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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,\textsuperscript{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,\textsuperscript{6} Clostridium perfringens;\textsuperscript{7} salmonellae\textsuperscript{8,9} and shigellae, Staphylococcus aureus,\textsuperscript{10} Listeria


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

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$^{14}$Thayer et al., 1996


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.

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, 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

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

(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. The use of chilling or freezing temperatures during the irradiation process can greatly diminish
the development of the irradiation off-odour.\textsuperscript{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\textsuperscript{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.\textsuperscript{33}

\section*{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.\textsuperscript{34, 35, 36,37,38}

\section*{iii. Shelf-life (Raw Red Meat):}

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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
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\textsuperscript{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\textsuperscript{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\textsuperscript{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.\textsuperscript{55, 56, 57, 58}


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.” Fifty 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. 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

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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, irradiated beef, 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 19 ppb, 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.

(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). 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

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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 bioavailability 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 proposed for addition to the Table in Division 26 are as follows:

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

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

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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.
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.


APPENDIX II

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


IFT Daily News 1997 (Chapter I)


APPENDIX III

Nutritional studies considered in assessing the safety of irradiated beef.


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.

APPENDIX IV

Toxicological studies considered in assessing the safety of irradiated beef.


MacGregor, J.T., Wilson, R.E., Neff, W.E. and Frankel, E.N., Mutagenicity tests of lipid oxidation products


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).”

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.

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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 and 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 irradiation 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 easily 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*. 