IACI Idaho Association of Commerce & Industry

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Ms. Susan Luong
Office of Environmental Health Hazard Assessment (OEHHA)
Proposition 65 Implementation Program
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RE: Comments in support of rules providing a limited exemption from the warning requirements of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), under specified circumstances, for exposures to listed chemicals that form in food solely as a result of naturally occurring constituents in the food being cooked or heat processed.

Dear Ms. Luong:

I am writing to express support for rules which would provide an exemption from the warning requirements of Proposition 65 for certain listed chemicals that form in food solely as a result of naturally occurring constituents in the food being cooked or heat processed. Specifically, in this letter, I will address acrylamide.

STATEMENT OF INTEREST

The Idaho Association of Commerce and Industry (IACI) is the largest business organization in Idaho, representing a diverse range of businesses and industry associations throughout Idaho. Our membership includes many farm organizations as well as companies in food processing and agricultural industries that market food products in California. Food processing companies alone employ 12,855 people (2003) in Idaho.

Idaho is a major agricultural state, probably best known for our production of potatoes. Idaho is first in the nation in potato production, totaling more than 13 billion pounds per year. Almost 60 percent of Idaho's crop is processed; and, because of the excellent storage characteristics of Idaho potatoes, the crop is shipped and processed throughout the year. The typical American consumes 140 pounds of potatoes yearly, either as fresh or processed products. Only wheat flour exceeds the consumption of potatoes in per capita use in the American diet.

In addition to potatoes, Idaho ranks in the top six nationally in production of milk, commercial trout, spring wheat, barley, dry beans, sugar beets, hops, spearmint, alfalfa hay, sweet cherries, prunes and plums, and summer storage onions. All of these products are marketed in California. It is clear that the application of California food labeling warnings

under Proposition 65 has a direct economic impact on IACI members, as well as on the general economy of Idaho.

COMMENTS

IACI agrees with the concerns raised in your April 8, 2005 ***Notice to Interested Parties***: *"... providing Proposition 65 warnings on many common food products may cause some consumers to avoid foods that may be necessary for a balanced diet."* In particular, we are concerned with:

- *". . . over-warning or warning fatigue"*
- *". . . potential for conflict with federal food labeling laws."*

With this in mind, we offer the following general and specific comments regarding the proposed rule:

Scientific Knowledge about Acrylamide is Expanding Rapidly so Warning Labels are Premature:

Requiring that foods containing acrylamide, which forms naturally during the cooking or heating process, would be an unnecessarily hasty decision. Such labeling is premature since the scientific knowledge about acrylamide is expanding rapidly and seems to be shifting away from the idea that acrylamide that naturally occurs in food being heated or cooked increases the risk of cancer. It is true that just three years ago studies by Swedish scientists concluded that acrylamide was a probable human carcinogen. However, as Dr. J.H. Exon of the University of Idaho's Department of Food Science and Toxicology stated in a recent article entitled A Review of the Toxicology of Acrylamide, "Acrylamide is classified as a 'probable human carcinogen.' The basis for this classification is [in part that] … *there is insufficient evidence of any carcinogenic effects in humans from epidemiological studies or occumpational exposure.*" See Attached at 16-17. Further, the results of the Swedish scientist have spawned more than 200 new research projects worldwide which are coordinated and evaluated by governments, the European Union, the U.S. Food and Drug Administration and the United Nations. Id. at 5.

The public health risks are still being determined by these ongoing studies. For instance, a new study by the Harvard School of Public Health and the Karolinska Institute in Stockholm, Sweden, suggests the amount of acrylamide in the diet does not pose an increased risk of breast cancer. Further, early animal studies used acrylamide exposure rates of 1,000 to 10,000 times greater than exposures through human diets. Additionally, researchers are finding other important information, including new processing techniques that can reduce acrylamide levels.

In speaking about the carcinogenic affects of acrylamide, Dr. Exon stated:

> Acrylamide (ACR) is a chemical used in many industries around the world and more recently has been found to form naturally in foods cooked at high temperatures. It has been shown to be a … carcinogen in animal species. … [However] The DNA adducts that form [as a result of interaction with acrylamide] do not correlate with tumor sites and ACR is

> mostly negative in gene mutation assays except at high doses which may not be achievable in the diet. All epidemiologic studies fail to show any increased risk of cancer from either high level occupational exposure or the low levels found in the diet. In fact, two of the epidemiologic studies show a decrease in cancer of the large bowel. A number of risk assessment studies have been performed to estimate increased cancer risk. The results of these studies are highly variable depending on the model. Regulatory agencies in several countries do not endorse the use of risk assessment models in estimating human cancer risk because assumptions are made beyond the scientific database and the values obtained are purely hypothetical. *There is universal consensus among international food safety groups in all countries that have examined the issue of ACR in the diet that not enough information is available at this time to make informed decisions on which to base any regulatory action. Too little is known about levels of this chemical in different foods and the potential risk from dietary exposure. Avoidance of foods containing ACR would result in worse health issues from an unbalanced diet or pathogens from under cooked foods. There is consensus that low levels of ACR in the diet are not a concern for neurotoxicity or reproductive toxicity and any relationship to cancer risk is strictly hypothetical*.

See Attached at pp. 3-4 (emphasis added). He continues:

> [T]here is no epidemiologic evidence that dietary ACR increases the risk of cancer in humans. … Most of these [cancer risk assessment] studies have used an average exposure level of 1 µg ACR/kg bw/da in a 65-70 kg person as the standard. The study by the Norwegian group estimated an increased cancer incidence of 6/10,000 individuals on average with children a little higher based on eating habits (Dybing and Sanner, 2003). Other estimates using this level of exposure have estimated increased incidences of cancer in groups of 10,000 to range from 7 (WHO 1996) to 45 (EPA 1993). *The 1 µg/kg bw/da is considered a high average dose based on actually studies that have estimated average daily consumption of ACR in the diet*. The estimated average daily intake of ACR in µg/kg bw/da from several studies has been 0.46-0.49 (Dybing and Sanner, 2003), 0.46 (Konings *et al.*, 2003), 0.5 (Svensson *et al.*, 2003), 0.3-0.8 (Mucci *et al.*, 2003; FAO/WHO 2003). The exposure estimates also vary with age groups with the highest exposure expected in children based on weight differences. A study in Belgium adolescents estimate median dietary exposure at 0.51 µg/kg bw/da with 95th percentile as high as 1.09 µg/kg bw/da (Matthys *et al.*, 2005). When the actual dietary exposure to ACR is used in risk estimates, the hypothetical risk of increased cancer incidence is much lower ranging from less than one to 4.5 per 10,000 individuals.

Id. at 22-23 (emphasis added).

Dr. Exon also addresses the inconsistencies among the results of tests to determine the levels of acrylamide in certain foods:

> Not all foods have been tested for ACR levels and the concentrations vary greatly in foods that have been tested, even within the same food types, brands and batches. Also, foods with low levels of ACR could account for significant exposure based on volume consumed in certain populations (e.g. coffee). Conversely, those foods with higher levels may contribute very little. In addition, there are significant differences in exposures based on cultural eating habits in different countries.

Id. at 23-24. Notwithstanding the Swedish scientists' acrylamide testing results, the majority of subsequent scientific data seems to conclude that acrylamide that naturally occurs in the foods we consume daily does not increase the risk of cancer in humans. Dr. Exon's conclusion most accurately states the position of IACI:

> Acrylamide is a rodent carcinogen when given at high doses or promoted with strong promoting agents. *There is no evidence from occupational or dietary exposures that ACR increases cancer risk in humans*. All epidemiologic studies are negative although some of these studies may lack the statistical power to detect small increases in cancer incidence related to diet. …
>
> *There is consensus among regulatory groups in a number of countries that not enough information is available concerning the amount of ACR in different foods*. Also, the amount that is there varies greatly even within the same brands and batches. There is also not enough information about the health effects of these low levels of ACR in the diet. Consequently, no … food safety group or government agency is recommending any changes in our food choices at this time to avoid foods that contain ACR. This could in fact result in dietary imbalances, nutritional issues or other food safety issues such as under cooked foods.

For example, a late 2002 study of french-fries at fast foods restaurants found varying ppb rates of acrylamide in McDonald's french-fries. The seven locations show ppb results of 193, 328, 155, 326, 245, 270, and 497. (http://www.cfsan.fda.gov/~dms/acrydata.html).

Research on acrylamide is still in its infancy and the results are not certain. In fact, the U.S. Food and Drug Administration's (FDA) studies on acrylamide, which began shortly after the discovery of acrylamide in 2002, are not expected to be concluded until 2007. (http://www.fda.gov/bbs/topics/news/2005/NEW01161.html). As such, any warning label requirements for acrylamide which forms in food solely as a result of naturally occurring constituents in the food being cooked or heat processed would be premature.

Determine which chemicals are to be included in warning exemptions:

OEHHA's proposed regulations are specifically directed at warning exemptions for certain levels of *acrylamide* found in food. However, further research may reveal other

unintended by-products of cooking various foods that may also logically be included in the exemption rules. To this extent, we urge OEHHA to thoroughly research this issue.

Be mindful of over-warning or warning fatigue:

In its April 8, 2005 Notice to Interested Parties, OWHHA discussed the concern of over-warning or warning fatigue. This same concern over Proposition 65 was raised by the Health and Welfare Agency in Nicolle-Wagner v. Deukmejian, 281 Cal. Rptr. 494 (Cal. Ct. App. 1991). In that case, a group of citizens challenged the agency's promulgation of a rule which exempted certain naturally occurring carcinogens from the warning requirements of Proposition 65. Id. at 495-96. The California Appellate Court upheld the regulation in part because "'[a]bsence of such an exemption could unnecessarily reduce the availability of certain foods or could lead to unnecessary warnings, which could *distract the public from other important warnings on consumer products*.' … [S]uch warnings would be diluted to the point of meaninglessness." Id. at 499.

While the labeling requirements of Proposition 65 are beneficial to the people of California, too many warning labels on too many consumer products may become counterproductive to the goals of Proposition 65. As more and more labels are placed on more and more consumer products, there is likelihood that these labels will lose their effectiveness as the citizens of California become immure to their message. Additionally, given the unsettled nature of the scientific knowledge about acrylamide discussed above, the risk of over-warning or warning fatigue is a risk that should not be taken at this time.

Be sensitive to the potential conflict between California warning labeling regulations and federal food labeling statutes and regulations:

The nature of food marketing in the United States, and our success in providing abundant and affordable food products to our citizens, relies on an efficient distribution system. Currently, there is significant federal involvement in dealing with the acrylamide issue. For example, the FDA is actively working to develop procedures for detecting acrylamide in food products. These activities, in conjunction with the studies discussed above, are providing new insight into the nature and extent of naturally occurring acrylamide in foods like potatoes. Finally, there are many U.S. statutes and regulations that govern food labeling in interstate commerce. We would caution OEHHA to ensure that any regulations passed on this matter do not improperly interfere with these requirements or with interstate commerce in general.

Consider the economic impacts to consumers, state governments, farmers, processors and retailers:

We understand that protecting public health is the main responsibility of OEHHA, and we support that mission. Likewise, Idaho's agricultural and food industry is committed to supplying safe and abundant food to consumers worldwide. However, regulation in the name of public health that does not improve food safety increases the cost of food to consumers, causes confusion and skepticism and makes it more difficult for the food industry to feed our citizens.

Idaho's agricultural and food industry does a significant amount of business with California each year. When it comes to potatoes, one of the food products directly affected by the proposed rule, one large Idaho company records the following annual business:

1. Total frozen foodservice potato volume into California: 730MM lbs.
2. Total frozen foodservice potato sales volume into California: $255MM
3. Sale to California food service operators: $306MM .
4. Approximate number of servings: 2.92 billion
5. Approximate profit of all California operators for frozen foodservice potato products: $3.8 billion

It is clear that impact of the warning requirements of Proposition 65 would have an affect that reaches far beyond the California borders.

The Considered Exemption is Consistent with the Purposes of Proposition 65:

The California courts have addressed rules under Proposition 65 which created an exception to the warning requirements. Nicolle-Wagner v. Deukmejian, 281 Cal. Rptr. 494 (Cal. Ct. App. 1991). As mentioned above, this case involved a suit brought by a group of citizens to challenge the Health & Welfare Agency's promulgation of a rule which exempted certain naturally occurring carcinogens from Proposition 65's warning requirements. Id. at 495-96. The specific issue before the court was whether or not such an exception conflicted "with the language of the act, and whether that regulation [was] reasonably necessary to effectuate the purposes of the act." Id. at 494. The court upheld the exception, which was promulgated as Section 12501.

In making its conclusion, the court asserted that, while the statutory language does not expressly distinguish between manmade and naturally occurring substances, the implication of the language is that Proposition 65 only intended to regulate manmade substances. Id. at 497-98. Specifically, the statute "provides that 'no person in the course of doing business shall *knowingly and intentionally expose* any individual.'" Id. at 498. Such language suggests "that some degree of human activity … is required." Id. It is clear, as the court concluded, that some degree of human culpability is required and that a "chemical is not 'put' into the environment it is naturally occurring in, for example, fruits and vegetables." Id. In fact, "human conduct which results in toxins being *added* to the environment is the activity to be controlled." Id. Finally, the court recognized that the exception was narrowly drawn and would only affect a limited number of substances. Id. at 499.

The proposed changes to Section 12705 are consistent with the court's holding in Nicole-Wagner. Much like the purpose of Section 12501, OEHHA is attempting to regulate a substance – acrylamide – that *naturally occurs* in foods that must be cooked. There is no intent on the part of farmers, producers or retailers to put acrylamide in the foods. Further, while certain forms of cooking may limit the amount of acrylamide in the products, there is no known way to remove the acrylamide altogether from the foods. As the Nicolle-Wagner court stated: "We all presume, so some extent that foods that have been eaten for thousands of years are healthful, despite the presence of small amounts of naturally occurring toxins." Id. Such is the case with potatoes – and many of the other

foods known to have acrylamide (i.e. grain-based breads and cereals as addressed specifically in Section 12705(e)).

The purpose of Proposition 65 is to provide meaningful warnings about carcinogens in the food/water of the citizens of California. However, this purpose is not met when warnings are so ubiquitous that they are "diluted to the point of meaninglessness." Id. Accordingly, this exception, which provides an alternate level for naturally occurring substances, is consistent with the purpose of Proposition 65.

Specific Comment as to Section 12705(e):

We appreciate an exception of Section 12705(e) which provides an alternative no significant risk level for grain-based breads and cereals. We agree that such foods "are important sources of dietary fiber and nutrients." In relation to this rule, we have two comments:

1. We are of the opinion that potatoes, much like the grain-based breads and cereals addressed in the amended section, are an important source of nutrients. As discussed above, potatoes are the second most consumed food items in the American diet (at 140 pound per year it is surpassed only by wheat flour). As such, potatoes and potato products should be included in the "alternative no significant risk level for" acrylamide.

2. Further, given the current state of scientific research, the restriction of subsection (e)(1)(a) appears to be quite stringent. As discussed above, there have been a number of studies addressing the increase in cancer risk on humans. These studies have tested with acrylamide levels ranging from .46 to 1.00 µg/kg bw/da. The general consensus among researchers is that, on average, .3-.8 µg/kg bw/da are consumed. The results from these studies have shown an increase of one to seven cases of cancer per 10,000 people. To a great extent, these numbers are based on the acrylamide exposure level. Those with higher exposure levels had higher increases of cancer. OEHAA should consider raising this standard slightly to more accurately reflect the wide range of test results.

CONCLUSION

We appreciate the opportunity to participate in the formal rulemaking. Good science and good knowledge is the basis for good regulation.

Sincerely,

Richard R. Rush
Vice President for Natural Resources

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