

To Docket No: 99F-5321



Dec. 8, 2004

~~Dr. Robert Brackett
U.S. Food and Drug Administration
CFSAN HFS-001
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835~~

~~Dr. Laura Tarantino
U.S. Food and Drug Administration
CFSAN OFAS, HFS-200
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835~~

~~Dr. Alan Rulis
U.S. Food and Drug Administration
CFSAN OFAS, HFS-200
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835~~

~~Dr. George Pauli
Associate Director for Science and Policy
U.S. Food and Drug Administration
CFSAN OFAS, HFS-205
1110 Vermont Ave., N.W. Rm. 1250
Washington DC 20201~~

Re: Food Additive Petition 9M4697, Use of ionizing radiation for pre-processed meat and poultry; both raw and pre-processed vegetables, fruits and other agricultural products of plant origin; and certain multi-ingredient food products; FAP 1M4727, Use of ionizing radiation for control of foodborne pathogens in crustaceans and processed crustaceans; FAP 9M4682, Ionizing radiation for the control of Vibrio and other foodborne pathogens in fresh or frozen molluscan shellfish; FAP 9M4695, Use of ionizing radiation to treat unrefrigerated (as well as refrigerated) uncooked meat, meat products, and certain meat food products; FAP 9M4696, Increase the maximum dose of ionizing radiation permitted in the treatment of poultry products; and Citizen Petition 2003-P0544, To modify existing food additive regulation to revoke approval for irradiated ground beef

Dear Drs. Bracket, Rulis, Tarantino and Pauli:

Your agency is considering the first five above-referenced food additive petitions to irradiate a much greater portion of the food supply, including the huge category of "ready-to-eat foods" (FAP 9M4697) comprising an estimated 37 percent of the average American's diet. As you know, our two organizations, the Center for Food Safety (CFS) and Public Citizen, have filed numerous detailed

99F-5321

C 79

DR. ROBERT BRACKETT ET AL.

comments on these matters addressing the serious safety and nutrition questions involved. Here we submit important new publications that further heighten our concerns.

You also are considering the last above-referenced item, a Citizen Petition that we filed **more than one year ago** to revoke the current approval for irradiation of ground beef and ground beef byproducts. We have received no substantive response to date; we here request you to provide FDA's response promptly. The comments below further bolster the requests in our Petition.

Please note: we also would like to meet with you personally to discuss these matters. More on this request is at the end of this letter.

Attachment A is an opinion by a leading colon cancer/nutrition expert, C.V. Rao, Ph.D., Associate Chief of the Division of Nutritional Carcinogenesis, Institute For Cancer Prevention, American Health Foundation-Cancer Center in Valhalla, New York. We earlier submitted an unpublished version of this opinion attached to our comments to you dated July 8, 2003. Dr. Rao has since revised that opinion and published it in a prominent peer-reviewed journal.¹

We will not again quote all the key parts of his opinion, as we did in our earlier comment. However the excerpt below of his ultimate conclusion is stronger against irradiated foods than his unpublished opinion was, stating:

A thorough investigation of the effect of 2-alkylcyclobutanones at levels consumed by human populations in models (in vitro and in vivo) of various types of cancers is warranted before proposing that irradiated foods do not increase the risk of colon cancer in human population.

This amounts to a stark warning by a national expert that the colon cancer promotion risk requires further careful investigation. Dr. Rao essentially states that, absent such research, the scientific presumption must be that irradiated foods do increase the risk. It would be reckless to ignore this conclusion as again none of the existing scientific research on irradiation has addressed this tumor promotion question to date, apart from the one published research paper that made a positive finding.²

¹ Rao, C.V. 2003. Do irradiated foods cause or promote colon cancer? *Nutrition and Cancer* 46(2):107-109.

² Raul, F., F. Gossé, H. Delincé, A. Hartwig, E. Marchioni, M. Miesch, D. Werner, and D. Burnouf. 2002. Food-borne radiolytic compounds (2-alkylcyclobutanones) may promote experimental colon carcinogenesis. *Nutrition and Cancer* 44(2):188-191.

PT 13

1582-799

DR. ROBERT BRACKETT ET AL.

Our retained toxicity consultant, Dr. William Au, also has taken part in a further peer-reviewed publication on irradiation. Attachment B is a report he co-wrote with his graduate students at the Univ. of Texas Medical Branch that reviews the overall questions on the safety of irradiation.³ Some key points made are (all from p. 6):

On animal studies -

...the current data from animal studies are inadequate for making valid health risk assessment and such assessment has not enjoyed wide-spread acceptance.

On the only two published human studies -

Although these results were from small scale investigations, the information is based on human responses and does raise some safety concerns about the health risk of irradiated food.

On 2-ACBs -

...compounds found exclusively in irradiated dietary fats may promote colon carcinogenesis in animals treated with a known carcinogen and identifies a new area of toxicity that the FDA and WHO have yet to examine. The 2-ACB tumor promotion activities should be further investigated, and their effects evaluated systematically.

Further key excerpts:

p. 7 - On the European Parliament's position -

Based on the observed adverse effects resulting from these [2-ACB] investigations, the European Parliament has retained the 10 kGy limit and has issued a moratorium on the addition of food items for irradiation.

p. 9 - Discussion -

³ Ashley, B.C., P.T. Birchfield, B.V. Chamberlain, R.S. Kotwal, S.F. McClellan, S. Moynihan, S.B. Patni, S.A. Salmon, and W.W. Au. In Press. Health concerns regarding consumption of irradiated food. *International Journal of Hygiene and Environmental Health* - Note: the attachment is a galley proof. Actual publication is expected in January or February, 2005.

The justification used for approving food irradiation is based mainly on early studies which demonstrate that (1) the process did not generate substances that are not also generated by other food preservation procedures and (2) the wholesomeness of irradiated food is safe based on animal bioassays. However, recent studies have propagated uncertainty with regard to the safety of irradiated food that is to be provided to the consumer....Up to this point in time, there have been no comprehensive and systematic studies to assess human toxic effects resulting from irradiated food. Given the history of use of this technology thus far, one could argue that if it were unsafe then we should have seen some specific adverse health effects. However, if the toxic by-products are acting as promoters we may only recognize a small increase in cancer in the population (in terms of percentages but not in terms of number of affected individuals) and it would be very difficult to prove that irradiated food was in fact the direct cause of increased cancer morbidity and mortality.

p. 9 - Recommendations:

In summary, it is quite clear that additional research is needed in order to fully address the issue and concerns of irradiated food. The toxicity of unique radiolytic products should be tested vigorously, especially in regards to the tumor promoting activities. Animal bioassays should be conducted systematically and comprehensively with whole food and with unique radiolytic products to generate a dose response understanding of the toxicity and safety of irradiated food. It would prove beneficial to establish a dose that does not cause any observable toxic effects in an experimental animal model. The data obtained would better substantiate extrapolation and application in human health risk evaluation. In addition, as of now, there are no extensive human trials available to assess irradiated food safety in human populations. Regulatory agencies in the US and around the world need to be proactive in resolving these health concerns prior to the ubiquitous consumption of irradiated food.

Finally, we call your attention to a certain statement made by Dr. Pauli, as reported in an article by the *New York Times*, and to related documents we obtained under the Freedom of Information Act (FOIA). We earlier attached that article to one of our comments.⁴ The key statements therein we are concerned about are:

⁴ *New York Times* article by noted food writer Marian Burros, Oct. 15, 2003, at p. D-6, entitled "Questions on Irradiated Food," which was attached at Tab 3 to our Nov. 14, 2003, comment to you on the above-referenced FAPs.

DR. ROBERT BRACKETT ET AL.

In 1980, an FDA Committee on irradiation recommended that the agency test the effects of substances called unique radiolytic compounds, that were found only in irradiated food. But Dr. Pauli said in an interview that by 1987, the agency decided that there was no need to separately test the effects of the compounds, because more than 400 tests on irradiated food since the 1960s had proved its safety.

In our FOIA request dated Oct. 17, 2003, our Request 3 sought specific documents to support the statements made by Dr. Pauli with respect to the decision he alleges FDA made by 1987 on toxicity testing for compounds found in irradiated foods. We did receive the 1980 FDA document entitled Recommendations for Evaluating the Safety of Irradiated Foods. That shows that FDA's expert committee did indeed then support testing of concentrations of unique radiolytic products (URPs) in foods irradiated at doses above 1 kGy, stating that the toxicology tests should use "extracts in which the concentration of radiolytic products is maximized" (p.18 therein).

This is, of course, the sort of testing of key concentrated substances such as 2-ACBs advocated by both Drs. Rao and Au, their colleagues, and many other commenters in this area.

However, in response to our quite specific FOIA request, FDA produced no papers that document any decision between 1980 and 1987, by which time Dr. Pauli stated the agency had changed its approach and decided not to test concentrated URPs. This leads to the conclusion that either Dr. Pauli's reported statement in the newspaper article was in error or else the FDA decision was verbal and never put on paper. For such a critical decision about not testing potentially toxic URPs to have been made without any clear "paper trail" to support Dr. Pauli's assertion is truly astounding.⁵ With the recent published work on 2-ACBs - found only in irradiated foods - it is clear now that FDA made the wrong decision, one that has placed consumers of irradiated foods at needless risk.

That decision put FDA far behind on the needed safety research. Had such URP research been carried out following the 1980 recommendation to do so, it is likely that the safety issues would have been fully resolved long ago. In our earlier comments we have repeatedly recommended to you the specific research that is needed and we again urge you to commit to it. Unless you do, the controversy over irradiated foods will remain at a high decibel.

Again, we urge you to **deny** the five industry petitions to expand food irradiation and to **approve** our petition to revoke the existing approval for irradiated ground beef. If you have further questions on the technical aspects of this comment, please contact CFS Attorney and Policy Analyst Peter T.

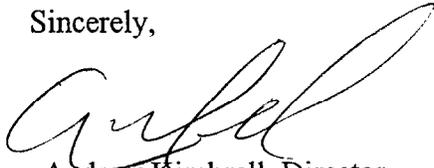
⁵ If the FOIA response was incomplete and there are more materials that document the "no URP testing" decision, FDA must produce them immediately.

DR. ROBERT BRACKETT ET AL.

Jenkins at 202.547.9359; email: peterjenkins@icta.org .

Meeting Request: Our groups had met with Dr. Brackett's predecessor, Joseph Levitt, on two occasions to discuss the pending food additive petitions and labeling issues. Also, our staff members have spent the past two years working with the National Advisory Committee on the Microbiological Criteria for Foods on the issue of redefining pasteurization, which could have a direct impact on the labeling of irradiated foods. As we have not discussed these issues with Dr. Brackett since he took over the directorship of CFSAN, we believe this is a good opportunity to meet, get acquainted, and share views. To arrange this requested meeting please contact Tony Corboof Public Citizen at tel: 202.454.5131; email: tcorbo@citizen.org .

Sincerely,



Andrew Kimbrell, Director
Center for Food Safety
660 Pennsylvania Ave., S.E.
Suite 302
Washington, DC 20003



Wenonah Hauter, Director
Public Citizen's Energy and Environment Program
215 Pennsylvania Ave., S.E.
Third Floor
Washington, DC 20003

Attachments (2)

cc (with attachments): FDA FAP Docket No.s: 99F-5522; 01F-0047; 99F-4372; 99F-5321; 99F-5322; Citizen Petition Docket No. 2003-P0544