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Joan Claybrook, President

March 21, 2003

Ronald Burke
Bureau of Regulatory, International and Interagency Affairs
Health Canada
Address Locator 0702C1
Ottawa, Canada K1A 0L2

Re: Health Canada's Proposed Amendments to Division 26 of the *Food and Drug Regulations* to Extend the Use of Irradiation to Mangoes; Fresh, Prepared, Dried and Frozen Shrimp and Prawns; and Fresh and Frozen Poultry and Ground Beef

Dear Mr. Burke:

Public Citizen is pleased to submit this public comment on Health Canada's proposed amendments to Division 26 of the *Food and Drug Regulations* to extend the use of irradiation to mangoes; fresh, prepared, dried and frozen shrimp and prawns; and fresh and frozen poultry and ground beef, as published in the *Canada Gazette* Part 1, Vol. 136, No. 47, pp. 3502-3510, Nov. 23, 2002 (hereafter "Proposal"). Public Citizen, established in 1971, is a non-profit organization with more than 150,000 members worldwide that advocates for consumer protection, and for government and corporate accountability.

A co-signer to this comment is the Council of Canadians, a citizens' organization founded in 1985 that has more than 100,000 members and more than 70 chapters across the country. The Council conducts research, lobbies Members of Parliament, and runs national campaigns related to social programs, economic justice, Canadian sovereignty, the environment and other issues.

As per the accompanying letter from Claudette Dalpé, we are submitting partial comments due to the fact that, as of today, Health Canada has not made available to the public the evaluation documents related to irradiated ground beef. Ms. Dalpé informed us that Health Canada would accept our additional comments until March 31, by which time we have been informed that the irradiated ground beef evaluation will be made available to the public.

Ralph Nader, Founder

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Additionally, because the evaluation documents related to 2-alkylcyclobutanones were made available only quite recently, our comments on this issue will be included in our follow-up comment.

This comment, therefore, is in reference to the Proposal's sections related to irradiated mangoes, poultry, and shrimp and prawns.

The Proposal is seriously flawed and, if implemented, could endanger the health of Canadians who eat these irradiated foods. Given the high popularity of these products, millions of people could be affected. The Proposal is based on inadequate analyses, flawed and inappropriate science, and studies that have actually detected adverse health effects in test animals that have eaten irradiated foods. In addition, the Proposal ignores a substantial amount of evidence suggesting that irradiated foods may not be safe for human consumption.

We will address each of the Proposal's sections separately.

Proposed Item 5, Division 26, Part B, *Food and Drug Regulations*.

This section of the Proposal is flawed in significant ways.

All seven studies the Proposal cites to support the toxicological safety of irradiated mangoes are inappropriate for this assessment.^{1,2,3,4,5,6,7} Each of the studies used a radiation doses of 0.75 – 0.8 kGy. The Proposal, however, would permit irradiation of mangoes with doses ranging from 0.25 kGy to 1.5 kGy. On their face, these seven studies cannot be used to assess the safety of mangoes irradiated with doses above 0.8 kGy.

Additionally, the six studies in which irradiated Kent mangoes were fed to rats (the WARF/Raltech studies) actually revealed adverse health effects. Again, the mangoes were irradiated with doses far below the Proposal's maximum dose.

- In the 90-day feeding study, the gonads of female rats fed stock diets containing 15 percent irradiated mangoes weighed 68 percent more than those fed stock rations, and 53 percent more than those fed stock diets including 15 percent non-irradiated mangoes.⁸ If the researchers made any effort to explain this abnormality, it was not detailed in their report.

In the two-year feeding study, several abnormalities were observed, including:

- The serum glutamic-oxaloacetic transaminase (SGOT) levels of male and female rats fed stock diets containing 15 percent irradiated mangoes were significantly different ($P \leq .05$) than rats fed stock rations and rats fed stock diets containing 15 percent unirradiated mangoes.⁹ These anomalies could indicate one or more liver problems or other health problems, including hemolytic anemia, liver necrosis or liver cancer.¹⁰ If the researchers made any effort to explain these abnormalities, it was not detailed in their report.
- The albumin and protein levels of male and female rats fed stock diets containing 15 percent irradiated mangoes varied greatly from rats fed stock rations and rats fed stock diets

containing 15 percent unirradiated mangoes.¹¹ These anomalies could indicate one or more liver problems or other health problems, including kidney damage, or diminished protein or antibody production.¹² If the researchers made any effort to explain these abnormalities, it was not detailed in their report.

- In the reproduction study, female rats fed stock diets containing 15 percent irradiated mangoes had a mating index far lower than rats fed stock rations and rats fed stock diets containing 15 percent unirradiated mangoes. Female rats fed stock diets containing 15 percent irradiated mangoes also lost more weight than rats fed unirradiated diets.¹³ If the researchers made any effort to explain these abnormalities, it was not detailed in their report.
- In the teratology study, female rats fed stock diets containing 15 percent irradiated mangoes had a mating index far lower than rats fed stock rations and rats fed stock diets containing 15 percent unirradiated mangoes. Further, rats fed irradiated mangoes gave birth to 24 percent more dead pups than rats fed unirradiated mangoes.¹⁴ If the researchers made any effort to explain these abnormalities, it was not detailed in their report.
- In the dominant lethal study, female rats fed stock diets containing 15 percent irradiated mangoes registered 5 percent more dead implants than rats fed stock diets containing 15 percent unirradiated mangoes.¹⁵
- In the seventh study, though no adverse health effects were noted, mangoes – as in the six other studies – were irradiated far below the maximum dose cited in the Proposal. Further, group sizes and exposure time were not stated, making this study seriously flawed and calling its findings into question.

Plainly, these studies do not demonstrate that mangoes irradiated at the proposed doses are safe for human consumption.

Proposed Items 6/7, Division 26, Part B, *Food and Drug Regulations.*

This section of the Proposal is flawed in significant ways.

First, the analysis of the radiolysis products formed in irradiated poultry is wholly inadequate. Despite a vast amount of published material on this subject dating to the 1950s, only 4 of the 8 cited in the Proposal studies were published. One of the published studies does not specifically address the formation of radiolysis products in irradiated poultry.¹⁶ Regarding the three other published studies, the Proposal makes no specific reference to data concerning the formation of radiolysis products in poultry.

The Proposal overlooks two major, published studies specifically addressing the formation of radiolysis products in irradiated chicken. One detected 17 radiolysis products, most of which have toxic, or even carcinogenic or teratogenic properties: ethane, methane, pentane, hexane, heptane, octane, nonane, pentene, hexene, heptene, octene, benzene, toluene, ethylbenzene, ethanol, acetone and ethanethial.¹⁷

- Benzene is a known human carcinogen and possible teratogen, and can affect blood-forming organs, the liver, immune system and central nervous system.
- Hexane is a possible human teratogen and reprotoxin, and can affect the central nervous system.
- Ethenol and toluene are possible human teratogens and can affect the central nervous system.
- Acetone can affect the central nervous system, liver, kidneys, gastrointestinal tract, blood and bone marrow.
- Pentane, heptene, nonane and octane can affect the central nervous system.^{18,19,20,21}

The other published study detected many of these chemicals in irradiated chicken plus others: pentane, hexane, heptane, octane, pentene, hexene, heptene, octene, pentadecane, heptadecene, heptadecadiene, hexadecanal, dihexadecanoyl propanedioldiester (1,2) and hexadecanoyl octadecenoyl propanedioldiester (1,2).²²

A complete analysis of the radiolysis products formed in the poultry species irradiated at doses cited in the Proposal must be conducted. The Proposal should not proceed unless the radiolysis products are determined to pose no threat to people who eat irradiated poultry.

Second, the conclusion by Health Canada staff toxicologists that the chemical compositions of carcasses from the poultry species covered by the Proposal are “substantially equivalent” is inaccurate. Also inaccurate is a conclusion by a University of Guelph researcher that (quoting from the Proposal) “it is illogical to consider the composition of other poultry species as being different.”

The fatty acid levels among the poultry species vary greatly, as this chart indicates.²³

Total fat (g/100 g)	Light muscle		Dark muscle	
	No skin	With skin	No skin	With skin
Chicken	1.65	11.07	4.31	18.34
Turkey	1.56	7.36	4.38	8.80
Duck	5.95	39.34	11.20	18.99
Goose	7.13	33.62	12.69	21.92
Pheasant	3.64	9.29	4.53	12.05

As shall be seen later, cancer-promoting, genotoxic and cytotoxic chemicals called 2-alkylcyclobutanones (2-ACBs) – which are only found in irradiated foods – are formed when certain fats are irradiated. Given that the fatty acid levels in these poultry species differ, the resulting levels of 2-ACBs also will differ. The Proposal’s blanket statement about the similarities among the poultry is therefore invalid.

Third, of the 51 studies cited in the Proposal, only 7 were published. Five of these studies are either are flawed to the point that they are inadequate to assess the safety of irradiated poultry, or they actually reveal adverse health effects:

- Rats fed a diet containing irradiated chicken and greens beans grew at a slower rate, weaned a smaller percentage of their young, and experienced more cases of blindness and microphthalmia (an abnormality in which both eyes fail to develop) than rats fed an unirradiated diet.²⁴
- A summary was presented but no data were reported in a study involving mice. The summary stated, however, that increased mortality and autolysis occurred in mice fed irradiated chicken.²⁵
- No positive control data were reported in a genetic toxicology study. And the positive controls were performed using only spot tests, which are not generally considered to be adequate positive controls for tests done by the plate incorporation assay. In addition, all *Salmonella typhimurium* strains were not subjected to positive controls with and without metabolic activation, as they usually are, and those positive control tests were performed using the spot tests rather than the plate incorporation assay. Further, the level of histidine present in the test sample is unknown. Amino acid analyses of the ultrafiltrates were performed, but no results of such analyses were given.²⁶ Taken together, these flaws make it difficult to validate the reliability of the negative controls on the irradiated food samples.
- The reported data in a test involving hamster ovary cells has several inadequacies, in particular the lack of duplicate cultures of the cells.²⁷ This study should not be used to assess the mutagenic nature of irradiated foods.
- The group size in a study involving dogs – two dogs per sex per group – is far too small for the study to be considered adequate.²⁸

Plainly, based on these flaws in the Proposal, no adequate assessment on the safety of irradiated poultry can be made.

Proposed Items 8/9, Division 26, Part B, *Food and Drug Regulations*.

This section of the Proposal is flawed in significant ways.

Most of the 12 studies cited in the Proposal are either are flawed to the point that they are inadequate to assess the safety of irradiated shrimp and prawns, or actually reveal adverse health effects.

- A higher rate of dead implantations was observed in mice fed an irradiated diet than those fed an unirradiated diet.²⁹
- The duration of a study designed to measure the effects that a diet containing irradiated shrimp could have on rat growth and blood enzymes was not sufficient to measure these effects.³⁰
- In a study involving dogs, flour – not shrimp – was fed to the animals. Even still, dogs fed irradiated flour contracted thyroiditis and atrophic acini, the severity of which increased as irradiation doses increased.³¹ This is of concern, because shrimp contains a far greater amount of fat than flour. Irradiated shrimp would therefore contain a far greater amount of the cancer-

promoting, genotoxic and cytotoxic chemicals 2-ACBs. (This will be discussed at length in our follow-up comments.)

- In a study involving dogs, the type of irradiated food, the level of irradiation and the length of feeding were not reported. It was not reported whether shrimp were included in the diet.³²
- Results and details of the experimental design were not given in a study on rats. Only a summary was presented.³³
- A study involving dogs, rabbits and hamsters presented no data on the irradiated foods and did not clearly state the type of tests performed.³⁴
- Group sizes were too small in a study in which irradiated shrimp were fed to rats.³⁵

Plainly, no adequate assessment on the safety of irradiated shrimp and prawns can be made on the basis of these studies.

Taken together, these flaws – which occur throughout the entirety of the Proposal – make the Proposal’s analysis of the safety of irradiated foods wholly inadequate. Given these systemic shortcomings, approval of the Proposal could put the health of millions of Canadians at risk.

We strongly urge Health Canada to withdraw the Proposal until a more comprehensive analysis of the safety of irradiated mangoes, poultry, shrimp and prawns, and ground beef is conducted. If Health Canada cannot demonstrate that these foods are safe for human consumption, then the Proposal should be abandoned.

Thank you for your consideration of this comment. We look forward to submitting the remainder of our comment, related to irradiated ground beef and 2-alkylcyclobutanones, in the near future.

Sincerely,



Wenonah Hauter
Director,
Critical Mass Energy and Environment Program

Notes

- ¹ “Toxicological studies on rats fed a diet containing 15% irradiated Kent mangoes: 90-day study. WARF Institute Inc., Madison, Wisconsin, USA. Study Nr. T-701, January 16, 1978.
- ² “Toxicological studies on rats fed a diet containing 15% irradiated Kent mangoes: Two-year feeding study. Raltech Scientific Services (formerly WARF Institute Inc.) Madison, Wisconsin, USA. Study Nr. T-604, June 1, 1980.
- ³ “Toxicology studies on rats fed a diet containing 15% irradiated Kent mangoes: Reproduction study. Raltech Scientific Services (formerly WARF Institute Inc.) Madison, Wisconsin, USA. Study Nr. T-605, January 17, 1978.
- ⁴ “Toxicology studies on rats fed a diet containing 15% irradiated Kent mangoes: Teratology study. Raltech Scientific Services (formerly WARF Institute Inc.) Madison, Wisconsin, USA. Study Nr. T-605, January 17, 1978.
- ⁵ Horton G.M.J. “The effects of low-dose gamma-irradiation on the wholesomeness of mangoes (*Mangifera indica*) as determined by short-term feeding studies using rats.” *British Journal of Nutrition*, 35(1):67-75, 1976.
- ⁶ “In vivo mutagenicity study in Chinese hamsters fed irradiated mangoes.” Institute of Biochemistry, Federal Research Center for Nutrition, Karlsruhe, Germany. Technical Report Series IFIP R64, November 1982.
- ⁷ “Dominant lethal studies on rats fed a diet containing 15% irradiated Kent mangoes. Raltech Scientific Services (formerly WARF Institute Inc.) Madison, Wisconsin, USA. (Additional study information not provided in the Proposal.)
- ⁸ Note 1, Op. cit.
- ⁹ Note 2, Op. cit.
- ¹⁰ National Institutes of Health.
- ¹¹ Note 2, Op. cit.
- ¹² National Institutes of Health.
- ¹³ Note 3, Op. cit.
- ¹⁴ Note 4, Op. cit.
- ¹⁵ Note 7, Op. cit.
- ¹⁶ Merritt, C. et al. “Effect of radiation parameters on the formation of radiolysis products in meat and meat substances.” *Journal of Agricultural and Food Chemistry*, 26(1): 29-35, 1978.
- ¹⁷ Merritt, C. “Qualitative and quantitative aspects of trace volatile components in irradiated foods and food substances.” *Radiation Research Reviews*, 3:353-368, 1972.
- ¹⁸ Physical and Theoretical Chemistry Laboratory, Oxford University, Oxford, England.
- ¹⁹ International Chemical Safety Cards, National Institute for Occupational Safety and Health, U.S. Centers for Disease Control.
- ²⁰ Integrated Risk Information System, U.S. Environmental Protection Agency.
- ²¹ National Institute of Standards and Technology, U.S. Department of Commerce.
- ²² Merritt, C. et al. “A quantitative comparison of the yields of radiolysis products in various meats and their relationship to precursors.” *Journal of the American Oil Chemists’ Society*, 62(4):708-713.
- ²³ Chow, D.K. (Ed.) *Fatty Acids in Foods and Their Health Implications*. New York, Basel: Marcel Dekker Inc., 2000.
- ²⁴ Richardson, L.R. et al. “A long-term feeding study of irradiated foods using rats as experimental animals.” *Federation of American Societies for Experimental Biology, Federation Proceedings*, 19(4):1023-1027.
- ²⁵ Proctor, B.G. “To determine the presence of carcinogenic substances in irradiated chicken by oral administration of the test food to mice throughout their entire life span.” *International Atomic Energy Agency, Food Irradiation Information*, 3:18, 1974.
- ²⁶ Phillips, B.J. et al. “As investigation of the genetic toxicology of irradiated foodstuffs using short-term test systems. I. Digestion in vitro and the testing of digests in the *Salmonella typhimurium* reverse mutation tests. *Food Cosmet. Toxicol.*, 18:371-375, 1980.
- ²⁷ Phillips, B.J. et al. “As investigation of the genetic toxicology of irradiated foodstuffs using short-term test systems. II. Sister chromatid exchange and mutation assays in cultured Chinese hamster ovary cells.” *Food Cosmet. Toxicol.*, 18:471-475, 1980.
- ²⁸ Blood, F.R. et al. “Feeding of irradiated chicken, beef and pineapple jam to dogs.” *Toxicology and Applied Pharmacology*, 8:241-246, 1966.
- ²⁹ Chauhan, P.S. “Dominant lethal mutations in male mice fed γ -irradiated diet.” *Food, Cosmetics and Toxicology*, 13:433-436, 1975.
- ³⁰ Brin, M. et al. “The effects of feeding irradiated pork, bread, green beans and shrimp to rats on growth and on five enzymes in blood.” *Toxicology and Applied Pharmacology*, 3:606-617, 1961.
- ³¹ Reber, E.F. “The effects of feeding irradiated flour to dogs. II. Reproduction and pathology.” *Journal of Toxicology and Applied Pharmacology*, 3:568-573, 1961.
- ³² Tucker, A. “Thyroiditis in a group of laboratory dogs.” *American Journal of Clinical Pathology*, 38(1):70-74, 1962.
- ³³ Vakil, U.K. Monograph from *Food Irradiation Now*, Re: Studies with feeding dehydro-irradiated shrimp to rats. Repeated in International Atomic Energy Agency, *Food Irradiation Information*, 4(Supp):49, 1975
- ³⁴ Watson, D.F. et al. “Feeding of dogs, rabbits and hamsters with irradiated shrimp and its effect upon thyroid activity.” Progress Report No. 11, Contract No. MD-784, U.S. Army Office of the Surgeon General, 1963.
- ³⁵ Van Logten, M.J. et al. “The wholesomeness of irradiated shrimp.” *Food, Cosmetics and Toxicology*, 10:781-788, 1972.