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# Technical Summary – Health Canada’s Safety Evaluation of Irradiation of Fresh and Frozen Raw Ground Beef

June 17, 2016

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch



Canada 

# Technical Summary – Health Canada’s Safety Evaluation of Irradiation of Fresh and Frozen Raw Ground Beef

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## Technical Summary – Health Canada’s Safety Evaluation of Irradiation of Fresh and Frozen Raw Ground Beef

### Purpose

The purpose of this document is to summarize [Health Canada’s safety evaluation](#) of a submission received by the Department requesting the enablement of the use of ionizing radiation on fresh and frozen raw ground beef to reduce the microbial load, including pathogens.

### Overview

Food irradiation is one of several techniques that can be used by food producers to improve food safety and quality by reducing the levels of bacteria that cause food poisoning and food spoilage.

The sale of irradiated foods in Canada is controlled under the *Food and Drug Regulations* (FDR). Section B.26.003 of the FDR prohibits the sale of all irradiated food in Canada, except for those foods listed in the table in this Division. The table also specifies the permitted sources of the ionizing radiation that may be used to treat those foods, the purpose of the ionizing radiation treatment, and the permitted absorbed dose for each food. The definition of “ionizing radiation” in section B.26.001 sets out the types and sources of ionizing radiation that are permitted. Division 1 of the FDR prescribes labelling requirements for irradiated foods. The FDR currently permits irradiation of potatoes, onions, wheat, flour, whole wheat flour, and whole or ground spices and dehydrated seasoning preparations.

In Canada, all new uses of food irradiation must undergo a thorough safety evaluation to ensure that the irradiation process does not negatively alter the nutritional quality or safety of the food and that the process is efficacious for its intended use. A request to approve irradiation of a food that is not currently in the table in Division 26, or to make any other change to the table, can be made by filing a food irradiation submission that meets the requirements of section B.26.005 of the FDR.

In 1998, Health Canada received a submission seeking approval to allow irradiation processing of fresh/chilled or frozen raw ground beef in its final packaging to reduce the microbial load, including the pathogenic microbial load. Health Canada’s Food Directorate evaluated the submission and the outcome was favourable. The Directorate published a summary of the safety evaluation on Health Canada’s website in 2002.<sup>1</sup> Proposed regulatory amendments to enable irradiation of ground beef were published the same year in Part I of the *Canada Gazette* (CGI), the official newspaper of the Government of Canada. During the CGI comment period, the Department received a number of comments from both public and industry stakeholders. The regulatory process to enable irradiation of ground beef was not completed due to the large number of questions received expressing concerns related to the safety of the food irradiation process in general.

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<sup>1</sup> This [summary](#) is now archived on the Health Canada website.

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In May 2013, Health Canada received a submission seeking approval to irradiate packaged fresh and frozen raw ground beef to reduce the microbial load, including pathogens such as *Escherichia coli* O157:H7 that could be present. The petitioner requested a minimum and maximum absorbed radiation dose for fresh raw ground beef of 1.0 kilogray (kGy)<sup>2</sup> and 4.5 kGy, respectively, and for frozen raw ground beef of 1.5 kGy and 7.0 kGy, respectively. The petitioner also requested that cobalt-60, cesium-137, electrons from machine sources [10 megaelectron volts (MeV)<sup>3</sup> maximum], and X-rays (5 MeV maximum, or 7.5 MeV maximum when the target material is tantalum or gold) be listed as permitted sources of ionizing radiation. This submission was nearly identical to the 1998 submission.

Health Canada’s Food Directorate has completed the safety and efficacy evaluation of the 2013 irradiation submission, taking into consideration the conclusions of the previous submission and relevant scientific information published since 2002. The Food Directorate has concluded that the available scientific data support the safety of irradiating fresh and frozen raw ground beef as described in the current submission, as well as the efficacy of reducing the level of bacteria, including pathogens, through the irradiation treatment. The updated scientific evaluation can be ordered through Health Canada website. Therefore, Health Canada is proposing to enable the use of irradiation as requested in the current submission.

### Summary of the Safety Evaluation

The petitioner’s 2013 submission was similar to the 1998 irradiation submission filed with the Food Directorate except that (1) the minimum absorbed radiation doses being requested for fresh and frozen raw ground beef are slightly lower than the doses requested in the 1998 submission (1.0 kGy versus 1.5 kGy for fresh raw ground beef and 1.5 kGy versus 2.0 kGy for frozen ground beef); and (2) the current requested maximum operating energy level is 5 MeV or, where the target material is tantalum or gold, 7.5 MeV, whereas in the 1998 submission, the requested maximum operating energy level of the X-ray machine source was only 5 MeV.

The Food Directorate’s recent safety evaluation focused on the two changes to the original submission described above and on scientific information that has become available since 2002. No safety information available since 2002 has been identified that would change the outcome of the previous safety assessment.

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<sup>2</sup> A kilogray (kGy) is a measure of the dose of absorbed radiation from an ionizing radiation source; equal to the absorption of 1000 joules of ionizing radiation by one kilogram of matter.

<sup>3</sup> An electron volt (eV) is a unit of energy equal to the energy acquired by an electron being accelerated through a potential difference of 1 volt; equal to  $1.602 \times 10^{-19}$  joules. A megaelectron volt (also called a million electron volt; MeV) is one million ( $10^6$ ) electron volts.

## Efficacy and Microbiological Safety

Since irradiation is being proposed as a means to decrease the level of bacteria that could be present in ground beef (e.g., *E. coli* O157:H7), it is important that this treatment be effective when used as described at the minimum absorbed dose. The Food Directorate focussed on the efficacy of the proposed lower minimum doses of absorbed ionizing radiation and on new information that has become available since 2002.

There was sufficient evidence in the published scientific literature that the use of ionizing radiation on ground beef can be expected to achieve a reduction of *E. coli* O157:H7 by at least 2 log<sub>10</sub> colony forming units per gram (CFU/g)<sup>4</sup> using a minimum dose of 1.0 kGy in fresh raw ground beef and 1.5 kGy in frozen ground beef. On the basis of these data, and the results of the previous evaluation, the Food Directorate concluded that irradiation at the lower dose levels requested in the 2013 submission would be effective in reducing the levels of pathogens such as *E. coli* O157:H7, if present, in fresh and frozen raw ground beef and can be an effective addition to existing meat processing protocols such as those based on Hazard Analysis Critical Control Point (HACCP) systems.

## Nutritional Safety and Quality

Unlike the microbiological evaluation, which evaluated the efficacy of the minimum absorbed doses of ionizing radiation as an antimicrobial treatment of fresh and frozen raw ground beef, the nutritional evaluation assessed the impact, if any, of irradiating fresh and frozen raw ground beef at the maximum absorbed doses. To do so, the Food Directorate considered the outcome of its evaluation of the 1998 submission, and updated the evaluation using new relevant nutritional information and more recent food consumption data that has become available since 2002.

The Food Directorate had concluded from the previous evaluation that nutrient loss in fresh and frozen raw ground beef, irradiated at the maximum absorbed dose levels requested (4.5 kGy for fresh raw ground beef and 7.0 kGy for frozen ground beef), was limited to the vitamin thiamin, and possibly the vitamins riboflavin and niacin. These losses were considered insignificant in the overall dietary context given that ground beef is a minor source of thiamin in the Canadian diet and the expected loss, if any, of riboflavin and niacin is minor. The Food Directorate noted that to minimize nutrient losses, irradiated foods should be manufactured using good manufacturing practices, the same as any other food. In this regard, nutrient losses could be mitigated by exposing foods to the lowest possible effective radiation dose within the range proposed, using low oxygen environments and using a low product temperature during the irradiation process.

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<sup>4</sup> A log<sub>10</sub> CFU/g reduction is a 10-fold reduction in colony forming units of bacteria per gram of food. A 2 log<sub>10</sub> reduction is a 100-fold reduction.

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Although the requested maximum absorbed doses of ionizing radiation in the 2013 submission are the same as those requested in 1998, the Food Directorate updated the nutritional safety evaluation using more recent food consumption data taken from the Canadian Community Health Survey, Cycle 2.2 (CCHS 2.2),<sup>5</sup> and taking into consideration new relevant nutritional information that has become available since 2002. The Food Directorate has confirmed its previous conclusion that any loss in the nutritional value of ground beef as a result of having been irradiated at the maximum absorbed doses would be minimal in the overall dietary context. For thiamin in particular, irradiation of fresh and frozen raw ground beef at doses between 1.0 and 4.5 kGy may lead to a loss of up to 55% of the thiamin content. Post-irradiation cooking may lead to an additional loss of up to 15% but this is still within the range of thiamin loss of up to 80% seen with cooking of non-irradiated beef. In addition, CCHS 2.2 one-day ground beef consumption estimates for Canadian consumers of ground beef indicate that the mean amount of ground beef consumption would provide less than 10% of the thiamin Recommended Daily Amount (RDA) for any age group. With respect to any potential impact of ground beef irradiation on inadequacy of thiamin intake, even in the worst case scenario of a loss of 55% of the thiamin content with irradiation of all ground beef products, dietary intake modelling failed to demonstrate any significant impact of irradiation on overall thiamin intake at the Canadian population level or for any subpopulations within the regions or provinces. Therefore, the impact of irradiation of ground beef on thiamin inadequacy is expected to be negligible.

### Toxicological Safety

The toxicological safety evaluation focussed on reviewing toxicological studies on fresh and frozen raw irradiated ground beef that have become available since 2002, to confirm that there are still no toxicological concerns with fresh and frozen raw ground beef irradiated at the maximum absorbed dose levels requested (4.5 kGy and 7.0 kGy, respectively), as the Food Directorate had concluded in 2002.

No new radiolytic products in irradiated ground beef have been identified in the scientific literature since the Food Directorate’s previous evaluation, and there are no reports of the previously assessed radiolytic products being found at significantly higher levels in irradiated ground beef than were previously evaluated. In addition, there have been no relevant animal feeding studies with irradiated foods published since the previous evaluation.

New in vitro, in vivo and metabolism studies on 2-alkylcyclobutanones (2-ACBs) have become available since 2002 and these were reviewed. 2-ACBs are unique radiolytic products that are produced when fatty acids are exposed to ionizing radiation. However, the levels of 2-ACBs found in irradiated fresh and frozen raw ground beef are very low and there is no clear evidence that the effects described in the literature based on in vitro tests with high doses are applicable to the levels of human exposure through the ingestion of irradiated foods.

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<sup>5</sup> Statistics Canada 2009. [Canadian Community Health Survey – Cycle 2.2 Nutrition \(2004\)](#).

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An in vivo tumour promoter study, administering pure 2-ACBs, found an increase in tumour number and size but not overall tumour incidence.<sup>6</sup> The level of 2-ACBs administered in the study was approximately three orders of magnitude (i.e., 1000 times) higher than the levels that would typically be consumed from ground beef irradiated with a proposed dose of 4.5 kGy. In addition, the study protocol had a variety of issues which decreased the relevance of the studies to human dietary exposure to 2-ACBs. Numerous long-term experimental animal feeding studies with irradiated foods have found no increases in spontaneous tumour incidence. Overall, this recent data does not contradict the previous evaluation’s conclusion that consumption of various irradiated foods by experimental animals has no effect on growth, longevity, reproductive capacity or spontaneous tumour incidence.

The Food Directorate has again concluded that there are no toxicological concerns with irradiating fresh and frozen raw ground beef at the maximum absorbed doses of 4.5 kGy and 7.0 kGy, respectively.

### Technical Aspects

In 1998, the petitioner had requested a maximum operating energy level for X-ray machine sources of 5.0 MeV for irradiation of fresh/chilled and frozen raw ground beef. The present request included an increase in this maximum level to 7.5 MeV if the target material is tantalum or gold. This increase in energy level would align with the level permitted for X-ray machine sources irradiating ground beef in the United States. Although this maximum energy level is higher, the maximum absorbed dose of ionizing radiation remains the same (4.5 kGy for fresh raw ground beef and 7.0 kGy for frozen raw ground beef).

The Food Directorate has not identified a safety concern with the proposed change to the maximum energy level. The evaluation took into consideration the scientific evidence provided by the petitioner, the rationale provided by the United States Food and Drug Administration in its approval of the higher energy level, and the available scientific literature. In addition, the Canadian Nuclear Safety Commission (CNSC), which is responsible for regulating the use of nuclear energy and materials to protect health, safety, security and the environment, has concluded that increasing the operating energy level from 5.0 MeV to 7.5 MeV for X-ray machine sources, when the target material is tantalum or gold, would not significantly increase the background radioactivity of food.

### Conclusion

Health Canada’s Food Directorate has concluded that the available scientific data support the safety of irradiating fresh and frozen raw ground beef as described in the current submission. In addition, it has also concluded that sufficient data is available supporting the efficacy of

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<sup>6</sup> Tumour number is the number of tumours in a single experimental animal; tumour incidence is the number of animals with one or more tumours.

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irradiation in reducing microbial levels, including for pathogens such as *E. coli* O157:H7 that may be present in these foods. The Directorate also considers that there is no reason to object to the proposed increase in the maximum operating energy level to 7.5 MeV for X-ray machine sources that use gold or tantalum as the target material.

Further [details of the safety evaluation](#), including the studies considered in the evaluation, have been made available through the Health Canada website.

### Other Relevant Information

The Canadian Food Inspection Agency (CFIA) has expressed its support of the proposed use of ionizing radiation to treat fresh and frozen raw ground beef.

Health Canada consulted with an industry association that represents the Canadian meat industry about the proposed use of irradiation on fresh and frozen raw ground beef. This association was supportive of the proposed use as described in the 1998 submission. The association has reiterated its support of the technology and continues to support making irradiation available as an option to the meat industry and making irradiated fresh and frozen raw ground beef available to consumers.

The Codex Alimentarius Commission has published a *Codex General Standard for Irradiated Foods*<sup>7</sup> and a *Code of Practice for Radiation Processing of Food*.<sup>8</sup> The Standard allows for the use of ionizing radiation from cobalt-60, cesium-137, X-rays generated from machine sources operated at or below an energy level of 5 MeV, and electrons generated from machine sources operated at or below an energy level of 10 MeV. The foods to which irradiation may be applied are not specified in the document; however, the standard does specify that the “minimum absorbed dose should be sufficient to achieve the technological purpose and the maximum absorbed dose should be less than that which would compromise consumer safety, wholesomeness or would adversely affect structural integrity, functional properties or sensory attributes. The maximum absorbed dose delivered to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose.”

The United States of America (USA) permits irradiation of refrigerated or frozen, uncooked intact or ground beef, for control of foodborne pathogens and extension of shelf life. The maximum absorbed doses are 4.5 kGy for refrigerated products and 7.0 kGy for frozen products. The USA also allows for the use of X-rays from a machine source operating up to a maximum energy level of 7.5 MeV if tantalum or gold is the target material. The USA does not prescribe a minimum absorbed dose for meat products treated with ionizing radiation. Permitting irradiation of fresh and frozen raw ground beef under the conditions requested in the 2013 submission to Health Canada would better align the approved uses of irradiation in Canada and the USA.

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<sup>7</sup> Codex Stan 106-1983, Rev.1-2003

<sup>8</sup> CAC/RCP 19-1979, Rev. 3-2003

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In the European Union (EU), the only foods that have been authorized for irradiation at the EU level are dried aromatic herbs, spices and vegetable seasonings. However, certain member states within the EU permit irradiation of other foods, including poultry.<sup>9</sup>

### Next Steps

Health Canada is inviting comments on the technical aspects of its safety evaluation of the 2013 submission to permit the irradiation of fresh and frozen raw ground beef. Any technical comments received on the evaluation will be taken into consideration. The safety evaluation will be revisited should any new relevant scientific data be submitted.

All comments received will be considered and the outcome made publicly available.

### Further Information

Additional details of the safety evaluation of irradiating fresh and frozen raw ground beef, including the evaluation, have been made available through the [Health Canada website](#).

### Contact Information

For additional information related to the safety evaluation, please contact the Food Directorate’s Bureau of Chemical Safety:

#### [Bureau of Chemical Safety](#)

251 Sir Frederick Banting Driveway  
Tunney’s Pasture, PL: 2202C  
Ottawa, Ontario K1A 0L2  
E-mail: [bc-s-bipc@hc-sc.gc.ca](mailto:bc-s-bipc@hc-sc.gc.ca)

If communicating by e-mail, please use the words “**Irradiation of Ground Beef**” in the subject line of your e-mail.

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<sup>9</sup> See the List of Member States’ authorisations of food and food ingredients which may be treated with ionising radiation (Directive 1999/3/EC of the European Parliament and of the Council of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation. *Official Journal of the European Union* L66/24 13. 3. 1999)