. The application of the ARL as defined in the OEHHA proposal will confuse and scare consumers without significant benefits in terms of acrylamide risks or in terms of nutritional quality of the diet. This approach would likely cause harm by undermining the credibility of OEHHA possibly to the point where OEHHA's advice will be discounted when situations arise where risks have been confirmed and consumer guidance is appropriate.

The Coalition strongly believes that a food that would not be subject to Proposition 65 in its raw form should not be regulated by Proposition 65 solely because it is cooked or heated. Additionally, The Coalition believes that all foods contain beneficial nutrients and that the ARL should therefore cover all foods. The Coalition continues to urge OEHHA to consider a tailored exemption for acrylamide and other Proposition 65 chemicals that are created as the unintended byproduct of cooking the natural constituents of food.

The sections below provide additional details to support our objection to the application of an ARL to a subset of foods and to the use of Proposition 65 as a tool for guiding consumer's nutritional practices. The Coalition has also concluded that the existing assessments are too preliminary to be relied on for agency decision making regarding potential effects of acrylamide and/or potential benefits of foods. Should OEHHA decide to proceed with the rulemaking process, a great deal more work needs to be done on these regulations in order to assure that any resulting regulations are based on sound science and that they have the intended effect in practice.

Although The Coalition strongly objects to the identification of "good" foods and "bad" foods, if OEHHA continues to adopt this approach it must consider the benefits of all nutrients. In evaluating the beneficial contributions of each food for each nutrient, clear criteria are required to allow determination of which foods contain sufficient levels of the nutrient to justify an ARL. For example, although OEHHA identified fiber as being of sufficient benefit to offset potential risks of acrylamide, OEHHA did not identify the levels of dietary fiber that would justify an ARL for any food or category of foods. The proposed categories mentioned for a proposed ARL in the *Intake of Acrylamide in Food* (March 2005) contain foods with a broad range of fiber concentration. Many foods in other categories would contain fiber concentration above the levels in many of the foods within the proposed categories. And some of the foods for which an ARL is proposed contain very little fiber, e.g. soft white breads. Further, the amounts of foods that are consumed must also be considered since some foods such as soft white breads might contain low concentrations of target nutrients and/or acrylamide, but may be consumed more frequently or in higher amounts.

In the *Intake of Acrylamide in Food,* OEHHA states that it "has conducted an analysis to characterize the daily intake of acrylamide from certain foods, based on currently available data." However, what follows in the OEHHA document is not a single analysis but rather a compilation of analyses conducted by the US FDA[1] and/or by OEHHA using a variety of different sources of data, different assumptions, and different food categorizations. It does not appear that OEHHA has applied consistent criteria for selecting data or methods for the analyses. OEHHA should not rely on this document to guide its establishment of an ARL (or for any other regulatory decision) because it will result in conclusions that are different from those that would be reached if a single comprehensive analysis were conducted using consistent methods, comprehensive datasets and common assumptions.

For most of the exposure estimates presented in OEHHA's Intake of Acrylamide in Food (March 2005), there is inadequate documentation to allow even a knowledgeable reader to understand how the results were derived (e.g. which residue data were used, what food consumption estimates were used and how they were used), let alone to determine how those estimates impact the decisions regarding an ARL or why a particular approach was followed.

Similarly the selection of data can be anticipated to greatly affect the estimates and the choice of an ARL. Yet there is no explanation for why some data were excluded, while other data were included. Likewise there is no explanation as to the choice of methods, or the significance of the weight placed on some estimates as opposed to others. Further, new data are now available from the US FDA and from other sources that are not included in the analyses.

OEHHA has attempted to compile data and analyses from a variety of sources and to create categories of foods to which different NSRLs and/or ARLs would apply. The definitions, terminology and conclusions are not adequately defined or consistently applied. Within the analyses and conclusions there appear to be decisions that are judgments and emotional conclusions that are without a basis in the available scientific datasets. For example, terms such as "high", "highly variably", "moderately confident", etc. are used without definition and in different ways in different sections. Although OEHHA has referenced FDA as a source for many analyses, it is often impossible to determine the specific data and/or methods used by FDA. It is also not clear why OEHHA picked one or another of FDA's analyses. Prior to selecting an ARL for any food or group of foods it is critical that consistent and relevant criteria be established.

The Coalition's detailed comments on each aspect are provided below.

[1] The majority of the consumption amounts in the OEHHA report, Table 1, are based on Robie and DiNovi (2003). Robie gave a presentation in Feb 2003 on their exposure assessment for acrylamide that is also cited in these comments.

II. Food categories used by OEHHA are inconsistent, unrelated to potential acrylamide levels and do not appear to match requirements of Proposition 65 for establishing exposure estimates or for establishing an ARL.

Critically, at least three different food categorization schemes were used within the same document. None of the categories appear to be related to the requirements of categories defined within Proposition 65's regulations.

For example, in the summary, OEHHA noted that food categories used by USDA were generally used. Yet within the body of the report, OEHHA cites different USDA food categories (without defining them) and most of the exposure assessments use "categories" that were created by FDA.

The survey of food consumption used by FDA and cited by OEHHA is the USDA's Continuing Survey of Food Intakes (CSFII). The CSFII food categories do not provide a consistent rationale for risk assessment for foods that may contain acrylamide. Rather they were designed to allow a survey respondent and their interviewer to quickly find the code to be assigned to a food – with the first digit representing a broad food category (1 = dairy, 2 = meats, 5 = grains, fruits, vegetables); the second digit provides more detail (11 = milks and milk drinks, 15 = milk desserts) and so on. In most cases the full code is required to capture the relevant information for useful risk assessments for acrylamide, e.g. variables that affect the levels of acrylamide.

A second set of food categories created by USDA are used for some of the values as cited in Smiciklas et al (2002). These categories were created to use in estimating portion sizes and were not related to the types of ingredients, types of processing or other variables that might be relevant to assessing the concentrations of acrylamide in foods as consumed. Also the Smiciklas categories range from very broad categories to single food items.

Additional food categories were created by FDA and by OEHHA to allow additional foods to be included in their assessments of exposure to acrylamide. The foods that are contained in these codes are not clearly outlined in the document but do appear to be different than either of the categories described above, e.g. canned olives.

Any system of categorization should be based on the anticipated levels of acrylamide in the foods as eaten – e.g. ingredients in the food and the form of the food as consumed (fried versus boiled). Regardless of which categories were used, the categories that are identified by OEHHA do not appear to be based on any rationale that is relevant for assessing exposures to acrylamide or to the nutritional value of the foods within the categories. For example, some categories are single foods (prune juice) while others are large categories (cereals). OEHHA states that in the case of prune juice, an intake was estimated for a single food due to "generally high" acrylamide levels while the levels in the food category (juices) are "generally low". OEHHA makes the statement that consumers of prune juice will be above the NSRL (page 2) but does not consider whether the exposure is due to processing of plums and prunes or due to juice

processing. This is a distinction that would appear to lead to a different regulatory decision in terms of an ARL. There are many beneficial nutrients in fruits and juices and yet these are not considered in the ARL proposal.

The identified categories are not generally based on ingredients, e.g. in the proposed ARL the nutritional benefits have been assigned to some wheat containing foods such as breads and cereals but not for other wheat containing foods such as cakes and cookies. Yet the categories are also not based on nutritional value. OEHHA identifies fiber as a beneficial nutrient that might offset risks of acrylamide so that an ARL can be justified. However, the "high fiber" categories identified in the context of an ARL contain foods that are low in fiber content but nonetheless contain acrylamide.

In many cases, from a risk assessment or regulatory point of view, the categories are essentially undefined (or nebulous) categories, e.g. what would be a cookie and what would be a cracker and how are these defined?

A reliable strategy for establishing an ARL should incorporate categories that are rationally derived and based on creating homogenous groupings in relation to the variables to be applied. The categories also must reflect foods as they are found in the marketplace and in the home and be categories that are meaningful to a consumer. The impact of the arbitrary definitions is highlighted by OEHHA itself in the first paragraph of page 8, where it is noted that average consumption of a single brand of cookie would not exceed the NSRL while eating the average amount of all cookies would exceed the NSRL.

III. OEHHA has not justified its selection of food consumption information to use in the risk assessment in considering the ARL.

The majority of the consumption amounts in the OEHHA report in their Table 1, are based on Robie and DiNovi (2003). In general, FDA relied on the USDA's nationwide surveys for its analysis, but it should be noted that when FDA conducted its original assessments, multiple analyses were conducted using the survey data in different ways. There is no explanation in the document as to why OEHHA selected the subset of FDA analyses that were selected and what the conclusions in regard to the ARL would have been if other FDA analyses had been selected.

Even if the datasets selected by OEHHA are appropriate, little consideration appears to have been given to how the data should be grouped/categorized and evaluated. On page 17, OEHHA states that "USDA (Smiciklas-Wright et al, 2002) includes consumption of infant cereals in its category of ready-to-eat cereals". This is a collapsing strategy used by Smiciklas-Wright for an entirely different purpose. The original food consumption survey collected data not only for infant cereals but by grain type and processing method – variables which are likely to be important in the assessment of acrylamide.

Many of the FDA analyses, including those cited by OEHHA rely on food consumption data that is 15-25 years old and is not expected to be representative of current eating practices. Of particular concern, are the analyses that rely on a 14-day food frequency survey that was conducted between 1982 and 1987. FDA also notes this and states it was included to allow for comparisons but OEHHA should obtain and utilize data that reflect current dietary practices in considering an ARL.

FDA did not include all of the different foods that could be sources of exposure (FDA excluded any foods that individually contributed less than 5% to the population's mean per capita exposure). Proposition 65 evaluates exposure on a per consumer basis so foods that are less than 5% of the population's exposure, might be important sources of exposure to individuals who are consumers of those foods. OEHHA tried to address these foods by using other sources of information. However, the approach used was not consistent with the analyses conducted by FDA. For example, intake of acrylamide from residues in sunflower seeds was estimated using Exponent's software, DEEM. DEEM estimates total daily intake from all sunflower seeds consumed – including those consumed as part of other foods. The comparable analysis for breads, etc. would have evaluated total exposures from wheat not from breads, cookies, etc. Thus the results are not comparable. The analyses using DEEM would not allow a determination of a "source" of the acrylamide exposures, e.g. was it sunflower seeds consumed separately (e.g. sunflower seeds alone) or as part of some baked product.

IV. OEHHA has not adequately incorporated the impact of differences in the frequency of consumption of foods into its assessments and consideration of an ARL.

In its 2003 analyses, FDA reported that total mean population acrylamide intake estimates were 0.48, 0.32, and 0.37 ug/kg bw/day in the 14-day, 3-day and 2-day consumption surveys, respectively. This is consistent with consumer behavior, e.g. in longer term surveys, for any given food, the percent used goes up as more days of individuals' consumption patterns is known and the average daily consumption amounts decline. FDA noted in their presentation that for some food groups this can be quite significant. For example, according to FDA, in the 3-day CSFII survey, 18% of the population were potato chip eaters while in the 14-day MRCA survey, 76% of the population ate potato chips. The impact of such differences should be included as part of the consideration of an ARL.

V. In considering the ARL, OEHHA has not considered the impact of the selection of acrylamide levels or the impact of more recent data.

As noted above, the rationale for selecting and using the available data is not presented. The available data represent levels in foods that have undergone different levels of processing. For example, foods that are collected and analyzed by FDA in the Total Dietary Study (TDS) are prepared following consumer practices whereas other

data collected by FDA may or may not be “consumer ready.” These important differences are not evaluated in the document. FDA’s analyses were conducted early in the evaluation of acrylamide and appear to have been conducted as preliminary or “range finding” assessments. In their Feb. 2003 presentation, FDA pointed out the large variability in acrylamide levels that exists even within a specific food category:

> “There is a significant amount of lot-to-lot variability, even more brand-to-brand variability. Different products can be included in the same food category. I don't want to pick on potato chips here but we have a lot of potato chip data so we have definitely seen this. We have seen differences in lot-to-lot, brand-to-brand and product-to-product. If you have a baked potato chip versus a fried potato chip, they both have acrylamide. The differences between the two are pretty drastic.” – Dr. Robie, Feb 2003.

One example of arbitrary decisions can be seen in the treatment of data for acrylamide in Postum. There is quite a bit of discussion about Postum (a coffee-substitute) which had high levels in the powdered samples (3747 ppb and 5399 ppb) but the level was 93 ppb when brewed. The level used in the intake assessment was the average of the two powdered values (the 93 ppb level was not used). The 1994-98 CSFII has consumption data on “Postum, dry powder” and “Postum, coffee substitute”. It is not clear what food codes were used to estimate intake of acrylamide from Postum consumption and if there was an appropriate adjustment for dilution, processing, etc.

Additionally, the form of the food as consumed is arbitrarily considered - in many cases without regard to likely impact on acrylamide levels. As noted above, exposure from prune juice is highlighted without consideration of whether dried prunes or fresh prunes/plums might also have acrylamide. Such distinctions might lead to a different approach to an ARL for foods containing prunes (and would certainly cause a consumer to avoid prune juice and select prunes). Yet no data are available that would suggest that there is a reason to make a distinction in the labeling of prunes vs. prune juice. Likewise, a distinction appears to be contemplated for canned black olives vs. “fresh olives” vs. “canned green olives.” OEHHA has included no data or discussion to support these assumptions.

It is clear from even a cursory examination of the FDA data that there are some samples with very high levels that might be considered to be “outliers”. It appears that some of these values have been excluded from the analysis. The impact of excluding certain values is not included in the assessment. No criteria are identified for including or excluding outliers or even for determining an adequate sample size. OEHHA does note that “the products sampled may not represent typical samples purchased by the average consumer” (p. 8, first paragraph) but then proceeds with the ARL determination.

OEHHA speaks at length of its treatment of cereals vs. baby food cereals without defining a “baby food” cereal adequately. For example, baby food cereals are defined as not toasted, roasted or fried while other cereals are considered by OEHHA to be

toasted, roasted or fried. Presumably this categorization places oat ring cereals in the non-baby food category. Yet these foods are consumed by babies.

OEHHA appears to believe that canned sweet potatoes have different levels than canned babyfood sweet potatoes. Given the similarity of the product, the difference in the observed levels may be due to the difference in the amount of water in baby food sweet potatoes. Alternatively, the differences may be due to the extremely limited sample sizes and/or inconsistencies in sample collection (4 composites and 4 individual samples for canned sweet potatoes and only 4 composites for baby food sweet potatoes).

It is not apparent that OEHHA has collected any California-specific data to use in their assessment. Proposition 65 applies specifically to foods available to California consumers since regional differences do exist in consumption patterns and food preparation and these should be considered in a decision making aimed at protecting the health of Californians.

The numbers of samples per food types vary enormously (from 1 to thousands). No criteria for adequacy of data or "fitness for purpose" are included in the document, nor does there appear to have been any consistent application of minimum criteria. OEHHA has noted a limitation to their assessments that identified the lack of data and states "where data permit." However it is not clear where OEHHA considered the data to be too limited. Sample size does not appear to have limited any analysis or conclusions for that analysis. Additionally, different methods of sampling are combined. For example, a weighted average for oat ring cereal is determined based on four composites, where each composite is treated as three individual samples, and two individual samples. This is not likely to be a sufficient number of samples to reliably estimate the range of acrylamide in oat ring cereal; nor is mixing composited and individual samples appropriate. Each composited sample is treated as three individual samples so the composited samples gets triple the weight of an individual sample and (artificially) increases the sample size yet does not help to reflect additional variability in acrylamide levels. OEHHA states there are "numerous" (n=104) cereal samples but when broken down by type (and considering the composite issues) there appear to be too few samples to reliably estimate intake.

OEHHA has made no attempt to evaluate the impact of home food preparation on acrylamide levels. The variability in consumers' taste and preparation preferences (preference for crispy fries or burned toast/popcorn, etc.) is also not considered. This may result in faulty conclusions by consumers and must be addressed prior to establishing an ARL.

It does appear that exposure levels may be lower today than the initial FDA assessment predicted, since intake levels calculated by OEHHA appear to be lower when the newer data are included. Elsewhere in the document OEHHA notes that "with each new round of foods tested, new surprises emerge…" This hardly creates a situation where

meaningful guidance can be provided to anyone or that can provide the scientific justification for an ARL.

VI. OEHHA has not appropriately evaluated the potential impact/lack of impact of labeling on food choices by consumers and the corresponding impact on acrylamide exposures in proposing an ARL.

Many foods have been shown to contain acrylamide. The FDA analyses that were the basis of most of the assessments presented by OEHHA also included several "what-if" scenarios. The FDA “what if” scenarios evaluated the effect of eliminating certain sources of acrylamide from the diet on intake of acrylamide. For example, in several cases FDA assumed that the acrylamide level for a certain food would be reduced to “zero” and then estimated acrylamide intake. Based on these evaluations, FDA concluded that no one food accounts for the majority of the mean population intake.

Importantly, FDA did not consider scenarios that resulted in substitution of one food for another. Assuming, as appears to be the case, that acrylamide cannot be reduced to zero in any of the foods that are under consideration for an ARL, then consumers’ exposure are only reduced by changing consumption patterns, e.g. by not eating that food and substituting a food without acrylamide or with lower levels of acrylamide. Yet so many foods contain acrylamide, it is highly likely that the consumer would substitute another acrylamide containing food, e.g. home fries instead of restaurant fries or a different grain-based product instead of cereal.

The impact of substitutions as a result of labeling under Proposition 65 is a critical set of scenarios to be tested that has not been conducted by OEHHA.
Consumers' choices of individual foods when they plan their meals, and particularly their determinations of which foods substitute for another, need to be carefully studied. For example, would consumers substitute a boiled for a fried food – when, how much and under what conditions?

VII. OEHHA has not justified its decisions regarding the underlying exposure assessment model in developing the proposed ARL.

OEHHA did not follow the definitions of an average consumer as specified under Proposition 65, but rather attempted to “mix and match” using per capita data (averaged exposure over eaters and non-eaters) and per user data to try to develop lower and upper bounds on eaters’ exposures to acrylamide. This discussion by OEHHA implies that distributional analyses were conducted – yet that is not the case. Given the difficulty in conducting the required assessment, this approach is somewhat understandable. Nonetheless it is not appropriate and it misuses the standard statistical definitions of “lower and upper bound” exposures. Risk managers are likely to conclude that the results are based on standard risk assessment methods. This is also not the case. Specific limitations in the OEHHA approach include: (1) most of the food

consumption data are derived from 1-2 days of food consumption per individual rather than longer time periods, (2) the food categories are not clearly defined, (3) in many cases the data are out of date and (4) the residue levels of acrylamide are not comprehensive, current and were not selected following standard statistically robust methods.

It also appears that consumption was estimated for the US population, including both adults and children and assumes a standard 70 kg bodyweight. This is not necessary since individual body weights accompany each individual's food consumption in the USDA surveys.

OEHHA did not look at different population groups. Several of the foods that are the top contributors to acrylamide intake in the total population would not be in the top contributors for children. For example, coffee would not be the main contributor to children's exposure.

VIII. In developing the proposed ARL, OEHHA makes sweeping (and often arbitrary) statements that are not supported by the underlying data and/or assessments.

OEHHA states on page 1 of their report that it is likely that all or most of the fried potatoes, potato chips, coffee, cookies, cereals, breads and toasts that have been tested would exceed the proposed NSRL of 1.0 ug/day. This statement is unlikely to be confirmed when statistically based robust data sets come available. In particular it should be noted that a relatively wide range of values are seen and to date there are relatively few samples that have been analyzed. Virtually NO samples of foods prepared in the home have been analyzed.

On page 15, OEHHA concludes that the levels in almonds are "high." This conclusion is not based on any apparent criteria, so we do not know how OEHHA determined that the levels are "high." Further the analysis is based on the analysis of only 4 individual samples. OEHHA also notes that prune juice levels are "high" yet those values are about half the level of almonds (159 ppb in prune juice, (N=14) vs. 320 ppb in almonds (N=4). The lack of consistent definitions as well as the wide range in the degree of robustness of the underlying data demand further work before consideration of an ARL.

The term "variability" is applied loosely and in non-consistent ways. For example, a set of chocolate samples were flagged as "highly variable" (because the levels ranged from non-detect to 900 ppb although the majority were low and non-detects). However, no distinction was made in the types of chocolate products (chocolate bars, mixes, cocoas), etc.

Throughout the document OEHHA assesses its own degree of confidence without any indication of its criteria. Examples of OEHHA's undefined criteria include "high confidence" and, "moderately high confidence". . Confidence should be based on the

quality and quantity of underlying data and the relevance of the methods used in evaluating that data for the intended purpose, e.g. complying with the requirements of Proposition 65. That does not appear to be the case.

On page 2 of their report, OEHHA concludes that consumers of "specialty foods such as Wheatena, roasted grain-based coffee substitutes, and prune juice, are exposed in excess of the NSRL". This is a strong conclusion that is based on N=3 samples for Wheatena (with a range in levels from 467 to 4057 ppb) and consumption data based on one serving size as listed on the Wheatena box, N=2 for the coffee substitutes (Postum) and N=13 for prune juice. And in the case of the prune juice, 12 of those 13 samples are actually 4 composite samples from the FDA's TDS with OEHHA counting each composite sample as 3 individual samples from TDS. While this approach does increase the perceived sample size, it does not provide any additional information on the potential variability of the acrylamide levels in those foods. The next sentence lists foods for which eaters "may" exceed the NSRL (canned black olives, popcorn, crackers, corn and tortilla chips). OEHHA then goes on to say "There is less confidence in either the food consumption data or the acrylamide concentration data, or both, for these foods." This makes it very unclear why OEHHA would have less confidence in these foods as compared to the foods listed in the previous sentence (Wheatena, prune juice) since the number of samples for these foods is often higher (popcorn N = 15 and olives N = 19). Additionally, the consumption data for Wheatena was based on "one serving size as appears on the box label" yet OEHHA did not state they had "less confidence" in this consumption data.

In another example, on page 12, "OEHHA has a moderately high degree of confidence that the acrylamide intake of the average eaters of most ready-to-eat cereals exceeds the NSRL (See Tables 1-2). Conversely on page 17, "OEHHA has limited confidence in determining if acrylamide levels in baby foods exceed the proposed NSRL, except in cases where these foods are also consumed in adulthood…" Yet, there is far more data for infant cereals than for other cereals. In fact there is no data for many brands of non baby cereals and even where there are data there are only results for a few samples.

OEHHA highlights some analyses by FDA for "soft breads" (all types) -- again without definitions or rationale for the category.

On page 13, OEHHA discusses assessments for "white breads" (presumably breads made from refined white flour) and apparently concludes that exposures would be lower if these breads are consumed instead of breads made from whole grains. Such advice would clearly be in direct conflict with Nutritional Guidelines yet the ARL is based on encouraging high fiber consumption.

Assessments are reported on page 14 for "total yeast breads" as though yeast might be an important determinant of acrylamide levels in bread. Yet no data are presented to support or refute that categorization.

IX. CONCLUSIONS

Although OEHHA has prepared a document outlining rough ranges of exposures to acrylamide in different foods, *Intake of Acrylamide in Food* (dated March 2005), has conducted workshops, and has undertaken other tasks to consider the potential risks of acrylamide, much more work is required to allow a science based policy to be established. At the present time, there are significant limitations that preclude any regulatory decision making including the establishment of an ARL for acrylamide.

OEHHA has not defined the nutritional criteria that would justify the application of an ARL to selected foods beyond a brief mention of the concept of high fiber foods. There has been no identification of nutrients that are of sufficient benefit to justify risks of acrylamide, or any other substance, nor any proposal of criteria for amounts that should be present or the relationship of the benefit to the implied risks, etc.

The proposed approach of trading a nutritional benefit for other risks will confuse consumers without providing any documented health benefits. Since there are many other nutrients and minerals that are critical to good nutritional status, it is the total diet and not a single food that must be considered to determine whether nutrient intake is adequate.

Acrylamide has been found in a wide range of foods as a result using traditional, age-old methods of cooking and processing rendering commodities edible, palatable and acceptable to consumers. The estimated exposures to acrylamide that have been presented by OEHHA are very preliminary, inconsistent and inadequate for establishing public policy. And in particular OEHHA has not included in its exposure estimates the acrylamide formed in many home-prepared foods.

The effects of acrylamide remain uncertain and no warnings should be made until the on-going data collection and evaluations of safety are complete. Again, there are significant limitations that preclude any regulatory decision making including the establishment of an ARL for acrylamide.