IRRADIATION OF GROUND BEEF: Summary of Submission Process

A. SUMMARY OF SITUATION

(a) *The Request*

In March, 1998, a submission was received from a Canadian association involved in beef production to allow the irradiation processing of fresh or frozen ground beef in its final packaging for the control of *Escherichia coli* O157:H7.

(b) *Divisions of the Food Directorate Responsible for Evaluating these Submissions*

Chemical Health Hazard Assessment Division, Bureau of Chemical Safety (Coordinating Division; also evaluates toxicological safety, chemical safety and dosimetry portions of submissions)

Evaluation Division, Bureau of Microbial Hazards (evaluates efficacy and microbial safety aspects)

Nutrition Evaluation Division, Bureau of Nutritional Sciences (evaluates nutritional effects)

B. EVALUATION SUMMARY

(a) *Purpose, Source of Radiation and (Absorbed) Dose*

The purpose of the irradiation is to disinfect fresh-chilled or frozen ground beef of the pathogenic organism, *Escherichia coli* O157:H7, to make these foods safer for human consumption. The petition is specific to ground (comminuted) beef, either fresh-chilled or frozen, that is in its final packaging ready for cooking by consumers or food-service chefs or, in packaging ready for further processing in the case of product to be used as an ingredient in other foods.

The proposed sources of ionizing radiation are gamma rays from Cobalt-60 or Cesium-137, accelerated electrons up to 10 million electron volts (10MeV) and X-rays with energies up to 5 MeV.

The proposed doses are as follows:

Fresh/chilled ground beef: minimum dose of 1.5 kGy and maximum dose of 4.5 kGy.
Frozen ground beef: minimum dose of 2.0 kGy and maximum dose 7.0 kGy.

(b) *Efficacy*

Note: The studies reviewed as part of the microbial evaluation are listed in Appendix I to this document.

The petitioner provided information on the effectiveness of the dosage in controlling

Escherichia coli **and concluded that, based on published research in the literature,[1,2,3,4,5] the dosages recommended should result in a minimum 3 log reduction in *E. coli* O157:H7 and a mean 6 log reduction.**

Staff microbiologists have reviewed the information supplied by the petitioner. The treatment is also intended to control microbial pathogens such as *Bacillus cereus,*[6] *Clostridium perfringens,*[7] salmonellae[8,9] and shigellae, *Staphylococcus aureus*,[10] *Listeria*

---

[1]Thayer, D.W. and Boyd, G. 1993. Elimination of *Escherichia coli* O157:H7 in meats by gamma irradiation. *Appl. Environ. Microbiol*., 59: 1030-1034.

[2]Thayer, D.W., Boyd, G., Fox, J.B. Jr., Lakritz, L. and Hampson, J.W. 1995a. Variations in radiation sensitivity of foodborne pathogens associated with the suspending meat. *J. Food Safety*, 60: 63-67.

[3]Clavero, M.R., Monk, S.J.D., Beuchat, L.R., Doyle, M.P. and Brackett, R.E. 1994. Inactivation of *Escherichia coli* O157:H7, *Salmonellae* and *Campylobacter jejuni* in raw ground beef by gamma irradiation. *Appl. Environ. Microbiol.*, 60: 2069-2075.

[4]Fu, A.H., Sebranek, J.G. and Murano, E.A. 1995. Survival of *Listeria monocytogenes*, *Yersinia enterocolitica*, and *Escherichia coli* O157:H7 and quality changes after irradiation of beef steaks and ground beef. *J. Food Sci*., 60: 972-977.

[5]Thayer, D.W. 1995b. Use of irradiation to kill enteric pathogens on meat and poultry. *J. Food Safety*, 15: 181-192.

[6]Thayer, D.W., Josephson, E.S., Brynjolfesson, A. and Giddings, G.G. 1996. *Radiation Pasteurization of Food*, CAST (Council for Agricultural Science and Technology), Issue Paper No. 7.

[7]Naik, G.N., Pushpa, P., Chawla, S.P., Sherikar, A.T. and Nair, P.M. 1993. Improvement of microbiological quality and shelf-life of buffalo meat at ambient temperature by gamma irradiation. *J. Food Safety*, 13: 177-183.

[8]Clavero *et al.*, 1994. *Op. cit.*

[9]Tarkowski, J.A., Stoffer, S.C.C., Beumer, R.R. and Kampelmacher, E.H. 1984. Low dose gamma irradiation of raw meat. I. Bacteriological and sensory quality effects in artificially contaminated samples. *Int. J. Food Microbiol*., 1: 13-23.

[10]Monk, J.D., Rocelle, M.A., Clavero, S., Beuchat, L.R., Doyle, M.P. and Brackett, R.E. 1994. Irradiation inactivation of *Listeria monocytogenes* and *Staphlococcus aureus* in low- and high-fat frozen and refrigerated ground beef. *J. Food Prot*., 57: 969-974.

monocytogenes[11,12] **and *Yersinia spp*.**[13] **and the vegetative forms of *Bacillus cereus***[14,15] **and *Clostridium perfringens***[16,17] **and to inactivate any infectious parasites (e.g. *Toxoplasma gondii*, *Cystericus bovis***[18]**), with the concomitant benefit of extending chilled/refrigerated edible market life through a delay of the onset of detectable, or recognizable spoilage by reducing levels of common, nonpathogenic meat spoilage microorganisms.**

Questions that were addressed in the submission were:

Is the dose requested sufficient to eliminate the pathogens of concern, specifically *Salmonella* and *E. coli*?

D values for a range of temperatures 4˚C to -18˚C were provided and the range requested should result in at least a 2-3 log reduction of both Salmonella and Listeria and a reduction of at least 4 logs, possibly, for E.coli.O157:H7.

Could meat irradiated in the dose range requested increase health concerns due to the survival and growth of spores of *Clostridium botulinum*?

***C. botulinum* spores are the most irradiation resistant pathogens found in meat and the illness induced by botulinum toxin is considered severe or life threatening. However, the prevalence of *C. botulinum* spores in meat is very low and the dose range requested will not result in the elimination of all the competitive flora. Studies**[19,20] **cited in the submission indicate that spoilage is expected to precede toxicity even under conditions of temperature abuse. Refrigeration is considered the primary tool for**

---

[11]Monk *et al.*, 1994. *Op. cit.*

[12]Fu *et al.*, 1995. *Op. cit.*

[13]Tarkowski *et al.*, 1984 and Fu *et al*., 1995. *Op. cit.*

[14]Thayer *et al.*, 1996

[15]Grant, I.R., Nixon, C.R. and Patterson, M.F. 1993. Effect of low-dose irradiation on growth of and toxin production by *Staphylococcus aureus* and *Bacillus cereus* in roast beef and gravy. *Int. J. Food Microbiol.*, 18: 25-36.

[16]Lostly, T., Roth, J.S. and Shults, G. 1973. Effect of irradiation and heating on proteolytic activity of meat samples. *J. Agr. Food Chem*., 21: 275-277.

[17]Naik *et al.*, 1993. *Op. cit.*

[18]Thayer, D.W. 1993. Extending the shelf-life of poultry and red meat by irradiation processing. *J. Food Prot*., 56: 831-846.

[19]Greenberg, R.A., Tompkin, R.B., Bladel, B.O., Kittaka, R.S. and Anellis, A. 1966. Incidence of mesophilic Clostridium spores in raw pork, beef and chicken in processing plants in the United States and Canada. *Appl. Microbiol*., 15: 789-793.

[20]Hauschild, A.H.W. 1989. *Clostridium botulinum*. In *Foodborne Bacterial Pathogens*, M.P. Doyle (ed.), (New York: Marcel Dekker, Inc., 1993), pp. 111-189.

> **reducing growth of and consequently the risk from pathogens like *Salmonella, E. coli* and *C. prefringens*. Proteolytic type strains of *C. botulinum* are those most likely to be found in meat. If the spore load does not exceed the normal level of contamination (1 spore/kg) it would typically take two week or more to produce toxin at temperatures of 16˚C or less. Research has established that the size of the spore load (number of spores present in the food) is an important factor in the growth of and toxin production by *C.botulinum.* When the number of spores is low, the probability that growth sufficient for toxin production to occur is reduced.[21]**

Staff microbiologists also considered other questions that might arise concerning irradiation of beef, namely:

> **Could the use of irradiation change virulence characteristics of bacteria making them more pathogenic if they should survive the process?**
>
> **There have been extensive studies done using irradiation and studying the effects on microorganisms. This has not be observed so far in bacteria that have survived irradiation process where the dose is in the range requested by this petition.**
>
> **The methods used to determine whether a food product has been irradiated either by presence/absence testing or quantitative testing are tedious and difficult. Should the acceptance of irradiation be delayed until better (microbiological) methods are in place to ensure compliance?**
>
> **Compliance action could be taken based on record keeping,[22] similar to action taken on retorted products where under-processing is suspected. If records are inaccurate or incomplete, compliance action could be taken. Methods for presence/absence testing are available and could be used when deemed necessary. In any case, there are many physico-chemical based methods for the detection of irradiated foods, including ground beef.**

After careful review of the literature available for microbiological safety, evaluators concluded that the information submitted in the petition is sufficient to support the claims regarding effectiveness against vegetative pathogens for the dose levels proposed. Staff microbiologists also concluded that the use of irradiation at the dose proposed is not likely to result in an increased microbial hazard due to *C. botulinum*. Staff microbiologists support the irradiation of red meats generally.

The petitioner has provided a proposed irradiation protocol as part of the ground beef petition which is shown in Appendix V to this document.

Packaging

Meats should be packaged prior to irradiation to avoid re-contamination. As noted in the first paragraph of Section (a) above, the intent is to treat meat that is packaged prior to irradiation.

(c) *Dosimetry*

The petitioner proposes that dosimetric methods published by the American Society for

---

[21]Lucke, F.-K, and Roberts, T.A. *Control in Meat and Meat Products.* In *Clostridium botulinum Ecology and Controls in Foods,* A.H.W. Hauschild and K.L. Dodds (eds.). 1993.

[22]Record-keeping is required under Section B.26.004 of the Canadian Food and Drug Regulations.

Testing Materials (ASTM) (1987; 1988; 1991)[23], Codex Alimentarius Commission (1992)[24], and Chadwick and Osterheert (1986)[25] be employed. In addition, the petitioner references various other guidelines published for red meat irradiation[26,27].

(d) *Alteration of Chemical, Physical and Microbiological Characteristics*

Note: The studies reviewed under this rubric are shown as Appendix II to this document.

i. Odour:

The relationship between odour production (smell) and dose is linear up to 140 kGy. The odour is the result of the production of more than 100 volatile compounds, the principle components of which are aliphatic hydrocarbons generated from fat breakdown. Protein-derived compounds such as sulfur compounds and aromatic hydrocarbons make up less than 1% of the total, and oxygenated compounds are also relatively less abundant[28]. The use of chilling or freezing temperatures during the irradiation process can greatly diminish

---

[23] *Standard Practice for application of Dosimetry in the Characterization and operation of a Gamma Irradiation Facility for Food Processing* (Designation E 1204-87) in Annual Book of ASTM Standards, Vol. 12.02, 1987; *Standard Guide for selection and application of Dosimetry Systems for Radiation Processing of Food* (Designation E 1261-88) in Annual Book of ASTM Standards, Vol. 12.0, 1988; *Standard Practice for Dosimetry and Bremsstralung Irradiation Facilities for Food Processing* (Designation E 1431-91) in Annual Book of ASTM Standards, Vol. 12.02, 1991.

[24] Codex General Standard for Irradiated Foods, CODEX STAN 106-1983, in Codex Alimentarius, Vol. 1, Section 8 (Rome: FAO/WHO, 1992, pp. 311-315. Recommended international code of practice for the operation of radiation facilities used in the treatment of foods, CAC/RCP 19-1979 (Rev. 1) in Codex Alimentarius, Vol. 1, Section 8.1 Rome: FAO/WHO 1992 pp. 317-323.

[25] Chadwick, K. H. and Oosterheert, W. F. 1986. Dosimetry concepts and measurement in food irradiation processing *Int. J. Rad. Appl. Instr.*(Part A), 37(1): 47-52.

[26] International Consultative Group on Food Irradiation. 1988. Provisional guidelines for the irradiation of fresh and frozen Red Meats and Poultry to control pathogens. Also, Irradiation of red meat: A compilation of technical data for its authorization and control. IAEA-TECDOC-902.

[27] *Standard Guide for the Irradiation of Fresh and Frozen Meats and Poultry* (to control pathogens) (Designation F 1356-91) in Annual Book of ASTM Standards, Vol. 12.02, 1993.

[28] Merritt, C. Jr., Angelini, P., Graham, R.A. 1978. Effect of radiation parameters on the formation of radiolysis products in meat and meat substances. *J. Agric. Food Chem.*, 26(1): 29-35.

the development of the irradiation off-odour.[29,30,31] Off-odours formed in meats packaged prior to irradiation, were found to dissipate rapidly after exposure to the atmosphere for several minutes. Samples irradiated at 6 kGy could be differentiated from the controls but there was no significant difference in their preference as rated on a scale from 1 (dislike extremely) to 9 (like extremely). Samples irradiated with 6 and 8 kGy were rated as less acceptable than the controls[32]. Increasing radiation dose appeared to decrease the acceptability of the raw ground beef odour, particularly over time, however the odour virtually disappears upon cooking.[33]

ii. Appearance/Colour:

Meat colour is stable or can be improved at the proposed irradiation doses although short-term colour damage can occur at higher levels. All colour effects are nullified upon cooking.[34, 35, 36,37,38]

iii. Shelf-life (Raw Red Meat):

---

[29]Urbain, W.M. 1986. Food irradiation. In *Meats and Poultry*. Academic Press.

[30]Dempster, J.R. 1985. Radiation preservation of meat and meat products: a review. Meat Sci., 12(2): 61-89.

[31]Merritt, C. Jr. *et al.*, 1978. *Op. cit.*

[32]Rhodes, D.N. and Shepherd, H.J. 1966. The treatment of meats with ionizing radiations. XIII. Pasteurisation of beef and lamb. *J. Sci. Food Agric*., 17: 287-297.

[33]Lefebvre, N., Thibault, C., Charbonneau, R. and Piette, J.-P.G. 1994. Improvement of shelf-life and wholesomeness of ground beef by irradiation. 2. Chemical analysis and sensory evaluation. *Meat Science*, 36: 371-380.

[34]Kropf, D.H., Hunt, S.E., Luchsinger, S.E., Garcia Zepeda, C.M., Chambers, E., Hollingsworth, M.E., Stroda, S.L., Rubio Cassas, E.J. and Kastner, C.L. 1996. Sensory analysis, colour and product life of low-dose irradiated beef and pork. *Activities Report/Research and Development Associates for Military*, 47(2): 327-345.

[35]Lefebvre, N. *et al.*, 1994, *Op. cit.*

[36]Fu, A.-H., Sebranek, J.G. and Murano, E.A. 1995. Survival of *Listeria monocytogenes, Yersinia enterolytica and Escherichia coli* O157:H7 and quality changes after irradiation of beef steaks and ground beef. *J. Food Science*, 60(5): 972-977.

[37]Millar, S.J. 1995. The effect of ionizing radiation in the appearance of meat. *Dissertation Abstract International*, C-56(4): 907.

[38]Risvik, E. 1986. Sensory evaluation of irradiated beef and bacon. *J. Sensory Studies*, 1: 109-122.

Although the stated primary objective of meat irradiation is pathogen control, based on references supplied by the petitioner, the delay of recognizable microbial spoilage of fresh and pre-frozen-thawed raw meat is an 'unavoidable' and concomitant benefit of radiation pasteurization. Conclusions reached by various researchers indicate that microorganisms are generally more radiation sensitive in high fat ground beef and are less supportive of growth of survivors than in low fat ground beef. Studies indicate that spoilage is delayed by over a week at doses of approximately 1 kGy and remained low after 21 days. A reduction in spoilage has been also demonstrated in pork and lamb.[39, 40, 41,42,43,44,45,46,47,48]

iv. Composition:

As discussed under Item i. above, the main chemical change is the formation of small

---

[39]Beuchat, L. B., Doyle, M. P. and Brackett, R. E. 1993. Irradiation inactivation of bacterial pathogens in ground beef. *Univ. of Georgia Center for Food Safety and Quality Enhancement report to the American Meat Institute,* September, 1993.

[40]Dempster, J. F., Hawrysh, Z.J., Shand, P., Lahola-Chomiak, L. and Corletto, L. 1985. Effect of low dose irradiation (radurization) on the shelf life of beefburgers stored at 3^{o}C. *J. Food Technology*, 120: 145-154.

[41]Ehioba, R.M., Kraft, A.A., Molins, R.A., Walker, H.W., Olson, D.G., Subbaraman, G. and Skowronski, R.P. 1988. Identification of microbial isolates from vacuum-packaged ground pork irradiated at 1kGy. *J. Food Science*, 53: 278-281.

[42]Maxcy, R. B., Tiwari, N.P. and Anagnostis, C.C. 1971. Study of control of public health problems using irradiation. *Annual Report to the division of Isotopes Development*, U.S. Atomic Energy Commission on Contract AT(11-1)-2038.

[43]Maxcy, R. B. and Tiwari, N.P. 1973. Irradiation of meats for public health protection. *Radiation Preservation of foods: Proceedings of a Symposium*. STI/PUB/317, IAEA, Vienna, pp. 491-503.

[44]Maxcy, R.B. 1982. Irradiation of food for public health protection. *J. Food Protection*, 45: 363-366.

[45]Niemand, J.G., Van der Linde, H.J. and Holzapfel, W.H. 1983. Shelf-life extension of minced beef through combined treatments involving radurization. *J. Food Protection*, 46: 791-796.

[46]Paul, P., Venugopal, V. and Nair, P.M. 1990. Shelf-life enhancement of lamb meat under refrigeration for gamma radiation: A research note. *J. Food Science*, 55: 865-866.

[47]Urbain, W.M. and Giddings, G.G. 1972. Factors related to market life extension of low dose irradiated fresh meat and poultry. *Radiation Research Reviews,* 3: 389-397.

[48]Urbain, W.M. 1973. The low-dose radiation preservation of retail cuts of meat. *Radiation Preservation of Food: Proceedings of a Symposium*, STI/PUB/317. IAEA, Vienna, pp. 505-521.

amounts of radiolytic products (RPs), some of which are volatile. The RPs formed as a result of irradiation have received extensive study and evaluation over the past several years. The July, 1980 Final Report of the then FDA Bureau of Foods Irradiated Foods Committee, states that "foods of a similar chemical composition would be expected to generate structurally similar radiolytic products". Recent studies[49, 50]show, among other things, that while the ratios vary among species, the main fatty acids of the lipid fractions of chicken, turkey, pork and beef are the same, as are their predictable radiolysis products. Key work on radiolytic product identification/quantification, undertaken by Merritt,[51] for the U.S. Army Natick Research Laboratories, was appropriated and published by the USDA in 1984. Merritt has undertaken several studies on radiolytic products in beef specifically.[52,53,54]

All available evidence suggests that the products formed on irradiation of meat at 0-5°C and in the frozen state are similar. There is no evidence of any significant differences in the identities of the products formed as a result of irradiation at the two temperature ranges. The yields of the products however, are generally lower in the frozen meats. The yields are also dose related. [55, 56, 57, 58]

---

[49]Morehouse, K.M. and Ku, Y. 1993. Identification of irradiated foods by monitoring radiolytically produced hydrocarbons. *Radiat. Phys. Chem*., 42: 359-362.

[50]Morehouse, K.M., Kiesel, M. and Ku, Y. 1993. Identification of meat treated with ionizing rqdiation by capillary gas chromatographic determination of radiolytically produced hydrocarbons, *J. Agric. and Food Chem*., 41: 758-763.

[51]Merritt, C. Jr. 1984. Radiolysis compounds in chicken and bacon. Final Report. September 18, 1981 -September 20, 1982. EERC/ARS-83. NTIS Order No. PB84-187095.

[52]Merritt, C. Jr. 1980. The analysis of radiolysis products in meats and meat substances. Food Irr. Info., 10: 20-33.

[53]Merritt, C. Jr., Angelini, P. and Graham, R.A. 1978. *Op. cit.*

[54]Merritt, C. Jr., Angelini, P. and Nawar, W.W. 1978. Chemical analysis of radiolysis products relating to the wholesomeness of irradiated food. From *Food Preservation by Irradiation*, Vol. II; IAEA, Vienna, 1978, pp. 97-112. IAEA Paper No. IAEA-SM-221/51.

[55]Merritt. C, Jr. *et al.* 1978. *Op. cit*.

[56]Nawar, W, W, and Balboni, J. J. 1970. Detection of irradiation treatment in foods, *J. Assoc. Analyt. Chem*., 53: 726.

[57]Nawar, W. W. 1986. Volatiles from food irradiation, *Food Reviews International*, 21: 45.

[58]Spiegelberg, A., Schulzki, G., Helle, N., Bogl, K. W. and Schreiber, G. A. 1994. Methods of routine control of irradiated food: optimization of a method for the detection of radiation- induced hydrocarbons and its application to various foods, *Radiat. Phys. Chem*., 43: 433.

In the complete data package provided by the USDA in 1984 to the FDA, there was a study performed by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB) entitled "Evaluation of the Health Aspects of Radiolytic Compounds found in Irradiated Beef."[59] Sixty-five radiolytic compounds were studied in beef irradiated to an average dose of 56 kGy.

The results may be summarized as follows:

(1) The amounts of individual compounds ranged from 1 to approximately 700 ppb or 0.7 ppm.

(2) Hydrocarbons were the most abundant compounds noted, both in terms of number and quantity (70% of all the substances which comprise 90% of the total weight of compounds collected fall into this category).

(3) Saturated aliphatics (i.e. alkanes) predominated and their content exceeded the combined total of alkenes and alkynes by 1.5 times and of the aromatic hydrocarbons by more than 60 times.

(4) Most of the aliphatic hydrocarbons were substantially more abundant in irradiated rather than in non-irradiated beef. However, quantitites of xylene and tetrachloroethylene were essentially the same whether or not the beef was irradiated.[60] Acetonitrile, carbonyl sulphide, dimethyldisulphide, methanol and methyl heptane were present in greater amounts in the thermally-sterilized samples than in the irradiated samples.

(5) Heat caused a significant loss of the volatile components, so the concentrations in the cooked samples were almost always lower than in the uncooked beef. Thus, ethane, for example, was found in the uncooked irradiated specimens, but could not be detected in the cooked samples. Methane, which is even more volatile, was absent from both cooked and uncooked beef fractions, although theoretically, significant quantities should have been produced by irradiation.

Data reviewed by the FDA committee in the early 1980s indicates that a low radiation dose would generate no more than 30 parts of RPs in a million parts of food. Of those 30 parts, about 90%, or 27 parts per million, have been identified as identical to natural food components and therefore are familiar. The remaining 10%, or 3 parts per million, were found to be chemically similar to natural food components. The committee concluded that the chance of any single unique radiolytic product (URP) of unusual toxicity being formed in significant amounts would be negligible. FDA officials recognized and evaluated the benzene formed when meat was irradiated at a dose more than fifteen times greater than

---

[59]Federation of American Societies for Experimental Biology (FASEB). Life Sciences Research Office. Select Committee on Health Aspects of Irradiated Beef, Herman J. Chin, Chairman). August, 1977 and March, 1979. Evaluation of the Health Aspects of Radiolytic Compounds Found in Irradiated Beef. NTIS Order No. PB84-187087.

[60]These two compounds were judged by the Select Committee to be of non-radiolytic origin. The presence of xylene was attributed to can end-sealing compounds and tetrachloroethylene from cleaning and degreasing preparations used in meat-plants.

that approved by the FDA. The amount of benzene found was 1% of that reported in non-irradiated eggs.

Notwithstanding the FDA evaluation, the Bureau of Chemical Safety has undertaken its own evaluation of benzene intake from foods, including irradiated beef. Benzene is found at 15 +/- 5.1 parts per billion (ppb) in Co-60 irradiated and 14 +/- 5.0 ppb in electron beam-irradiated beef at an average dose of 56 kGy. It has been demonstrated that benzene formation in irradiated beef is proportional to the radiation dose. The estimated benzene level would be about 3 ppb in the dose range (1.5-4.5 kGy) requested by the petitioner for the fresh beef.

Benzene, toluene and xylene have been reported in numerous foods, including meat, vegetables, nuts, diary products and beverage. Large amount of benzene have been reported in boiled beef and in canned beef stew. Benzene and toluene (but not xylene) have also been detected in fruits, fish and eggs.

Eggs are especially rich in aromatic hydrocarbons for their content of benzene and toluene, estimated to be more than a hundred times that in the irradiated beef.[61] Large amounts of both these compounds are also found in haddock kept under refrigeration for 14 days; as much as 200 ppb benzene and 500 ppb of toluene. Applying recent Eater's Only Food Consumption Survey data to haddock (121.85 g/day) containing 200 ppb (ug/kg) benzene and to ground beef (97.22 g/day) containing 3 ppb benzene, the intakes would be 24.37 and 0.29 ug, respectively.

In a Health Hazard Assessment performed in 1992, benzene was cited as being ubiquitous in the environment and the primary routes of exposure were cited as being occupational, atmospheric, food and drinking water. Recognizing that benzene was present in butter, beef, <u>irradiated beef</u>, boiled eggs, haddock, oranges, mangoes and various fruits, a Health Risk Assessment was conducted and it was concluded that the daily intake of benzene through foods for the average consumer, assuming All Persons Mean Intakes for each food, was 0.12 ug/kg bw/day or 9.3% of the low end of the Tolerable Daily Intake (TDI) range (1.26 - 2.7 ug/kg bw/day). The level used in this risk assessment for irradiated beef was <u>19 ppb</u>, over 6 times the amount of benzene estimated to be present in irradiated beef. As such, the risk of benzene derived from irradiated beef is considered to be insignificant.

The Bureau of Chemical Safety has also undertaken a separate risk assessment on 2-dodecylcyclobutanone (2-DCB), a unique alkylcyclobutanone (ACB) radiolytic compound found in fat-containing foods such as chicken or beef. Insofar as it is unique to irradiated fat-containing foods, this compound has been useful as a "marker compound" in the detection of irradiated foods. But being "unique," it was also considered appropriate to undertake a safety assessment relating to its presence in irradiated fat-containing foods such as chicken or beef, particularly in the light of concerns over its potential genotoxicity.[62]

---

[61] The levels cited in a 1992 Health Canada Health Risk Assessment were 150-1900 ppb in raw eggs, but only 2 ppb in boiled eggs.

[62] Delincée, H. and Pool-Zobel, B.L. 1998. Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat. *Radiat. Phys. Chem.*, 52(1):39-52.

(e) *Packaging*

With regard to specific packaging materials that may be used on foods offered for sale in Canada, letters of opinion are offered upon request to packaging material manufacturers upon submission of appropriate technical data, including extraction data. The same voluntary procedure is followed in the case of materials intended to package foods to be irradiated. In all cases, the letters of opinion consider the requirements of Section B.23.001 of the Regulations which states that "No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food."

(f) *Nutritional Aspects*

Nutrition evaluators reviewed the report submitted by the petitioner, and also other scientific literature obtained by an independent literature search, on the effects of irradiation on the content and composition of lipids, proteins and amino acids, and the content of vitamins and minerals. Available scientific literature includes irradiation of intact or comminuted pork, chicken, lamb and other red meats including beef. The studies considered are shown in Appendix III.

The effects of irradiation reported were evaluated with respect to the contribution that ground beef makes to the intake of those nutrients. Also, the effects of irradiation were contrasted with the effects of other processes where data were available and evaluated with respect to the relationship between irradiation and other types of processing likely to be applied to ground beef. The need to use particular processing techniques to achieve safe levels of microbial contamination or remove contaminants or make a food more palatable, edible and digestible, always must be balanced against their impact on nutrient composition and bio-availability. Most food processing methods remove nutrients in one way or another although they also can make some nutrients more bio-available and the nutrients left in the food more accessible for consumption by making the food more edible. Considering the impact of gamma-irradiation on the nutritional value of foods must be done against this background.

Ground beef contains significant levels of several nutrients including niacin, riboflavin, vitamin B6, vitamin B12, lipids, proteins and minerals. Significance of nutrients in a given food was determined by identifying those nutrients present in a reasonable daily intake of the food at 10% or more of the Weighted Recommended Nutrient Intake (WRNI)[63]. The review of the data on irradiation effects on nutrients in ground beef led to the conclusion that irradiation at the proposed doses can be expected to reduce the thiamin and possibly the riboflavin and niacin contents of ground beef. These were the only nutrients affected. Vitamins are the most radiation-sensitive of the nutrients with thiamin the most sensitive of the vitamins of significance in beef. Thiamin is present in ground beef at less than 10% WRNI. The impact on it of irradiation was evaluated because of its sensitivity. Thiamin losses reported in the literature ranged from 28 to 59% at an irradiation dose of 5 kGy, varying mainly due to the temperature of the food during irradiation. Due to their inherent stability, vitamins B6 and B12 show little or no effect of irradiation at the proposed doses. Some studies have reported irradiation appearing to increase rather than decrease the

[63] The Weighted Recommended Nutrient Intakes are listed in the *Food and Drug Regulations*, in Table II of Part D, Division 1 (vitamins) and Table II of Part D, Division 2 (minerals).

niacin, riboflavin, vitamin B6 and vitamin B12 contents but this effect is inconsistent and unexplained.

Although the impact of thiamin was evaluated in ground beef, as a contributor to thiamin intake in the diet, this food has a minor impact. Thus, the significance to the total diet of the loss of thiamin from ground beef caused by irradiation is inconsequential. Similarly, the possible loss of niacin and riboflavin in the total diet would also be, at most, slight as a result of irradiation of ground beef at the dose levels proposed.

It should be noted that cooking also causes significant loss of thiamin and the combined effects of cooking and irradiation, both destructive on their own, may be greater than the sum of the two. It was generally found that thiamin losses can be reduced by lowering the irradiation dose, reducing the temperature of the meat product during irradiation, and irradiating in an anaerobic environment.

There are few reports in the literature of experimental results on the effect of irradiation on minerals in food. Most of the conclusions regarding minerals are based on assumptions about the chemistry of irradiation and of minerals. These assumptions, however, are reasonable since the impact of ionizing irradiation at food irradiation doses is, at most, to break intermolecular bonds and produce ions and short-lived free radicals. Thus, mineral elements would remain essentially unchanged. One paper does report that iron can change from the oxidized to the reduced state which could have an impact on bio-availability but this also occurs during cooking and storage.

Numerous studies have demonstrated that macronutrients in foods (lipids, proteins and carbohydrates) are not significantly affected by irradiation.

It is concluded that the losses of nutrients in irradiated ground beef are limited to the vitamins, thiamin and possibly, riboflavin and niacin, and that these losses are insignificant. In the case of thiamin, this is because of the minor contribution of ground beef to thiamin intake in the Canadian diet, and in the case of riboflavin and niacin it is because of the minor rates of loss, if any, expected. As with all food processing, however, good manufacturing practice should be followed to minimize unnecessary losses. This can be done through the administration of the lowest possible effective radiation dose, the use of low oxygen environments, and low product temperature during irradiation.

Because the effect of irradiation increases with dose, if significantly higher irradiation dose levels or higher product temperatures during irradiation (above refrigeration) are proposed at any time in the future, reconsideration of this recommendation may be necessary.

(g) *Toxicological Studies*

The toxicological database reviewed for the above submissions for red meat/ground beef included approximately 9 chronic studies plus 3 reproduction studies in rodents (mice and rats) and dogs in which beef, alone or in combination with other protein sources (fish, pork, dairy) was irradiated with doses from 27.9 - 93.0 kGy. Evidence supplied indicates that consumption of a variety of irradiated foods by experimental animals has demonstrated no effect on growth, longevity, reproductive capacity and spontaneous tumour incidence. No indication could be found that irradiation of red meats would result in them representing a significant source of cholesterol/lipid oxidation products (COPs/LOPs) or that treatment of meat with irradiation would result in greater exposure to

these compounds compared to levels formed through standard food preparation and storage practices. It should be noted that the majority of animals in the reproduction experiments required additional vitamin supplements to compensate for the destruction of fat-soluble vitamins by the high doses of irradiation.

Staff toxicologists concluded that the levels and types of generated radiolytic products in a particular food are directly proportional to the radiation dose and that at the absorbed dose levels requested by the petitioner, there are no toxicological concerns with the ground beef irradiation submission.

The toxicological studies reviewed are shown as Appendix IV to this document.

C. PROPOSED AMENDMENT

New items[64] proposed for addition to the Table in Division 26 are as follows:

Item	Column I Food	Column II Permitted Sources of Ionizing Radiation	Column III Purpose of Treatment	Column IV Permitted Absorbed Dose
8.1	Fresh/chilled ground beef	Cobalt-60, Cesium-137, electrons from machine sources (10 MeV max.) or X-rays (5 MeV max.)	To control pathogens, reduce microbial load and extend durable life.	1.5 kGy (minimum) 4.5 kGy (maximum)
8.2	Frozen ground beef	Cobalt-60, Cesium-137, electrons from machine sources (10 MeV max.) or X-rays (5 MeV max.)	To control pathogens, reduce microbial load and extend durable life.	2.0 kGy (minimum) 7.0 kGy (maximum)

D. CONSULTATION

Consultation was undertaken on the safety, nutritional quality and the efficacy of the irradiation treatments at the proposed dose levels with the following, as noted above:

- **The Toxicological Evaluation Section, Chemical Health Hazard Assessment Division**
- **Evaluation Division, Bureau of Microbial Hazards**
- **Nutrition Evaluation Division, Bureau of Nutritional Sciences.**

Canadian Food Inspection Agency Consultation

The Canadian Food Inspection Agency's evaluation addresses several issues that need to be dealt with by other agencies, i.e. the Canadian Nuclear Safety Commission, Environment Canada, Occupational Safety and Health. CFIA's primary concerns were: the establishment of Best Before Date labelling, the establishment of HACCP requirements, packaging material requirements and import/export issues. However, none of these issues

---

[64] Items 5, 6 and 7 are reserved for mangoes, poultry and shrimp respectively.

are reason to delay regulatory action on this submission.

A major Canadian nutritional institute

This institute indicated that all can benefit from having the choice of irradiated foods, but especially those at greater risk (e.g., people with compromised immune systems, such as transplant recipients and individuals with cancer and HIV/AIDS, and those in hospitals and long term care facilities). Another benefit would be a reduction in the direct costs of food borne illness: hospital and medical expenses, loss of income, investigation costs and loss to food suppliers.

This institute also expressed the need for education, labelling, continued good manufacturing practice and HACCP.

External Support and Testimonials:

An association representing the Canadian meat processing industry recommends that irradiation be approved by Health Canada and the Canadian Food Inspection Agency (CFIA) for ground beef products) and that it be extended to all red meat products.

Food Directorate
Health Products and Food Branch
Health Canada
October 29, 2002

APPENDIX I:

Microbiological studies considered in assessing the safety of irradiated beef

APPENDIX II

Studies considered in assessing the alteration of physical and chemical characteristics

APPENDIX III

Nutritional studies considered in assessing the safety of irradiated beef

APPENDIX IV

Toxicological studies considered in assessing the safety of irradiated beef

APPENDIX V

Proposed Irradiation Protocol for Beef Irradiation

APPENDIX I

Microbiological studies considered in assessing the safety of irradiated beef.

Aguirre M. and M.D. Collins. 1993. Lactic acid bacteria and- human clinical infection. J. Appl. Bacteriol. 75: 95-107.

Aker, S.N.. 1984. On the cutting edge of dietetic science: Irradiation of hospital food for patients with reduced immuno-responses. Nutrition Today July/August, 1984.

Altekruse, S.F., Cohen, M.L. and Swerdlow, D.L. 1997. Emerging foodborne diseases. Emerging Infectious Diseases 3(3): 285-293.

American Meat Institute Foundation. 1993. Consumer Awareness, Knowledge and Acceptance of Food Irradiation. November, 1993.

Anderson, I. 1989. Food Irradiation: An Alternative Food Processing Technology. Agriculture Canada, Agri-Food Development Branch.

Anellis, A., Shattuck, E., Morin, M., Srisara, B., Qvale, S., Rowley, D.B. and Ross, E.W. Jr. 1977. Cryogenic gamma irradiation of prototype pork and chicken and antagonistic effect between Clostridium botulinum types A and B. Appl. Microbiol. 34: 823-831.

Anonymous. 1997. E. coli food irradiator. USDA ARS News. Feb. 12 1997.

Anonymous. 1996. Position of the American Dietetic Association: Food Irradiation. J. Amer. Dietetic Assoc. 96 (1): 69-72.

Anonymous. 1995. Consumer reaction to irradiation still being studied. Feedstuffs, October 2 1995.

Beers, K.N. and Mohler, S.R. 1985. Food poisoning as an in-flight safety hazard. Aviation, Space and Environmental Medicine, June 1985.

Berg, G. 1978. Indicators of Viruses in Water and Food. Ann Arbor Science Publishers Inc., Ann Arbor, Michigan.

Beuchat, L.B., Doyle, M.P. and Brackett, R.E. Irradiation inactivation of bacterial pathogens in ground beef. Univ. of Georgia Center for Food Safety & Quality Enhancement. Report to the American Meat Institute, September 1993.

Blickstad, E. and Molin, G. 1988. Numerical taxonomy of psychrotrophic lactic acid bacteria from prepacked meat and meat products. Antonie van Leeuwenhoek 54: 301-323.

Bruhn, C.M. 1995a. Consumer attitudes and market response to irradiated food. J. Food Prot. 58(2): 175-181.

Bruhn, C.M. 1995b. Strategies for communicating the facts on food irradiation to consumers. J. Food Prot. 58 (1): 213-216.

Bruhn, C.M. 1993. Setting the record straight about food irradiation. Dairy, Food and Environmental Sanitation 13 (4): 220-221.

Bruhn, C.M., Sommer, R. and Schutz, H.G. 1986. Effect of an educational pamphlet and posters on attitude toward food irradiation. J. of Indust. Irradiation Tech. 4(1): 1-20.

Buchanan, RL. and Palumbo, S.A. 1985. Aeromonas hydrophila and Aeromonas sobrai as potential food poisoning species: a review. J. Food Safety 7: 15-29.

Burslem, C.D., Kelly, M.I. and Preston, F.S. 1990. Food poisoning -a major threat to airline operations. J. Soc. Occup. Med. 40: 97-100.

CAC 1990. Food Safety in Canada: A Survey of Consumer Attitudes and Opinions. Consumers Association of Canada.

Carter, A.O., Borczyk, A.A., Carlson, I.A.K, Harvey, B., Hockin, I.C., Karma1i, M.A, Krishnan, C., Korn, D.A. and Lior, H. 1987. A severe outbreak of Escherichia coli O157:H7 associated hemorrhagic colitis in a nursing home. New England J. Med. 317(24): 1496-1500.

Clavero, M.R, S.J.D. Monk, L.R. Beuchat, M.P. Doyle, and R.E. Brackett. 1994. Inactivation of Escherichia coli 0157:H7, Salmonellae, and Campylobacter jejuni in raw ground beef by gamma irradiation. Appl. Environ. Microbiol. 60: 2069-2075.

Collins, C.I., Muranot E.A. and Wesley, I. V. 1996. Survival of Arcobacter butzleri and Campylobacter jejuni after irradiation treatment in vacuum-packaged ground pork. J. Food Prot. 59: 1164-1166.

Crutch.field, S.R., Buzby, I.C., Roberts, T., Ollinger, M., Jordan Lin, C.T. 1997. An economic assessment of food safety regulations: the new approach to meat and poultry inspection. Economic Research Service. U.S.D.A. Jan-Apr. 1997. http://www.econ.ag.gov/epubs/ pdf/foodrevw/jan97.

Devriese, L.A., Laurier, L., De Herdt, P. and Haesebrouck, F. 1992. Enterococcal and streptococcal species isolated from faeces of calves, young cattle and dairy cows. J. Appl. Bacteriol. 72: 29-31.

Dow Jones/Reuters. 1997. U.S. House/FDA Overhaul: Beef irradiation provisions. In FSNET October 7, 1997. Douglas Powell, Dept Food Science, University of Guelph, Guelph, Ont. NIG 2Wl.

Eklund, M.W. 1982. Significance of Clostridium botulinum in fishery products preserved short of sterilization. Fd. Technol. 36: 107-115.

El-Shenawy, M.A., Yousef, A.E. and Marth, E.H. 1989. Radiation sensitivity of Listeria monocytogenes in broth or in raw ground beef. Lebensm.-Wiss. & Technol. 22: 387-390.

El-Zawahry , A. Y. and Rowley, D .B . 1979. Radiation resistance and injury of Yersinia enterocolitica. Appl. Environ. Microbiol. 37: 50-54.

Enfors, S.-O., Molin, G. and Ternstrom, A. 1979. Effect of packaging under carbon dioxide, nitrogen or air on the microbial flora of pork stored at 4˚C. J. Appl. Bacteriol. 47: 197-208.

Farber, J.M. and Peterkin, P.I. 1991. Listeria monocytogenes, a food-borne pathogen. Microbiol. Rev. 55: 476-511.

Farkas, I. 1989. Microbiological safety of irradiated foods. Int. J. Food Microbiol. 9: 1-15.

Federal Register, (Vol. 62, No. 232, p.64107), December 3, 1997.

Fu, A., Sebranek, I.G. and Murano, E.A. 1995a. Survival of Listeria monocytogenes, Yersinia enterocolitica and Escherichia coli O157:H7 and quality changes after irradiation of beef steaks and ground beef. J. Food. Sci. 60: 972-977.

Fu, A., Sebranek, I.G. and Murano, E.A. 1995b. Survival of Listeria monocytogenes and Salmonella typhimurium and quality attributes of cooked pork chops and cured ham after irradiation. J. Food. Sci. 60: 1001-1005.

Gasser, F. 1994. Safety of lactic acid bacteria and their occurrence in human clinical infections. Bull. Inst. Pasteur. 92: 45-67.

Grant, I.R. and Patterson, M.F. 1991. Effect of irradiation and modified atmosphere packaging on the microbiological and sensory quality of pork stored at refrigeration temperatures. Int. J. Food Sci.Technol. 26: 507-519.

Grant, I.R., Nixon, C.R. and Patterson, M.F. 1993. Effect of low-dose irradiation on growth of and toxin production by Staphylococcus aureus and Bacillus cereus in roast beef and gravy. Int. J. Food Microbiol. 18: 25-36.

Greenberg, R.A., Tompkin, R.B., Bladel, B.O., Kittaka, R.S. and Anellis, A. 1966. Incidence of mesophilic Clostridium spores. in raw pork, beef and chicken in processing plants in the United States and Canada. Appl. Microbiol. 15: 789- 793.

Greer, G.G., Gill, C.O. and Dilts, B.D. 1994. Evaluation of the bacteriological consequences of the temperature regimes experienced by fresh chilled meat during retail display. Food Res. Int. 27: 371-377.

Hanna, M.O., Zink, D.L., Carpenter, Z.L., and Vanderzant, C. 1976. Yersinia enterocolitica-like organisms from vacuum-packaged beef and lamb. J. Food Sci. 41: 1254-1256.

Hastings, I.W., Holzapfel, W.H. and Niemand, J.G. 1986. Radiation resistance of Lactobacilli isolated from radurized meat relative to growth and environment. Appl. Environ. Microbiol. 52: 898-901.

Hauschild, A.H.W. 1989. Clostridium botulinum, pp. 111-189 In M.P. Doyle (ed.) Foodborne Bacterial Pathogens. Marcel Dekker, Inc. New York.

Hauschild, A.H.W., Poste, L.M. and Hilsheimer, R. 1985. Toxin production by Clostridium botulinum and organoleptic changes in vacuum-packaged raw beef. J. Food Prot. 48: 712- 716.

Ibrahim, A and MacRae, I.C. 1991. Isolation off: enterocolitica and related species from red meat and milk. J. Food Sci. 56: 1524-1526.

IFT Daily News. 1997. Food Irradiation 'Sky's the Limit'. In FSNET October 7, 1997. Douglas Powell, Dept Food Science, University of Guelph, Guelph, Ont. NIG 2Wl.

Johnson, J.L., Doyle, M.P. and Cassens, R.G. 1989. Listeria monocytogenes and other Listeria spp. in meat and meat products: A review. J. Food Prot. 53: 81-91.

Klarman, D.,1989. Clostridium botulinum in faecal samples of cattle and swine and samples of raw material and pulverized dehydrated meat of different rendering plants. Berl. Munch. Tierarztl. Wschr. 102: 84. Cited in "Clostridium botulinum: Ecology and Control in Foods (ed. A.H.W .Hauschild and K. Dodds). 1993. p.58. Marcel Dekker, Inc. New York.

Konuma, H., Shinagawa, K., Tokumaru, M., Onoue, Y., Konno, S., Fujino, N., Shigehisa, T., Kurata, H., Kuwabara, Y and Lopes, C.A.M. 1988. Occurrence of Bacillus cereus in meat products, raw meat and meat product additives. J. Food Protect. 51: 324-326.

Lagunas-Solar, M.C. 1995. Radiation processing of foods: an overview of scientific principles and current status. J. Food Prot. 58 (2): 186-192.

Lambert, J.B. and Maxcy, R.B. 1984. Effect of gamma radiation on Campylobacter jejuni. J. Food Sci. 49: 665-667, 674.

Lambert, A.D., Smith, J.P. and Dodds, K.L. 1991a. Combined effect of modified atmosphere packaging and low-dose irradiation on toxin production by Clostridium botulinum in fresh pork. J. Food Prot. 54: 94-101.

Lambert, A.D, Smith, J.P. and Dodds, K.L. 1991b. Effect of headspace, CO_2 concentration on toxin production by Clostridium botulinum in MAP, irradiated fresh pork. J. Food Prot. 54: 588-592.

Lambert, A. D. Smith, J. P. and Dodds, K. L., 1991. Effect of initial 0_2 and CO_2 and low dose irradiation of toxin production by *Clostridium boulinum* in MAP fresh pork, J. Food Prot. 54: 939-944.

Lambert, A.D., Smith, J.P., Dodds, K.L. and Charbonneau, R. 1991. Microbiological changes and shelf life of MAP irradiated fresh pork, Food Microbiol., 9: 231-244.

Lauer, B.H. 1993. A historical perspective on the development of current control mechanisms and preclearance procedures governing the sale of irradiated foods in Canada. Environmental Health Review 37(2) :32-35, 47-48.

Lebepe, S., Molins, R.A, Charoen, S..P., Farrar, H.I.V. and Skowronski, R.P. 1990. Changes in microflora and other characteristics of vacuum-packaged pork loins irradiated at 3.0 kGy. J. Food Sci. 55: 918-924.

Lefebvre, N., Thibault, C. and Charbonneau, R 1992. Improvement of shelf-life and wholesomeness of ground beef by irradiation. 1. Microbial aspects. Meat Science 32: 203-213.

Lescano, G., Narvaiz, P., Kairiyama, E. and Kaupert, N. 1991. Effect of chicken breast irradiation on microbiological, chemical and organoleptic quality. Lebensm.-Wiss &Technol. 24: 130-134.

Lostly, T., Roth, J.S. and Shults, G. 1973. Effect of irradiation and heating on proteolytic activity of meat samples. J. Agr. Food Chem. 21: 275-277.

Lucke, F.-K, and Roberts, T.A. Control in Meat and Meat Products. In *Clostridium botulinum* Ecology and Controls in Foods (ed A.H.W Hauschild, and K.L. Dodds), 1993.

Ma, K and Maxcy, RB. 1981. Factors influencing radiation resistance of vegetative bacteria and spores associated with radappertization of meat. J. Food Sci. 46: 612-616.

Mano, S.B., Garcia de Fernando, G.D., Lopez-Galvez, D., Slegas, M.D., Garcia, M.L., Cambero, M.I. and Ordonez, I.A. 1995. Growth/survival of natural flora and Listeria monocytogenes on refrigerated uncooked pork and turkey packaged under modified atmospheres. J. Food Safety 15: 305-319.

Marcotte, Michelle. 1994. Commercial Food Irradiation, Market Tests and Consumer Attitude Research -Summary Tables. Discussion document for the United Nations Environment Programme. Methyl Bromide Technical Options Committee.

Mattila-Sandholm, T. and Skytta, E. 1991. The effect of spoilage flora on the growth of food pathogens in minced meat stored at chilled temperature. Lebensm-Wiss & Technol. 24: 116-120.

McMullen, L.M. and Stiles, M.E. 1996. Potential for use of bacteriocin-producing lactic acid bacteria in the preservation of meats. J. Food.Prot. Suppl. 64: 73.

Meischen, H. W .1987. Branded Beef- Product of tomorrow, today. Reciprocal Meat Conference 40: 37-45.

Mitchler, C. 1997. personal communication regarding CAC Policy and Positions on Food. Consumers Association of Canada. November 1991: 6.

Monk, I.D., Rocelle, M.A., Clavero, S., Beuchat, L.R, Doyle, M.P. and Brackett, R.E.. 1994. Irradiation inactivation of Listeria monocytogenes and Staphylococcus aureus in low- and high-fat, frozen and refrigerated ground beef. J. Food Prot. 57: 969-974.

Monk, I.D., Beuchat, L.R. and Doyle, M.P. 1995. Irradiation inactivation of food-borne micro-organisms. J. Food Prot. 58(2): 197-208.

Mossel, D.A.A. 1977. The elimination of enteric bacterial pathogens from food and feed of animal origin by gamma irradiation with particular reference to Salmonella radicidation. J. Food Quality 1: 85-104.

Murray, B.E. 1990. The Life and Times of the Enterococcus. Clin. Microbiol. Rev. 3: 46-65.

Morganthau, T. 1997. E. coli alert. Newsweek September 1 1997.

Morrison, R M., Buzby, J.C. and Jordan Lin, C.T. 1997. Irradiating ground beef to enhance food safety. Food Review Newsletter of the Economic Research Service. U.S.D.A. Jan-Apr. 1997. http://www .econ.ag.gov/epubs/pdf/foodrevw/jan97.

Naik, G.N., Pushpa, P., Chawla, S.P., Sherikar, A.T. and Nair, P.M. 1993. Improvement of microbiological quality and shelf-life of buffalo meat at ambient temperature by gamma irradiation. J. Food Safety. 13: 177-183.

Niemand, I.G., Van der Linde, H.I. and Hozapfel, W.H. 1981. Radurization of prime beef cuts. J. Food Prot. 44: 677-681.

Niemand, I.G., Van der Linde, H.I. and Hozapfel, W.H. 1983. Shelflife extension of minced beef through combined treatments involving radurization. J. Food Prot. 46: 791-796.

Palumbo, S.A., Maxino, F., Williams, A. W., Buchanan, RL. and Thayer, D.W. 1985, Starch ampicillin agar for the quantitative detection of Aeromonas hydrophila. Appl. Environ. Microbiol. 50: 1027-1030.

Palumbo, S.A., Jenkins, R.K., Buchanan, R.L. and Thayer, D.W. 1986. Determination of irradiation D-values for Aeromonas hydrophila. J. Food Prot. 49: 189-191.

Patterson, M. 1988. Sensitivity of bacteria to irradiation on poultry meat under various atmospheres. Lett. Appl. Microbiol. 7: 55-58.

Pszczola, D.E. 1997. 20 ways to market the concept of food irradiation. 1997. Food Technology 51: 46-48.

Pszczola, D.E. 1993. Irradiated poultry makes US debut in Midwest and Florida markets. Food Technol. 47(11): 89,92, 94, 96.

Radomyski, T., Murano, E.A., Olson, D.G. and Murano, P.S. 1994. Elimination of pathogens of significance in food by low-dose irradiation: a review. J. Food Prot. 57: 73-86.

Resureccion, A. V.A., Galvez, F.C.F., Fletcher, S.M. and Misra, S.K. 1995. Consumer attitudes toward irradiated food: Results of a new study. J. Food Prot. 58(2): 193-196.

Robeck, M.R 1996. Product liability issues raised by the growth in the irradiated food market. Proc. Food Irradiation...It Works, Its Safe and Its Time. June 3-4, 1996. Institute of Food Science and Engineering. Texas A & M University.

Schiemann, D.A. 1989. Yersinia enterocolitica and Yersinia pseudotuberculosis pp. 601-672. In M.P. Doyle (ed.), Foodborne Bacterial Pathogens. Marcel Dekker, Inc. New York.

Singh, H. 1997. Isolation and identification of Aeromonas spp. for ground meats in Eastern Canada. J. Food Prot. 60: 125-130.

Soulsby, E.J.L. 1974. Parasitic Zoonoses: Clinical and Experimental Studies. Academic Press Inc., New York, N.Y.

Stecchini, M.L., Sarais, I., Deltorre, M. and Fuochi, P.G. 1995. Effect of electron irradiation and packaging atmosphere on the survival of Aeromonas hydrophila in minced poultry meat. Radiation Physics and Chemistry 46: 779-784.

Stern, N.I., Hernandez, M.P., Blankenship, L., Deibel, K.E., Doores, S., Soyle, M.F., Ng, H., Pierson, M.D., Sofos, I.N., Sveum, W.H. and Westhoff, D.C. 1985. Prevalence and distribution of Campylobacter jejuni and Campylobacter coli in retail meats. J. Food Prot. 48: 595-599.

Sullivan, R, Scarpino, P.V., Fassolitis, A.C., Larkin, E.P. and Peeler, J. 1973. Gamma radiation inactivation of coxsackie virus B-2. Appl. Microbiol. 26: 14-17.

Tarkowski, I.A., Stoffer, S.C.C., Beumer, R.R and Kampelmacher, E.H. 1984a. Low dose gamma irradiation of raw meat. I. Bacteriological and sensory quality effects in artificially contaminated samples. Int. J. Food Microbiol 1: 13-23.

Tarkowski, I.A., Beumer, RR and Kampelmacher, E.H. 1984b. Low dose gamma irradiation of raw meat. II. Bacteriological effects on samples from butcheries. Int. J. Food Microbiol. 1: 25-31.

Tauxe, R V. 1991. Salmonella: a postmodern pathogen. J. Food Prot. 54: 563-568.

Thayer, D. W. 1993. Extending the shelf-life of poultry and red meat by irradiation processing. J. Food Prot. 56: 831-846.

Thayer, D.W., G. Boyd, J.B. Fox Jr., L. Lakritz, and J.W. Hampson. 1995a. Variations in radiation sensitivity of foodborne pathogens associated with the suspending meat. J Food Safety 60: 63-67.

Thayer, D.W. 1995b. Use of irradiation to kill enteric pathogens on meat and poultry. J. Food Safety 15: 181-192

Thayer, D.W. and B. Boyd. 1993. Elimination of Escherichia coli O157:H7 in meats by gamma irradiation. Appl. Environ. Microbiol. 59: 1030-1034.

Thayer, D. W. and Boyd, G. 1996. Inactivation of Shewanella putrefaciens by gamma irradiation of red meat and poultry. J. Food Safety 16: 151-160.

Thayer, S. W., Josephson, E.S., Brynjolfsson, A., Giddings, G.G. 1996. Radiation pasteurization of food. Council for Agricultural Science and Technology (CAST) Issue Paper 7. Ames, Iowa.

Todd. E.C.D. 1992. Foodborne disease in Canada: a 10-year summary from 1975 to 1984. J. Food Prot.

55(2): 123-132.

Todd, E.C.D. 1989. Preliminary estimates of costs of foodborne disease in Canada and the costs to reduce salmonellosis. J. Food. Prot. 52(8): 595-601.

Todd, E.C.D. 1987. Legal liability and its economic impact on the food industry. J. Food Prot. 50(12): 1048-1057.

Todd, E.C.D. 1985a. Economic loss from foodborne disease outbreaks associated with foodservice establishments. J. Food Protection 48: 169-180.

Todd, E.C.D. 1985b. Economic loss from foodborne disease and non-illness related recalls because of mishandling by food processors. J. Food. Prot. 48(7): 621-633.

Tongpim, S., Beumer, RR and Kampelmacher, E.I. 1984. Comparison of modified Rappaport's medium (RV) and Muller-Kauffmann F medium (MK-ISO) for the detection of Salmonella in meat products. Int. J. Food Microbiol 1: 33-42.

Tsuji K. 1983. Low dose cobalt 60 irradiation for reduction of microbial contamination in raw materials for animal health products. Food Technol. 37(2): 48-54.

Van Garde, S.I. and Woodburn, M.I. 1987. Food discard practices of householders. Am. Diet. Assoc. J. 87: 322-329.

Wegener, H.C., Madsen, M, Nielsen, N. and Aarestrup, F.M. 1997. Isolation of vancomycin resistant Enterococcus faecium from food. Int. J. Food Microbiol. 35: 57-66.

Wolin, E.F., Evans, I.B. and Niven, C.F. Jr. 1957. The microbiology of fresh and irradiated beef Food Res. 22: 682-686.

APPENDIX II

Studies considered in assessing the alteration of physical and chemical characteristics.

Bowes, J.H. and Moss, J.A. 1962. The effect of gamma radiation on collagen. Rad. Res., 16: 211

Davies, K.J.A., Delsignoret, M.E., Lin, S.W. 1987. Protein degradation by oxygen radicals. 3. Modification of secondary and tertiary structure. J. Biol. Chem., 262: 9902.

Davies, K.J.A., Delsignoret, M.E. Lin, S.W. 1987. Protein degradation by oxygen radicals. J. Biol. Chem., 262: 9895.

Delincée, H. 1983. Recent advances in radiation chemistry of proteins. In Recent Advances in Food Irradiation. P.S. Elias and A.J. Cohen (eds.). Elsevier Biomedical, Netherlands, p.129.

Dillon, J.C., Joyeux, J., Levillain, M., Brechet, V. 1986. Cahier de nutrition et de diététique, 21: 461.

Federation of American Societies for Experimental Biology (FASEB). Life Sciences Research Office. Select Committee on Health Aspects of Irradiated Beef, Herman J. Chin, Chairman). August, 1977 and March, 1979. Evaluation of the Health Aspects of Radiolytic Compounds Found in Irradiated Beef. NTIS Order No. PB84-187087.

Groninger, H.S. and Tappel, A.L. 1956. The destruction of thiamine in meats and in aqueous solution by gamma radiation. Food Research, 21: 555.

Groninger, H.S., Tappel, A.L. and Krapp, F.W. 1956. Some chemical and organoleptic changes in gamma irradiated meats. Food Research, 21: 555.

Grootveld, M., Jain, R., Claxson, A.W.D., Naughton, S. and Blake, D.R. 1990. The detection of irradiated foodstuffs. Trends in Fd. Sci. Technol., July 7-14.

Hampson, J.W., Fox, J.B., Lakirtz, L., and Thaer, D.W. 1966. Effect of low dose gamma radiation on lipids in five different meats. Meat Science, 42: 271.

Hassan, I.M. and Shams El-Din, N.M. 1986. Effect of irradiation and cold storage on fatty acid composition of meat phospholipids. 11th International Congress for Statistics, Computer Science and Demographic Research. Cairo, Egypt., p.47.

IFT Daily News 1997 (Chapter I)

Karam, L.R. and Simic, M.G. 1990. Formation of ortho-tyrosine by radiation and organic solvents in chicken tissue. J. Biol. Chem., 265: 11581.

Kilcast, D. 1994. Effect of irradiation on vitamins. Fd. Chem., 49: 157.

Lakritz, L., Fox, J.B., Hampson, J., Richardson, R., Kohout, K. and Thayer, D.W. 1995. Effect of gamma irradiation on levels of α-tocopherol in red meats and turkey. Meat Sci., 41: 261.

Lea, C.H.J., Macfarlane, J. and Parr, L.J. 1960. Treatment of meats with ionizing radiation. II. Radiation pasteurization of beef for chilled storage. J. Sci. Food Agric., 11: 690.

Lefebvre, N., Thibault, C., Charbonneau, R. and Piette, J.P.G. 1994. Improvement of shelf life and wholesomeness of ground beef by irradiation. II. Chemical analysis and sensory evaluation. Meat Sci., 36: 371-380.

Ley, F.J., Bleb, J., Coates, M.E. and Patterson, J.S. 1969. Sterilization of animal diets using gamma radiation. Lab Animals, 3: 221.

Love, J.D. and Pearson, A,M, 1971. Lipid oxidation in meat and meat products, a review. J. Am. Oil Chem. Soc., 48: 547.

Merritt, C. Jr., 1972. Qualitative and quantitative aspects of trace volatile components in irradiated foods and food substances. Radiation Research Reviews, 3: 353-368.

Merritt, C. Jr. 1980. The analysis of radiolysis products in meats and meat substances. Food Irr. Info., 10: 20-33.

Merritt, C. Jr. 1984. Radiolysis compounds in chicken and bacon. Final Report. September 18, 1981 - September 20, 1982. EERC/ARS-83. NTIS Order No. PB84-187095.

Merritt, C. Jr., Angelini, P. and Graham R. A. 1978. Effect of radiation parameters on the formation of radiolysis products in meat and meat substances, *J. Agri. Food Chem*.**,** 26(1): 29-35.

Merritt, C. Jr., Angelini, P. And Nawar, W.W. 1978. Chemical analysis of radiolysis products relating to the wholesomeness of irradiated food. From: Food Preservation by Irradiation, Vol. II; IAEA, Vienna, 1978, pp. 97-112. IAEA Paper No. IAEA-SM-221/51.

Millar, S.J. 1995. The effect of ionizing radiation on the appearance of meat. Dissertation Abstracts International C-56.

Miller, E.C. and Miller, J.A. 1986. Carcinogens and mutants that may occur in foods. Cancer 58: 1795-1803.

Morehouse, K.M., Kiesel, M. and Ku, Y. 1993. Identification of meat treated with ionizing radiation by capillary gas chromatographic determination of radiolytically produced hydrocarbons, *J. Agric. and Food Chem*., 41: 758-763.

Morehouse, K.M. and Ku, Y. 1993. Identification of irradiated foods by monitoring radiolytically produced hydrocarbons. *Radiat. Phys. Chem*., 42: 359-362.

Nawar, W, W, and Balboni, J. J. 1970. Detection of irradiation treatment in foods, *J. Assoc.Analyt. Chem*., 53: 726.

Nawar, W.W., Zhu, Z.R. and Yoo, Y.J. 1990. In “Food irradiation and the chemist.” Eds. D.E. Johnston and M.H. Stevenson, Belfast, Northern Ireland.

Nawrot, P.S., Vavasour, E.J. and Grant, D.L. 1999. Food irradiation, heat treatment, and related processing techniques: Safety evaluation. Chapter 18 in International Food Safety Handbook. Kees van der Heijden, Maged Younes, Lawrence Fishbein and Sanford Miller (Eds.), Marcel Dekker, Inc., New York, Basel.

Pryor, W.A. (Ed.) 1984. Free radicals in biology. Academic Press, London.

Rhee, K.S., Anderson, L.M. and Sams, A.R. 1996. Lipid oxidation potential of beef, chicken and pork. J. Food Sci., 61: 8-12.

Schreiber, G.A., Schulzki, G., Spielberg, A., Helle, N., Bogl, K.W. 1994. Evaluation of a gas chromatographic method to identify irradiated chicken, pork and beef by by detection of volatile hydrocarbons. J. AOAC International 77: 1202-1217.

Singh, H., Lacroix, M., Gagnon, M. 1991. Post-irradiation chemical analyses of poultry: a review., November, 1991.

Spiegelberg, A., Schulzki, G., Helle, N., Bogl, K. W. and Schreiber, G. A. 1994. Methods of routine control of irradiated food: optimization of a method for the detection of radiation- induced hydrocarbons and its application to various foods, *Radiat. Phys. Chem*., 43: 433.

Stadtman, E.R. 1994. Oxidation of free amino acids and amino acid residues in proteins by radiolysis and by mtasl-catalyzed reactions. Ann. Rev. Biochem., 62: 797.

Taub, I.A. 1983. Reaction mechanisms, irradiation parameters, and product formation. In Preservation of Food by Ionizing Radiation. Eds. E.S. Josephson and M.S. Peterson. CRC Press, Incorporated.

Taub, I.A., Angelini, P. and Merritt, C. 1976. Irradiated food: validity of extrapolating wholesomeness data. J. Food Sci., 41: 942-944.

Taub, I.A., Kaprielian, R.A. and Halliday, J.W. 1978. Radiation chemistry of high protein foods irradiated at low temperature. From: Food Preservation by Irradiation, Vol. I; IAEA, Vienna, 1978, pp. 371-384. IAEA Paper No. IAEA-SM-221/59.

Taub, I.A., Kaprielian, R.A., Halliday, J.W., Walker, J.E., Angelini, P., Merritt, C. 1979. Factors affecting radiolytic effects in food. Radiat. Phys. Chem., 14: 639.

Thomas, M.H. 1988. Use of ionizing radiation to preserve a food. In Nutritional Evaluation of Food Processing (3rd Edition). Endel Karmas and Robert S. Harris (Eds.). AVI Publications.

WHO 1977. Wholesomeness of irradiated foods. Report of a Joint FAO/IAEA/WHO Expert Committee. Technical Report Series No. 604. World Health Organization, Geneva, Switzerland.

WHO 1981. Wholesomeness of irradiated foods. Report of a Joint FAO/IAEA/WHO Expert Committee. Technical Report Series No. 659. World Health Organization, Geneva, Switzerland.

WHO 1997. Food Irradiation. Press Release WHO/68. 19 September 1997.

Wierbicki, E. 1980. Technology of irradiation preserved meats. 26th Eur. Meeting Meat Res. Wkrs 31 August - 5 September, p.194.

APPENDIX III

Nutritional studies considered in assessing the safety of irradiated beef.

1. American Council on Science and Health, Irradiated Foods, 2nd Edition, July 1985.

2. Basson, R.A., Advances in Radiation Chemistry of Food and Food Components - An Overview, in Recent Advances in Food Irradiation, Elias, P.S. and Cohen, A.J. (Eds), Elsevier Biomedical, 1983.

3. Council for Agricultural Science and Technology, Report #109, Ionizing Energy in Food Processing and Pest Control, I. Wholesomeness of Food Treated with Ionizing Energy, 1986.

4. Codex Alimentarius Commission, (Vol. 4), "General Principles for the Addition of Essential Nutrients to Foods", CAC/GL 09-1987 (1994).

5. Diehl, J.F., Effects of combination processes on the nutritive value of food, in Combination Processes in Food Irradiation, IAEA Symposium Proceedings, IAEA, Vienna, 1981, p. 349-366.

6. Diehl, J.F., International Status of Food Irradiation, Food Technology in Australia, 36(8): 356, p. 358-366, 1984.

7. Diehl, J.F., Safety of Irradiated Foods, 2nd ed., Marcel Dekker, Inc., p. 273, 1995.

8. de Groot, A.P., van der Mijll Dekker, Slump, P., Vos, H.J., and Willems, J.J.L., Composition and Nutritive Value of Radiation-Pasteurized Chicken, Report # R3787, Central Institute for Nutrition and Food Research, The Netherlands, 1972.

9. Délincée, H., Recent advances in radiation chemistry of proteins, in Recent Advances in Food Irradiation, ed. P.S. Elias and A.J. Cohen, Elsevier Biomedical Press, 1983.

10. FAO/IAEA/WHO (Food and Agriculture Organisation/International Atomic Energy Agency/World Health Organisation) Joint Expert Committee, Wholesomeness of Irradiated Foods, WHO Technical Report Series #659, 1981.

11. Fox, J.B., jr., Lakritz, L., Thayer, D.W., Effect of reductant level in skeletal muscle and liver on the rate of loss of thiamin due to gamma-radiation, Int. J. Radiat. Biol., 64(3), p. 305-309, 1993.

12. Fox, J.B., Jr., Thayer, D.W., Jenkins, R.K., Phillips, J.G., Ackerman, S.A., Beecher, E.R., Holden, J.M., Morrows, F.D., and Quirbach, D.M., Effect of Gamma Irradiation on the B Vitamins of Pork Chops and Chicken Breasts, Int. J. Radiat. Biol., 55(4), p. 689-703, 1989.

13. Fox, J.B., Jr., L. Lakritz, J. Hampson, R. Richardson, K. Ward, and D.W. Thayer, Gamma irradiation effects on thiamin and riboflavin in beef, lamb, pork, and turkey, J. Food Science, 60 (3):596-598, 603, 1995.

14. Gallien, Cl. L., Paqiun, J., Ferradini, C. and Sadat, T., Electron Beam Processing in Food Industry - Technology and Costs, Radiat. Phys. Chem., 25(1-3), p.81-96, 1985.

15. Gruiz, K. and Kiss, I., Effect of Ionizing Radiation on the Lipids in Frozen Poultry, I. Fatty Acids and Hydrocarbons, Acta Alimentaria, 16(2), p.111-127, 1987.

16. Hampson, J.W., Fox, J.B., Lakrtiz, L., and Thayer, D.W., Effect of Low Dose Gamma Radiation

on Lipids in Five Different Meats, Meat Science, 42 (3), p.271-276, 1996.

17. Hanis, T., Jelen, P., Klir, P., Mnukova, J., Perez, B. and Pesek, M., Poultry Meat Irradiation - Effect of Temperature on Chemical Changes and Inactivation of Microorganisms, J. Food Protection, 52(1), p.26-29, 1989.

18. Health Canada, Canadian Nutrient File, 1997.

19. Ibrahim, S., El-Said, F., and Ahmed, A.K., Gamma irradiation of fats and fatty oils. Part II. Effect of gamma radiation on the fatty peroxy compounds and on the stability of fats, Bull. Fac. Pharm., Cairo Univ. 7, p. 11-25, 1968.

20. Josephson, E.S., Thomas, N.H. and Calhoun, W.K., Nutritional aspects of food irradiation: An overview, J. Food Proc. Pres. 2, p.299-313, 1978.

21. Kanatt, S.R., Paul, P., D'Souza, S.F., and Thomas, P., Effect of Gamma Irradiation on the Lipid Peroxidation in Chicken, Lamb and Buffalo Meat During Chilled Storage, J. Food Safety, 17, p.283-294, 1997.

22. Katta, S.R., Rao, D.R., Sunki, G.R., and Chawan, C.B., Effect of Gamma Irradiation of Whole Chicken Carcasses on Bacterial Loads and Fatty Acids, J. Food Sci., 56(2), p.371-372, 1991.

23. Kraybill, H.F., Effect of processing on nutritive value of food: Irradiation, in Handbook of Nutritive Value of Processed Food, Vol. I, M. Rechcigl Jr., (ed.), CRC Press, Boca Raton, Fl., 1982, p. 181-208.

24. Lorenz, Klaus, Irradiation of cereal grains and cereal grain products, Critical Reviews in Food Science and Nutrition,, Vol. 6 (4), p. 317-382, 1975.

25. Mast, M.G. and Clouser, C.S., The Effect of Further Processing on the Nutritive Value of Poultry Products, World Poultry Science Association, 7th European Symposium on Meat Quality, p.219-234, 1985.

26. Maxwell, R.J., and Rady, A.H., Effect of Gamma Irradiation at Various Temperatures on Air and Vacuum Packed Chicken Tissues II. Fatty Acid Profiles of Neutral and Polar Lipids Separated from Muscle and Skin Irradiated at 2-5°C, Radiat. Phys. Chem., 34 (5), p.791-796, 1989.

27. Meister, K.A., Irradiated Foods, American Council on Science and Health, 1985.

28. Mills, S., Issues in Food Irradiation, Discussion Paper, Science Council of Canada, 1987.

29. Murray, T.K., Nutritional aspects of food irradiation, in Recent Advances in Food Irradiation, Elias, P.J. and A.J. Cohen, eds., Elsevier Biomedical Press, Amsterdam, p. 203-216, 1983.

30. Nawar, W.W., Radiolysis of Non-Aqueous Components of Foods, in Preservation of Food by Ionizing Radiation, Vol. II, Josephson, E.S. and Peterson, M.S. (eds), CRC Press, 1983.

31. Nova Scotia Heart Health Program, Report of the Nova Scotia Nutrition Survey, 1993.

32. Rady, A.H., Maxwell, R.J. Wierbecki, E., and Phillips, J.G., Effect of Gamma Irradiation at Various Temperatures and Packaging Conditions on Chicken Tissues I. Fatty Acid Profiles of Neutral and Polar Lipids Separated from Muscle Irradiated at -20°C, Radiat. Phys. Chem., 31 (1-3), p.195-202, 1988.

33. Sadat, T. and Vassenaix, M., Use of a Linear Accelerator for Decontamination of Deboned Poultry Meat, Radiat. Phys. Chem., 36(5), p.661-665, 1990.

34. Santé Québec, Rapport de l'Enquête québécoise sur la nutrition, 1990, Gouvernement du Québec, 1995.

35. Shamsuzzaman, K., Chuaqui-Offermanns, N., Lucht, L., McDougall, T. and Borsa, J., Microbiological and Other Characteristics of Chicken Breast Meat Following Electron-Beam and Sous-Vide Treatments, J. Food Protection, 55(7), p. 528-533, 1992.

36. Skala, J.H., McGown, E.L. and Waring, P.P., Wholesomeness of Irradiated Foods, J. Food Protection, p.150-160, 1987.

37. Thomas, M.H. and Josephson, E.S., Radiation preservation of foods and its effects on nutrients, Sci. Teacher 37, p. 59-63, 1970.

38. U.K. Advisory Committee on Irradiated and Novel Foods, Report on the safety and wholesomeness of irradiated foods, Department of Health and Social Security, Ministry of Agriculture, Fisheries and Food, U.K., 1984.

39. U.S. Federal Register, 55(85), Rules and Regulations, p. 18538-18544, 1990.

40. Urbain, W.M., Radiation Chemistry of Proteins, Chapter 4 in Radiation Chemistry of Major Food Components, ed. P.S. Elias and A.J. Cohen, Elsevier, New York, 1977.

41. Wood, B.F., A research project to demonstrate the efficacy of controlling microorganisms in poultry and poultry products by gamma irradiation - part of the Processing, Distribution, and Retailing (PDR) program. Food Research Institute, Research Branch, Agriculture Canada, Ottawa, 1986.

42. World Health Organization, Safety and Nutritional Adequacy of Irradiated Food, p.139, 1994.

APPENDIX IV

Toxicological studies considered in assessing the safety of irradiated beef.

Addis, P.B. and Park, P.S.W., Cholesterol oxide content of foods, *Biological Effects of Cholesterol Oxides*. CRC Press, 1992.

AIC/CIFST Joint statement of food irradiation, *J. Inst. Can. Sci. Technol. Aliment*., 22(3), p.190- 196, 1989.

Bischoff, F., Carcinogenic effects of steroids. *Adv. Lipid Res*., 7, p.165-244, 1969.

Bull, A.W., Nigro, N.D., Golembieski, W.A., Crissman, J.D. and Marnett, L.J., In vivo stimulation of DNA synthesis and induction of ornithine decarboxylase in rat colon by fatty acid hydroperoxides, autooxidation products of unsaturated fatty acids. *Cancer Res.,* 44, p.4924-4928, 1984.

Engeseth, N.J. and Gray, J.I. Cholesterol oxidation in muscle tissue. *Meat Science*, 36, p.309-320, 1994.

Gray, M.F., Lawrie, T.D.V. and Brooks, C.J.W. Isolation and identification of cholesterol α-oxide and other minor sterols in human serum. *Lipids,* 6, p.836-843, 1971.

Hampson, J.W., Fox, J.B., Lakrtiz, L., and Thayer, D.W., Effect of Low Dose Gamma Radiation on Lipids in Five Different Meats, *Meat Science*, 42(3), p. 271-276, 1996.

Hwang, K.T. and Maeker, G. Quantitation of Cholesterol Oxidation Products in Unirradiated and Irradiated Meats. *J. Amer. Oil Chem Soc*., 70(4), p.371-375, 1993.

Jacobson, M.S. Cholesterol oxides in Indian ghee: possible cause of unexplained high risk of atherosclerosis in Indian immigrant populations. *Lancet*, 8560, p.656-658, 1987.

Johnson, L.P., Williams, S.R., Neel, S.W., Reagan, J.O. Foodservice industry market profile study: Nutritional and objective textural profile of foodservice ground beef. *J. Animal Sci*., 72, p.1487-1491, 1994.

Kanazawa, K., Kanazawa, E. and Natake, M., Uptake of secondary antioxidation products of linoleic acid by the rat. *Lipids,* 20(7), p.412-419, 1985.

Kanazawa, K., Ashida, H., Minamoto, Sl and Natake, M., The effect of orally administered secondary autooxidation products of linoleic acid on the activity of detoxifying enzymes in the rat liver. *Biochim. Biophys. Acta*, 879, p.36-43, 1986.

Kilcast, D., Effect of irradiation on vitamins. *Food Chem*., 49, p.157-164, 1994.

Lakritz, L. et al., Effect of gamma radiation on levels of alpha-tocopherol in red meats and turkey. *Meat Science*, 41(3), p.261-271, 1995.

Lipkin, M.., Reddy, B.S., Weisburger, J. and Schechter, L. Nondegradation of fecal cholesterol in subjects at high risk for cancer of the large intestine. J. *Clin. Invest*., 67(1), p.304-307, 1981.

van Logten, M.J., deVries, T., van der Heijden, C.A., van Leeuwen, F.X.R., Garbis-Berkvens, M.J.M. AND Strick, J.J.T.W.A. Long-term wholesomeness study of autoclaved or irradiated pork in rats. National Institute of Public Health Report No. 617401001, The Netherlands, 1983.

MacGregor, J.T., Wilson, R.E., Neff, W.E. and Frankel, E.N., Mutagenicity tests of lipid oxidation products in *Salmonella typhimurium*: monohydroperoxides and secondary oxidation products of methyl linoleate and methyl linolenate. *Fd. Chem. Tox*., 23(12), p.1041-1047, 1985.

McCay, C.M. and Rumsey, G.L., Effect of irradiated meat upon growth and reproduction in dogs. *Fed. Proc*., 19, p.1027-1030, 1960.

Maeker, G. and Jones, K.C., Gamma-irradiation of individual cholesterol oxidation products. *J. Amer. Oil Chem Soc.,* 69(5), p.451-455, 1992.

Merritt Jr., C.M., Angelini, P. and Graham R. A. Effect of radiation parameters on the formation of radiolysis products in meat and meat substances. *J. Agri. Fd. Chem*., 26(1), p.29-35, 1978.

Merritt Jr., C. and Taub, I.A., Commonality and predictability of radiolytic products in irradiated meats, in *Recent Advances in Food Irradiation.* p. 27-57, Elsevier Biomed. Press,1983.

Merritt Jr., C., Vajdi, M. and Angelini, P. A Quantitative Comparison of the Yields of Radiolysis Products in Various Meats and their Relationship to Precursors. *J. Amer. Oil Chem Soc*., 62(4), p.708-713, 1985.

Mittler, S., Failure of irradiated beef and ham to induce genetic aberrations in Drosophila. *Int. J. Radiat. Biol*., 35, p.583-588, 1979.

Nakayama, T., Kaneko, M. and Kodama, M., Detection of DNA damage in cultured human fibroblasts induced by methyl linoleate hydroperoxide. *Agric. Biol. Chem.*, 50(1), p.261-2, 1986.

Nielsen, J.H., Olsen, C.E., Duedahl, C. and Skibsted, L.H. Isolation and quantification of cholesterol oxides in dairy products by selected ion monitoring mass spectrometry. *J. Dairy Res*., 62, p.101-113, 1995.

Park S.W. and Addis, P.B. Identification and Quantitative Estimation of Oxidized Cholesterol Derivatives in Heated Tallow. *J. Agri. Fd. Chem*., 34(4), p.653-659, 1986.

Park, S.W. and Addis, P.B., Cholesterol oxidation products in some muscle foods. *J. Food Sci*., 52(6), p.1500-03, 1987.

Peng, S.-K. Cytotoxicity of cholesterol oxides, *Biological Effects of cholesterol oxides*. CRC Press, 1992.

Peng, S.K., Morin, R.J., Tham, P. and Taylor, C.B. Effects of oxygenated derivatives of cholesterol on cholesterol uptake by cultured aortic smooth muscle cells. *Artery*, 13, p.144-164, 1985.

Peterson, A.R., Peterson, H., Spears, C.P., Trosko, J.E. and Sevanian, A. Mutagenic characterization of cholesterol epoxides in Chinese hamster V79 cells. *Mut. Res*., 203, p.355-366, 1988.

Petrakis, N.L., Gruenke, L.D. and Craig, J.D. Cholesterol and cholesterol epoxides in nipple aspirates of human breast fluid. *Cancer Res.*, 41, p.2563-2565, 1981.

Raaphorst, G.P., Azzam, E.I., Langlois, R. and Van Lier, J.E. Effect of cholesterol and epoxides on cell killing and alpha and beta transformation. *Biochem. Pharmacol*., 36(14), p.2369-2372, 1987.

Radomski, J.L., Deichmann, W.B., Austin, B.S. and MacDonald, W.E. Chronic toxicity studies on irradiated beef stew and evaporated milk. *Toxicology and Applied Pharmacol*., 7, p.113-121, 1965.

Rady, A.H., Maxwell, J., Wiebicki, E., Phillips, J.G. Effect of gamma irradiation at various temperatures and packaging conditions on chicken tissues. 1. Fatty acid profiles of neutral and polar lipids separated from muscle irradiated at -20^{o}C. *Radiat. Phys. and Chem*., 31(1-3), p.195-202, 1988.

Raica, Jr., N. and Howie, D.L., Review of the U.S. Army wholesomeness of irradiated food program. *Food Irradiation Proc. Symp*., Karlsruche, SM-73/5. IAEA, p.119-135, 1966.

Reddy, B.S. and Wynder, E.L. Metabolic epidemiology of colon cancer. *Cancer*, 39, p.2533-2539, 1977.

Reddy, B.S. and Watanabe, K. Effect of cholesterol metabolites and promoting effects of lithocholic acid in colon carcinogenesis in germ-free and conventional F344 rats. *Cancer Res*., 39, p.1521-1524, 1979.

Renner, H.W., Graf, U., Wurgler, F.E., Altmann, H., Asquith, J.C. and Elias, P.S. An Investigation of the genetic toxicology of irradiated foodstuffs using short-term test systems. Part 3. *In vivo* in small rodents and in *Drosophila melanogaster*. *Food Chem. Toxicol.*, 20, p.867-878, 1982.

Sander, B.D., Addis, P.B., Park, S.W. and Smith, D.E. Quantification of Cholesterol Oxidation Products in a Variety of Foods. *J. Food Protection*, 52(2), p.109-114, 1989.

Schweigert, B.S., The nutritional content and value of meat and meat products. *The Science of Meat and Meat Products*, p. 275-305, Food and Nutrition Press, 1987.

Sevanian, A. and Peterson, A.R., Cholesterol epoxide is a direct acting mutagen. *Proc. National Academy Science*, 81, p.4198-4202, 1984.

Smith, L.L, Smart, V.B. and Ansari, G.A.S. Mutagenic cholesterol preparations. *Mut. Res*., 68, p.23-30, 1979.

Sporer, A., Brill, D.R. and Schaffner, C.P. Epoxycholesterols in secretions and tissues of normal, benign and cancerous human prostate glands. *Urology*, 20(3), p.244-250, 1992.

Suzuki, K., Bruce, W.R., Baptista, J., Furrer, R., Vaughan, D.J. and Krepinsky, J.J. Characterization of cytotoxic steroids in human faeces and their putative role in the etiology of human colonic cancer, *Cancer Letters*, 33, p.307-316, 1986.

Taub, I.A., Robbins, F.M., Simic, M.G., Walker, J.E. and Wierbicki, E. *Food Tech.*, 33, p.184-193, 1979.

Taub, I.A., Angeline, P. and Merritt, C. Irradiated food: validity of extrapolating wholesomeness data. *J. Food Sci*., 41, p.942-944, 1976.

Thayer, D.W., Shieh, J.J., Jenkins, R.K., Phillips, J.G., Wierbicki, E. and Ackerman, S.A. Effect of gamma ray radiation and frying on the thiamine content of bacon. *J. Food Quality*, 13, p.147-169, 1990.

Vaca, C.E., Wilhelm, J. and Harms-Ringdahl, M. Interaction of lipid peroxidation products with DNA: a review, *Mut. Res.*, 195, p.137-149, 1988.

World Health Organization (WHO), Safety and Nutritional Adequacy of Irradiated Food. 1994.

Zubillaga, M.P. and Maeker, G. Quantitation of three cholesterol oxidation products in raw meat and chicken. *J. Food Sci*., 56(5), p.11964-11997, 1991.

APPENDIX V

Proposed Irradiation Protocol for Beef Irradiation

1.1 General Comments

Radiation processing of ground beef products is intended as an antimicrobial barrier used in addition to practices normally included in the manufacture of the unirradiated ground beef. Specifically, ground beef intended for irradiation must be manufactured in licensed and inspected processing plants, in full compliance with any and all particular regulations appropriate to ground beef. The objective must be to produce a product that is of the highest possible microbiological quality, prior to the irradiation step.

The benefits of irradiation are most tangible for those products that are of good microbiological quality prior to irradiation. In such cases the microbial reductions effected by irradiation can, with high probability, eliminate *Escherichia coli* O157:H7. Benefits of irradiation may be significantly diminished if the levels of target microorganisms prior to irradiation are so high as to preclude any possibility of elimination or practically significant reduction. It must be emphasized that irradiation is not to be used as a substitute for good manufacturing practice.

The actual processing in a given irradiation facility would be carried out according to a detailed irradiation protocol which specifies all the standard operating procedures (SOPs) which must be followed to assure that the process is carried out in an effective manner and in full compliance with all regulatory requirements. Preparation of SOPs is, of necessity, facility-dependent, as well as product-dependent, and cannot be done without the detailed specifications associated with a particular application for which the product is intended. In what follows, the principal considerations required for the development of an irradiation protocol are described in a series of guidelines.

1.2 Guideline Considerations

These guidelines are excerpted from "Standard Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry (to Control Pathogens).[65]

1.2.1 Desired Benefits

The purpose of radiation pasteurization is to disinfect, of the pathogenic organism, *Escherichia coli* O157:H7**,** fresh-chilled or frozen ground beef to make these foods safer for human consumption. Disinfection by irradiation significantly reduces the numbers of viable, vegetative *Escherichia coli* O157:H7.

1.3 Pre-irradiation Product Handling

1.3.1 Good Manufacturing Practice (GMP)

Relevant guidelines for GMP should be followed in maintaining the initial quality of the fresh meat before processing and during pre-irradiation handling. This includes the slaughter of only healthy animals, employment of sanitary dressing operations, prompt and effective reduction of product temperature to between -2°C and +4°C, and appropriately controlled cutting, trimming, de-boning, and grinding operations. In general, appropriate measures should be taken at all times to minimize microbial contamination and growth.

---

[65] Anonymous. 1991. Standard Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry (to Control Pathogens). ASTM F 1356-91.

1.3.2 Cold Chain Management-Fresh

During pre-irradiation transport and storage of fresh meats, the principal requirement, aside from maintenance of proper hygienic conditions, is for maintenance of temperature between -2°C and +4°C without freezing. An additional requirement is that the pre-irradiation storage period be kept as short as possible.

1.3.3 Cold Chain Management-Frozen

For frozen meats, a final product temperature below -18°C should be obtained an maintained at all times. With frozen products, it is not particularly critical to keep the pre-irradiation storage time to an absolute minimum. Nevertheless, this period should be minimized since product quality does deteriorate somewhat in the frozen state.

1.3.4. Optimal Handling

Handling red meats different from the procedures described above, especially holding under refrigeration for an unduly long time, does not constitute good manufacturing practice. Such conditions may result in excessive bacterial growth and undesirable changes in the product. Radiation pasteurization cannot reverse such undesirable changes.

1.4 Packaging

1.4.1 Pre-packaging

In most cases, meats should be packaged prior to irradiation to avoid recontamination.

1.4.2 Materials

Generally, at the absorbed doses considered in this application, commonly-used packaging materials are functionally satisfactory. They protect the product adequately during treatment and subsequent handling. In Canada, only materials that have received approval, in the form of a Letter of No-Objection from Health Canada, should be used. Such materials should be listed in the “Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products” (in preparation) maintained by the Canadian Food Inspection Agency. If irradiation significantly alters properties of a packaging material in such a way as to render it functionally inadequate, that material should not be used.

1.4.2.1 Gas Permeability

Care must be taken to ensure that functional requirements relating to gas permeability of the packaging materials be fully considered. Oxygen permeability is very important as it related to the *Clostridium botulinum* consideration, as well as for consumer preferences relating to colour of meat products. In some instances, it may be desirable to use a dual packaging system with only the inner layer being oxygen permeable. Keeping the outer layer intact would allow irradiation in oxygen-free conditions (modified atmosphere or vacuum). Removal of the outer barrier, post-irradiation, would then allow oxygen to permeate the product during storage or display. Again, care must be taken that final packaging design is in compliance with Health Canada regulatory requirements.

1.4.2.2 Moisture Permeability

In addition to providing appropriate gas permeability, the packaging material must be a moisture barrier to prevent drying of meats.

1.4.3 Package Dimensions

The allowable size and shape of containers used to hold food for irradiation are determined partly by certain design parameters of the irradiation facility. Critical parameters include the characteristics of the product handling systems and of the energy source as they relate to the dose distribution obtained within the production unit. With irradiation facilities employing high-energy electrons as the form of ionizing energy used for processing, penetration limitations require that the thickness of packages be carefully considered in the process design stage. Care must be taken to ensure that product packages are compatible with the overall operational requirements of the irradaition facility. This is best done by close consultation with experts familiar with the requirements of the particular facility, during the meat irradiation design stage.

1.4.3.1 Uniformity

The product packages must be geometrically well defined and uniform.

1.4.4 Packing

For frozen meats, the package should be as free as possible of voids and open spaces. Such spaces cause a form of desiccation known as “freezer burn.”

1.5 Irradiation

1.5.1 Source

Sources of ionizing energy to be used for treating ground beef are limited to Cobalt-60 and Cesium-137 gamma ray sources, machine sources of accelerated electrons of energies up to 10 MeVs and X-rays with energy up to 5 MeV.

1.5.2 Operational Control

Because it is generally not possible to distinguish irradiated from unirradiated products by inspection, a physical barrier is essential to keep irradiated and unirradiated product separate.

1.5.3 Verification of Irradiation

Commercially-available devices, such as paper stickers, which undergo a colour change or some other eaily determined and time-stable change when exposed to radiation pasteurization doses, may be useful as a rapid verification method for the irradiation status of product packages.

1.5.4 Record-keeping

It is important that adequate records of the operation of the irradiation facility be kept to enable verification of the irradiation treatment. Lot number or other suitable means should identify irradiated ground beef. All record keeping procedures must be in compliance with regulatory requirements.

1.5.5 Radiation Processing Parameters

1.5.5.1 Calibrating and Monitoring Dose

The absorbed dose is the most important parameter used in controlling the irradiation process. The range of doses administered to the particular product must be within the minimum and maximum limits specified by regulations. Determining the capability of an irradiator to process within these limits is necessary prior to the irradiation of product for consumption. Once this capacity is established, it is necessary to monitor and record the actual dose extremes for each production run.

1.5.5.2 Fresh versus Frozen Dose Limits

Frozen products generally require higher absorbed doses than refrigerated products to achieve equivalent effects. This difference is reflected in the dose ranges specified by regulations for the two types of products.

1.5.5.3 Temperature Considerations

Steps should be taken to ensure that temperature rise during irradiation of refrigerated products is minimal. The actual temperature of fresh chilled product should not exceed 10°C during irradiation. Frozen product temperature should be maintained as low as possible during irradiation and should not exceed -10°C. Use of insulated product transport containers may be satisfactory or the refrigeration of the irradiation chamber may be helpful.

1.6 Post-irradiation Handling and Storage

1.6.1 Good Manufacturing Practice

Irradiated products are to be handled and stored in the same manner as the corresponding unirradiated product. For fresh-chilled product, the product temperature should be maintained between ⁻2° C and +4°C at all times. For frozen product, the product temperature should be maintained below ⁻18°C at all times.

1.6.2 Organoleptic Quality

Attention should be given to all aspects of product deterioration not associated with microbial content. For example, pigment changes can cause product discolouration, and lipid oxidation can effect flavour. If vacuum packaging or oxygen-free modified atmosphere packaging is used, particular care should be taken to ensure that the storage temperature does not exceed +4°C in order to prevent abuse of the product and subsequent outgrowth of *Clostridium botulinum*.