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April 2, 2008

Dr. Richard Raymond,
Under Secretary for Food Safety, Department of Agriculture
% Mr. Keith Payne
Food Safety and Inspection Service, Room 405
1400 Independence Ave., SW
Aerospace Building
Washington, DC 20250

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2008-0011
2008-0011-4
Harlen E. Clemmons

Re: FSIS Food Safety Public Meeting on April 9-10, 2008

Dear Dr. Raymond:

I enjoyed visiting with you during the House Oversight Subcommittee hearing on March 12. As you are aware, Sadex provided the irradiated product displayed and tasted at the hearing. I am pleased that your visit to our plant in May of last year allowed you to see Sadex's capabilities firsthand.

Irradiation is by no means a new technology. The USDA, FSIS, and ARS have years of study and published documentation which substantiates irradiation as a "Kill Step" which is safe, effective, and economical.

During the hearing on March 12th, Dr. Sundlof stated that furan was the reason the FDA has delayed the approval of the USDA petitions to allow irradiation of Ready to Eat Foods (RTEs). USDA/ARS researchers have studied the formation of furan with irradiation in great detail over the last four years. Their findings substantiate that furan is not a problem and the FDA's concern is unfounded. FDA, for some reason, has chosen to dig in their heels and use the furan issue to compromise food safety by preventing these products from being irradiated.

Although furan is the FDA's current primary issue, there is another FDA hurdle which could prevent irradiation of many RTEs. The polymers used in most food packaging are fully approved for irradiation, but the additives used in these packaging films do not have full approval. The FDA's concerns about these additives are unfounded. The irony is that it might be possible to irradiate a RTE product, but then there would be no FDA approved packaging material to put it in. This is similar to the situation we faced in 2005, when FDA temporarily withdrew approval of the packaging material for irradiated ground beef. Clearly, this is an issue that needs immediate attention.

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I am attaching a copy of supplemental testimony presented to the Oversight Subcommittee by Professor Dennis Olson, whose testimony includes references to the USDA/ARS research papers on furan.

Dr. Raymond, as a public health official, you stated "to prevent and not just respond to illness" is critical for restoring trust in our nation's food supply. I agree with you completely.

If we may be of service to you in connection with the FSIS hearing on April 9th and 10th, or in any other matter, please feel free to call on me. I have attached a copy of our picture at the March 12 Food Safety hearing that appeared in the iiA Newsletter.

Regards,

Harlan E. Clemmons,
President
Sadex Corporation

Enclosures

1. Dr. Olson's Supplemental Testimony
2. iiA Newsletter

Extended Testimony by Dennis G. Olson
Subcommittee on Oversight and Investigations
Committee of Energy and commerce
U.S. House of Representatives

March 12, 2008

Comments on Furan:

Furan:

Furan is a colorless liquid with a low boiling point of approximately 89 degrees Fahrenheit. This means that at ambient temperatures it would easily enter a gas phase, or evaporate. Furan is produced naturally when certain compounds are heated, but because of its volatility and reactivity it quickly dissipates. The result is that under most circumstances, human exposure to furan is virtually nil. One exception to that rule is that some compounds in food produce furan when they are heated.

Cooking foods that contain these compounds will result in the formation of minute amounts of furan. However, since cooking temperatures exceed 89 degrees, furan instantly enters a gas phase. Some of the furan will react with food components, the rest will dissipate as soon as it reaches the surface of the food. People will be exposed to furan only if they eat the food before the furan has an opportunity to escape.

FDA Concern:

The FDA's heightened concern about furan was a combination of three factors: 1) the fact that furan is listed by the Department of Health and Human Services (DHHS) as a possible carcinogen, 2) the unexpected discovery that a number of food compounds can produce furan when heated, and 3) that foods heated in air tight containers, for example cans and plastic wrap, can have detectable levels of furan when finally opened. Canning and air tight plastic does not allow the furan to escape after heating, until the package is opened. At which point it dissipates as in conventionally heated food.

Furan is listed by US DHHS and by the International Agency for Research on Cancer (IARC) as a possible carcinogen. The primary basis for this listing is a series of feeding studies on rodents reported by the National Toxicity Program. The threshold concentration for damage to rodents in those studies appeared to be at dietary concentrations of 2mg/kg (2 parts per million). The initial study conducted by the National Toxicity Program found carcinogenic effects at levels of 2mg/kg fed 5 days a week. A second bioassay study confirmed carcinogenic effects at levels above 2mg/kg, but not at dietary levels below that amount. This would suggest that, at least in rodents, the threshold dietary level for toxic effects is 2mg/kg/day.

The FDA recently estimated the current dietary exposure to furan in US adults to be .26ug/kg (0.26 parts per billion) for the mean, and .61ug/kg for those in the 90^{th} percentile of exposure

(those with highest exposure) (1). To put this in perspective, the minimum exposure known to cause effects in rodents is more than 7,000 times greater than the FDA estimated human exposure.

The operative assumption of high dose risk analysis is that if relatively short term exposure to high concentrations of a chemical can cause damage, then, low dose exposure over a longer period may have a similar effect. Whatever the merits of high dose studies in identifying potential chemical risks, that method can have severe limitations when applied to compounds in food. Many components of food, if ingested in artificially high concentrations, can cause injury or disease. On the other hand, many of those same components in normal concentrations are beneficial, and sometimes are even essential elements in the diet.

The other limitation of equating high dose damage with low dose exposure is the issue of cumulative effects. Chemicals that accumulate in the body or that cause cumulative, irreversible damage are the real targets of concern. Furandoes not fit that profile. It is readily metabolized, which means that it does not accumulate. In addition, furan's metabolic by-products are not known to pose any health danger, and are quickly removed by normal bodily processes.

Furan is not added to food, as stated above, it is formed when certain foods are heated.. Heat adds energy, and the energy induces the chemical changes that result in furan. The FDA has published furan concentration data for off the shelf foods, and the results show, as expected, that canned products tend to have the highest levels of furans. As mentioned above, the furans produced in heating cannot escape from the can. Nonetheless, the types of foods that produce detectible furan when canned would also produce furan when heated in the kitchen. As a result, potential furan exposure is not limited to canned products, but exists whenever food is cooked, and immediately eaten.

People have been cooking their food for generations, they tend to eat it while it is hot and theoretically contains furan. In effect, we have a long term feeding study on furan that spans human history.

The FDA estimate of furan exposure in adults suggests that the primary source of furan in the adult diet is brewed coffee. In fact, FDA estimate that approximately 60% of the mean exposure to humans is attributable to brewed coffee (.15ug/kg out of .26ug/kg). Without brewed coffee, furan exposure in the diet drops from 1/7,000 of the level known to cause harm down to 1/18,000. The rodents in the studies cited by FDA only showed damage when given furan at levels of 2mg/kg/day. In other words, at the level at which damage appeared, the rodents received as much furan (by weight) in 24 hours as a human would ingest in 50 years (no coffee) or 21 years (with coffee).

When the relatively high concentration of furan required to cause harm is considered in combination with the fact that humans have eaten heated food and any resulting furan for ages, the practical conclusion would seem to be that furan in food should have an extremely low priority. This is particularly true since the level of furan in most food is at the margin of what modern science can detect and quantify.

Of course, the potential risk of furan is only part of the story. The press has reported that brewed coffee may have health benefits. If true, those benefits may be attributable to furan and its associated compounds. Dr. Takauki Shibamoto and other researchers at UC Davis have studied heat-induced compounds in food, including furans, for nearly 30 years. They have determined that furan is a strong antioxidant, that it is present in relatively high concentrations in brewed coffee (as confirmed by FDA), and that the aggregate effect of the antioxidant constituents in coffee could prevent disease by stopping oxidative damage (2). In other words, if people drank more coffee, and thereby increased their consumption of furans, they might be healthier.

Furan and Irradiation:

While irradiation is a "cold" process, it does add energy to food. In fact, it is the sudden burst of energy from irradiation that destroys pathogens. Heating food also adds energy. As a result, the compounds produced by heating of food are virtually identical to the compounds produced through irradiation. The difference is that compared to heating, the energy-induced changes in food due to irradiation are far less extensive, and in many cases are undetectable. Nonetheless, irradiation of certain foods can cause the formation of furan, as would occur if those same foods were heated.

In 1997, in response to a large number of pathogen related recalls, Congress required the FDA to adopt an "expedited" procedure for approving methods to control pathogens. Irradiation was specifically identified as a technology for which expedited review was expected. Two years later the, so called, Ready-to-Eat (RTE) petition was filed on behalf of the Food Irradiation Coalition by the National Food Processors Association. Two companion petitions were submitted at the same time by the USDA. These petitions, when approved, would allow a great many additional foods to be irradiated for pathogen control.

FDA immediately placed the three petitions in "expedited" status, and presumably began its review. Now, more than eight years later, the FDA still has not made a final determination. For purposes of the following discussion, the foods covered by the RTE petition can be divided into three categories: 1) leafy greens, including lettuce and spinach, 2) other fruits and vegetables, and 3) meat and poultry products, including hot dogs and deli meats.

Leafy greens have been the subject of frequent recalls, the most notable being the recall of bagged salads in the fall of 2006 due to contamination by E. coli 0157: H7. Hot dogs and luncheon meats have also been the subject of large recalls, frequently for contamination by Listeria monocytogenes. Since leafy greens and ready to eat meat products are often eaten right from the package, any pathogen contamination is passed directly to the consumer. Irradiation can kill the pathogens in the package without damaging the quality of the food. However, before that can happen, FDA must approve the pending petitions.

From the time FDA began to focus on furan in 2004, the agency has stated that it could not approve the RTE petition until the effect of irradiation on furan levels could be determined. In fact, FDA has suggested, most recently on March 12, 2008, before a House Energy and Commerce Subcommittee, that the only remaining hurdle to approval of the RTE petition is the furan evaluation.

FDA has solicited information on furan from other agencies and from research scientists. In addition, the FDA has done extensive testing of furan levels in a variety of off-the-shelf foods, and has published those results in a series of reports. The foods that had some of the highest levels of furan were canned baby food. In fact, FDA estimates that dietary exposure to furan is more than 50% greater in infants than in adults.

The FDA has also done extensive testing of furan levels in irradiated foods, however, that information has not been published. Notwithstanding the FDA's failure to release its data, scientists outside the FDA have published a significant body of research concerning the effect of irradiation on furan. As a result, definitive conclusions are now possible. The primary source of this research comes from the Agricultural Research Service of the USDA, and consists of both extensive literature reviews and original research. The result is a series of articles, including those listed below (3).

Based on the studies by USDA scientists, the conclusions with respect to the three categories of food covered by the RTE petition can be summarized as follows:

1. Leafy Greens: There is no detectible furan produced at irradiation levels of 5 kGy. That dose level is higher than the dose sought to be approved under the RTE petition (4.5 kGy for products not frozen), and is approximately three times the average dose likely to be used for commercial treatment of leafy greens, including spinach and lettuce.

2. RTE Meat and Poultry Products:

    a) Although it is possible for irradiation to induce furan in simple solutions of some ingredients, the USDA researchers found no detectable furan produced by irradiation of the actual meat and poultry products themselves. There was no furan induced at doses of 4.5 kGy in refrigerated products or at 10 kGy in frozen products. In other words, no detectable furan is produced due to irradiation of meat and poultry products at the doses requested in the RTE petition (4.5 kGy refrigerated and 10 kGy frozen).

    b) Certain heat processed meat products, such as hot dogs, had low levels of furan, measured at 6 to 8 ng/g in their retail packages (ng/g and ug/kg both denote parts per billion). However, when those products were irradiated, the original levels of furan were **reduced** by 25-40% as a result of the irradiation treatment.

3. Other Fruits and Vegetables: USDA scientists used the FDA method for measuring furan concentrations in a number of common fruits and vegetables. Out of fifteen fruits and vegetables tested, only grapes had detectable furan. The furan level in irradiated grapes, at 2 ng/g, was just above the level of detection. When the USDA employed a more sensitive methodology, irradiated pineapple also showed detectable furan. The researchers concluded that the common feature of grapes and pineapple is a high sugar content in combination with high acidity.

In summary, none of the products commonly thought of as vegetables produced furan when irradiated. Among fruits, only those with both high sugar concentrations and high acidity produced furan under irradiation. Even then, the furan levels were just above the level of detection, using the most stringent experimental protocols.

Conclusion:

While FDA sets the gold standard in the world to ensure that food additives not be used if they would jeopardize human health, furan and irradiation are neither food additives.

The risk of furan in normal dietary concentrations for both infants and adults is pure speculation. Human exposure at current levels has likely been present for generations, and is compelling evidence that furan does not pose a dietary risk. In addition, the limited amount of research on furan in the human diet suggests that the anti-oxidant properties of furan may be beneficial.

Regardless of the final verdict on furan, there is absolutely no scientific basis for withholding approval of irradiation because of a potential increase in furan. Research has shown that irradiation of leafy greens, vegetables and meat and deli products does not produce furan. In fact, research on the chemistry of furan formation indicates that for leafy greens and vegetables, furan production would be impossible. In the case of fruits, only fruits with a combination of high sugar and high acidity have the potential to produce furan with irradiation. In the fruits tested, only grapes and pineapple fell in that class.

Citations:

(1) DiNovi, M. and Mihalov, J. An Updated Exposure Assessment for Furan from the Consumption of Adult and Baby foods. April 18, 2007
http://www.cfsan.fda.gov/~dms/furanexp/sld01.htm

(2) Yanagimoto K, Ochi H, Lee K-G, Shibamoto T. 2004. Antioxidative activities of fractions obtained from brewed coffee. J. Agric. Food Chem. 52:592-596.

(3) ARS Published Research:
Fan X. 2005. Formation of furan from carbohydrates and ascorbic acid following exposure to ionizing radiation and thermal processing. J Agric Food Chem 53:7826–31.

Fan X. 2005. Impact of ionizing radiation and thermal treatments on furan levels in fruit juice. J Food Sci 71:E409–14.

Fan X, Sommers CH 2006. Effect of gamma radiation on the formation of furan in ready-to-eat products and their ingredients. J Food Sci 71:C407–12.

Fan, X. and Mastovska, K. 2006. Effectiveness of Ionizing Radiation in Reducing Furan and Acrylamide Levels in Foods. J Agric Food Chem 54:8266-70

Fan, X. and Sokorai, K.J.B. 2008. Effect of ionizing radiation on furan formation in fresh-cut fruits and vegetables. J Food Sci 73:C79-83.

US Congressman Stupak on Food Safety

The latest hearing, titled "Regulatory Failure: Must America Live with Unsafe Food?" is the sixth food safety hearing Stupak has held since January 2007. Due to the interest raised in the last hearing, the one on March 12 explored - food irradiation.

The House Energy and Commerce Committee, Subcommittee on Oversight and Investigations heard testimony from Dr. Dennis Olson, a professor of animal science at Iowa State University testified regarding the potential benefits of irradiation. Mr. Daniel Wegman, the CEO of Wegman's Food Markets discussed why his company chooses to offer irradiated products to its customers. While food irradiation was the only technology discussed at this hearing, the committee is also exploring other food safety technologies.

Committee Members tasted tested the irradiated spinach provided by Sadex. As Representative Bart Stupak, D-Michigan commented, "No difference". Representative John Shimkus, R-Illinois responded "I think Popeye would approve".

The video of the hearing is in 4 sections. Discussion of food irradiation begins on the second one (204391-1-0-0-2) at approximately 41 minutes into the tape.

C-Span Video Library