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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99F-2673

To whom it may concern:

I am writing on behalf of the Organic Consumers Association. OCA is a nonprofit, grassroots national organization that promotes food safety, organic farming and sustainable agricultural practices in the U.S. and internationally. Our monthly newsletter has approximately 30,000 subscribers. Our web site <www.purefood.org> is the most active U.S. site dealing with food safety, irradiation, genetic engineering, and organic agriculture. Our views are shared by a coalition that includes 32 national organizations and over 100 state and local groups.

We strongly object to the FDA approval of ionizing radiation on seeds for sprouting, and demand that the FDA reevaluate its decision.

1) The FDA acknowledges that "analogous to other food processes, [irradiation's] use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food..." However, irradiation changes food in ways *other* than reduction in the microbial load. In *addition* to the radiolysis products, irradiation is known to deplete vitamins, damage or inactivate enzymes, and break DNA. A seed is a concentrated package of nutrition, the *only* source for the growing plant. The petitioner did not submit any toxicity studies specifically dealing with sprouts grown from irradiated seeds. It is reasonable to assume that such sprouts, drawing on a damaged source of nutrients and DNA, may be chemically and nutritionally different from sprouts grown from nonirradiated seeds. Certainly the FDA should not assume that sprouts from irradiated seeds have the same toxicological characteristics as fruits irradiated after picking, as the petitioner requests.
2) The FDA's dismissal of the radiolytic products problem is not justifiable. First, whether or not they are similar to those in other foods, radiolytic products are an added load in the irradiated food. Second, the FDA's approval of irradiation for fruits and vegetables, which was based on a theoretical calculation of the amount of radiolytic products in the average diet, assumed a 7.5 oz. serving of irradiated food per day (see attachment). This calculation ignores the cumulative effect of a diet containing a greater amount of irradiated food. The FDA can go on forever considering individual foods in isolation from the rest of the diet. That is as scientifically indefensible as a doctor writing a prescription while ignoring the other medications her patient is taking. Furthermore, because sprouts from irradiated seeds may be more nutritionally and toxicologically impaired, the FDA's approval of fruits and vegetables cannot be the legitimate basis for approval of seeds. The FDA's "expectation" that the radiolysis problem will not be significant is nothing more than wishful thinking. We are greatly distressed at the FDA's willingness to accept wishful projections when they come from petitioners, and reject prudent policies when they are requested by public-interest groups.
3) The FDA approved irradiation of seeds at a maximum dose of 8 kiloGray although data were submitted on the nutritional changes in seeds irradiated at only 6 kiloGray and the petitioner provides no justification for the 8 kiloGray level.

Yours truly,

Danila B. Oder

Attachment: An analysis of the effect of radiolytic products in the diet, based on the FDA-approved dose for fruits and vegetables

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Liver Cancer: Danger of Radiolytic Products in the Diet

June 26, 2000

This scientific materials in this document were prepared by chemist Jeffrey Reinhardt, M.Sc., co-founder of The National Coalition to Stop Food Irradiation.

Summary

- FDA estimates the amount of Radiolytic Products (RP) in foods irradiated at 100 Krad at 0.3 parts per million (PPM). Source.
- 100 Krad is the maximum permitted dose of irradiation for fruits and vegetables. Poultry may receive 3 x 100 Krad, red meat may receive 4.5 x 100 Krad, frozen meat may receive 7 x 100 Krad, spices receive 30 x 100 Krad. Therefore this calculation is a low estimate if people eat a diet containing irradiated meat and poultry as well as fruits and vegetables.
- Assumes consumption of 7.5 ounces of irradiated foods with an average water content of 80% (fruits and vegetables range from 75-90%) with 0.3 PPM of RPs. 7.5 ounces is a large serving of fruit or one piece of fruit and one serving of poultry or meat.
- If only 1 out of 10,000 RP molecules is a potential carcinogen, co-carcinogen or mutagen, then for every 7.5 ounce meal with 0.3 PPM of RPs, 2,560 potentially carcinogenic or mutagenic RP molecules will contact each cell in the adult liver. See the entire calculation.
- Irradiation depletes anti-oxidant vitamins in food,

which help regenerate the liver.

- Over a long period of time, the RP assault on the liver combined with fewer anti-oxidants in the diet will create a "fertile field for the ultimate growth of cancer cells" and "almost certainly evolve" to produce liver cancer.
- "Even at one-tenth the concentration of radiolytic products known by the FDA to be formed by irradiation at 100 Krad, irradiation of foods in the human diet represents predictably unacceptable risks to the public's health."

FDA estimate of amount of RPs produced

"Calculations based on radiation chemistry clearly indicate that irradiation doses of 100 Krad or less yield a concentration of total radiolytic products in food that is so limited that it would be difficult to detect and subsequently measure toxicological properties. In addition, at this dose unique radiolytic products (URPs) will be on the order of 3 parts per million (PPM), and since the number of individual URPs is likely to be greater than ten, the amount of any particular URP will be considerably less than 1 PPM. Finally, our estimates of URPs may be exaggerated.

"Hence, because of the low level of total unique radiolytic products (URPs) produced, it is concluded that food irradiated at doses not exceeding 100 Krad is wholesome and safe for human consumption. This rationale is based solely on an estimate of the concentration of individual URPs produced by the radiation dose to the food, and pertains even if a high proportion of the total human diet is irradiated at 100 Krad."

p. 16, *Recommendations for evaluating the safety of*

irradiated foods. Final report, July 1980. Director, Bureau of Foods, FDA.

Calculation of number of molecules of RPs produced by 7.5 ounces of irradiated food.

Analysis of the Impact of Radiolytic Products (RPs) at 0.3 PPM

Mathematical Calculations

A. Seven and one-half (7.5) ounces of irradiated "foods" equals 42.5 grams of "food" substance:

1) 7.5 oz. x 28.35 gm. per oz. = 212.63 gm. of "food"

2) 212.63 gm. x 1000 mg. per gm. - 213,630 mg. of "food"

3) If 80% of the "food" is water,

then 0.8 x 212,630 mg. = 170,104 mg. of water

OR 213,630 mg. of "food" - 170,104 mg. of water = 42,526 mg. of "food" substance

B. RPs at 0.3 PPM in 7.5 ounces of "food" substance yield 0.01275 mg. of RPs per 7.5 ounce meal.

1) 42,526 mg. of "food" substance = 0.0425 Kg.

0.0425 Kg. x 0.3 PPM x 1 mg. per Kg. per PPM

equals 0.01275 mg. of RPs in "food" substance

C. Assuming an average Molecular Weight (MW) of one RP molecule equals 300 Daltons, permits the calculation of the total number of RP molecules ingested in a 7.5 ounce meal of irradiated "food":

1) 0.01275 mg. RPs ÷ 300 Daltons = 0.0000425 milliMoles of RPs

OR 2) 0.0000425 milliMoles RPs = 0.0425 microMoles of RPs

OR 3) 0.0425 microMoles of RPs = 4.25×10^{-8} moles of RPs

D) To convert to the number of RP molecules, the Mole fraction is multiplied by Avogadro's Number (6.023×10^{23} molecules per Mole):

1) (4.25×10^{-8} Moles of RPs) x (6.023×10^{23} molecules per Mole) = (25.6×10^{15}) molecules of RPs in a 7.5 ounce meal of irradiated "food"

OR 2) 25,600,000,000,000,000 RP molecules per meal

E) Since there are approximately one million liver cells ("hepatocytes") in the adult human liver, there will be 25,600,000,000 RP molecules potentially targeted at each liver cell.

1) 25,600,000,000,000,000 RP molecules ÷ 1,000,000 cells = 25,600,000,000 RP molecules per liver cell

F) If, however, only 1 out of 1,000 RP molecules is actually assimilated from the small intestine into the hepatic portal circulation (ed: blood flow through the liver), then

for every 7.5 ounce meal with 0.3 PPM of RPs, 25,600,000 of these reactive RPs will enter the liver:

1) 25,600,000,000 RP molecules per liver cell ÷ 1 in 1,000 RP molecules actually assimilated into hepatic portal circulation = 25,600,000 RP molecules per liver cell in the "Best Case"

G) Further, if only 1 out of 10,000 RP molecules is a potential carcinogen, co-carcinogen, or mutagen, then for every 7.5 ounce meal with 0.3 PPM of RPs, 2,560 potentially carcinogenic or mutagenic RP molecules will contact each cell in the adult liver:

1) 25,600,000 RP molecules per liver cell ÷ 1 in 10,000 RP molecules as potential carcinogens or mutagens = 2,560 (potentially carcinogenic or mutagenic) RP molecules will come in contact with each hepatocyte (liver cell).

H) If, over protracted periods of time, the liver is depleted of protective, anti-oxidant nutrients which are destroyed by irradiation, then the inherent capability of the liver's protective and regenerative mechanisms will be compromised. This reduction in the quality and quantity of functional nutrients available is caused by the consumption of diets containing irradiated "foods" over long periods. This depletion in the intake of functional anti-oxidant nutrients, in conjunction with genetic, lifestyle, and occupational factors, will lead to a tissue environment in the liver which will evolve to unique susceptibility to RP-induced initiator and/or promoter carcinogenesis mechanisms.

Thus, I believe that ingesting irradiated "foods" containing even 0.3 PPM of RPs will inevitably lead to neoplastic transformations of liver cells in a fertile field for the ultimate growth of cancer cells; these will almost certainly

evolve to produce hepatocellular (liver) carcinoma.

Even at one-tenth the concentration of radiolytic products known by the FDA to be formed by irradiation at 100 Krad, irradiation of foods in the human diet represents predictably unacceptable risks to the public's health.

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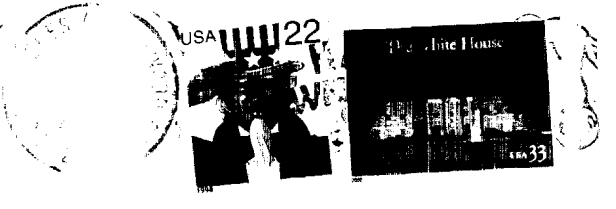

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