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Canada Gazette, Part I Consultation Summary: Irradiation of Fresh and Frozen Raw Ground Beef

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Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

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Background

On May 3, 2013, Health Canada received a submission from the Canadian Cattlemen's Association (CCA) requesting approval to irradiate fresh and frozen raw ground beef for sale in Canada. This request aligned with one of the recommendations from the Report of the Independent Expert Advisory Panel following the 2012 XL Foods Inc. beef recall, which was the largest recall of beef products in Canadian history.

In accordance with the Panel's recommendation that "*Health Canada should give the application prompt consideration*", the Department conducted a safety assessment of the requested uses on a priority basis and concluded that the irradiation of fresh and frozen raw ground beef is safe and effective.

On June 18, 2016, Health Canada published in *Canada Gazette*, Part I (CGI) proposed amendments to the *Food and Drug Regulations* (FDR) to permit the sale of irradiated fresh and frozen raw ground beef. The 75-day consultation period ended on September 1, 2016.

The purpose of this document is to provide a summary of comments received during the CGI consultation and Health Canada's responses to the feedback received.

Summary of Consultation

Participation

Health Canada received a total of 18 comments during the CGI consultation. Of these, 34% were from consumers, 22% from industry, 22% from industry associations, and 11% each from consultants and government. Respondents varied in their views, with a majority (72%) supporting the proposal and a minority (28%) expressing concerns.

Comments Received and Health Canada Responses

In support of the proposal

The positive feedback received from stakeholders mainly aligned with factual information provided in the Regulatory Impact Analysis Statement (RIAS). Stakeholders were generally supportive for the following reasons:

- the scientific evidence supports the safety and efficacy of irradiation;
- the technology has the potential to increase food safety and improve public health (reduce potential for foodborne illness);
- other irradiated foods are already permitted on the market in Canada;
- food irradiation facilities are currently in place in Canada (straight-forward implementation);
- it is a technology endorsed by the World Health Organization and the Food and Agriculture Organization of the United Nations;
- internationally, irradiation is already permitted for various products, including ground beef;
- the regulatory proposal aligns with existing/current U.S. regulations; and
- irradiation provides an additional choice for consumers, and labelling will allow informed choice and potentially increase public confidence in the food supply.

While these stakeholders were supportive of the proposal, additional comments were provided for the Department's consideration. These comments and Health Canada's responses are summarized as follows:

Consumer education campaign

Comment: It was suggested that the Government of Canada (GoC) consider developing a consumer education campaign to enhance consumer understanding and acceptance of food irradiation.

Response: While Health Canada can provide science-based safety rationales for food irradiation and other educational material on this topic, promoting this technology through a targeted campaign to facilitate consumer acceptance and marketability of irradiated foods is not within Health Canada's mandate. Such an activity would fall to other entities, such as the food industry. The Department has published various documents on food irradiation, including Questions and Answers, the "*Technical Summary – Health Canada's Safety Evaluation of Irradiation of Fresh and Frozen raw Ground Beef*" and links to the associated regulatory proposal (RIAS) on its website. The Canadian Food Inspection Agency (CFIA) has also published information (factsheet) on their website for consumers to learn more about this technology and the agency's role related to irradiated foods. This science-based information is made publicly available to increase transparency and to allow interested stakeholders to enhance their understanding of the regulatory assessment process and scientific basis by which food irradiation has been determined to be safe and effective.

Allowing irradiation of other food products

Comment: One stakeholder proposed that Health Canada consider permitting the irradiation of additional food products, including those already approved in the United States (U.S.). It was also suggested that Health Canada use a regulatory instrument, such as Incorporation by

Reference (IbR), to allow updates to the list of approved irradiated food products in a timely fashion.

Response: In Canada, the sale of irradiated foods is subject to mandatory premarket approval and labelling requirements prescribed in Divisions 26 and 1 respectively of the FDR. Only foods listed in the Table under Division 26 may be irradiated and sold in Canada.

For new food irradiation uses to be permitted, an application would need to be submitted to Health Canada containing supporting safety and efficacy data. Following a thorough safety and efficacy evaluation, if it has been determined that the irradiation process does not negatively alter the nutritional quality or safety of the food, a proposal to amend the regulations to include those food products in the Table contained in Division 26 of the FDR would be published in *Canada Gazette*, Part I for consultation. Irradiation of those products would be allowed following the publication of final amendments in *Canada Gazette*, Part II.

In October 2012, the GoC brought forward new regulatory instruments, including the authority to incorporate documents by reference (IbR), as a key component of Health Canada's food regulatory modernization efforts to meet evolving changes, challenges and innovation. The IbR authority is designed to streamline the regulatory process for science-based decisions and reduce red tape, while maintaining the same high level of scientific rigour and transparency in a consultative process. The Department is considering other ways of modernizing the regulatory framework for food irradiation which could include the incorporation by reference of the table to Division 26 of permitted irradiated foods in Canada.

Interpretation of terminology

Comment: One stakeholder suggested that since the current regulations allow for the irradiation of whole or ground spices and dehydrated seasoning preparations, a guidance note could be added to address the "meaning, interpretation and intent of 'total overall average dose'", as well as provide "details on how second and third generation irradiated ingredients are to be declared in the ingredient list with some examples."

Response: This comment does not pertain to the current regulatory proposal for fresh and frozen raw ground beef. However, Health Canada will consider whether guidance should be added to its Food Irradiation webpage to provide additional clarity on the meaning of "total overall average dose" as it relates to the irradiation of whole or ground spices and dehydrated seasoning preparations.

Labelling

Comment: A number of stakeholders submitted comments about the labelling of irradiated beef, including the use of labelling as a means of supporting consumer choice, labelling in food establishments such as restaurants and using synonyms for "irradiated" such as "ionization" or "ionized" to alleviate public concerns about the safety of food irradiation.

Response: The labelling requirements for irradiated food, as outlined in the FDR, and general labelling requirements in food establishments are outside the scope of the current regulatory proposal. Under the current regulations, no provision exists in the FDR to require the food service and restaurant industry to identify when irradiated foods are used. Restaurants have the ability to advertise their use of irradiated or non-irradiated ground beef as a voluntary way of appealing to consumers as long as they are truthful and not misleading. If consumers have questions about how their food was produced, they should request this information directly from the food service establishment.

The terminology used in the FDR ("treated with radiation", "treated by irradiation" or "irradiated") is the same as that of internationally recognized guidance and standards such as the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), as well as aligns with regulatory authorities and industry practices around the world. Health Canada believes that the use of terms such as "ionization" or "ionized" could be confusing for consumers should it be unclear that these terms are synonymous with "irradiated".

Dose Setting

Comment: One stakeholder did not support setting a minimum absorbed dose of ionizing radiation required to satisfactorily irradiate food in the FDR. Instead, it was suggested that the minimum absorbed dose be determined by food producers using validated dose setting methods.

Response: As part of the submission, the petitioner provided efficacy data supporting a minimum absorbed dose necessary to satisfactorily achieve the desired microbial reduction level in fresh and frozen raw ground beef. The submission also identified the option of not setting a minimum absorbed dose in the FDR in order to be consistent with the U.S. However, a minimum absorbed dose is being set out in the regulations given that no information was provided in the submission on the implementation of other antimicrobial processes to be used in addition to irradiation in order to achieve the desired microbial reduction level.

Packaging

Comment: While generally supportive of the proposal, one stakeholder noted that it may be possible for the beef industry to not irradiate the final package containing the ground beef intended to be sold at retail, rather the beef industry could irradiate in bulk and repackage in

smaller amount for sale at retail, which could result in re-contamination and pose a health risk to consumers.

Response: The proposed regulatory amendments would allow the sale of irradiated ground beef, either as a prepackaged product for consumers or as a prepackaged product for restaurants.

The proposed amendments do not specifically prevent a processor from repackaging irradiated ground beef before sale. However, doing so would defeat the purpose of irradiating ground beef as it could result in re-contamination and pose a health risk to consumers. This would also not be aligned with the "*Recommended Canadian Code of Practice For Food Irradiation*" and the international "*Code of Practice for Radiation Processing of Food*". These documents collectively highlight that food irradiation should conform with all relevant codes of hygienic practice and with Good Manufacturing Practices (GMPs) in order to minimize contamination and, if packaged, to maintain package integrity. The international Code also notes that radiation is applied to food products in forms in which they are normally prepared for commercial trade.

This means that prepackaged irradiated raw ground beef is expected to be sold in the packaging in which it was irradiated in order to avoid possible recontamination. The petitioner has confirmed that ground beef in Canada would be irradiated in its final packaging, in the form of prepackaged ground beef patties and prepackaged chubs (rolls of bulk ground beef).

Health Canada's recommendations for the safe handling and cooking of ground beef will apply regardless of whether or not the ground beef is irradiated given that it remains a raw food commodity that needs to be cooked before consumption to ensure the absence of pathogenic bacteria.

In opposition to the proposal

Of the five stakeholders who expressed opposition to the current regulatory proposal, three were from consumers, one was from industry and one was from an industry association.

Justification for the use of irradiation to treat ground beef

Comment: One stakeholder expressed the opinion that the low number of annual reported incidents of *E.coli* contamination did not justify the use of irradiation on ground beef.

Response: While annual reported cases of foodborne illness due to contamination by *E.coli* O157:H7 from ground beef may be low, the potential consequences of an outbreak are high and could result in serious health issues, particularly for vulnerable populations, including children, elderly people and people with weakened immune systems. Allowing industry to use a scientifically proven safe and effective technology as another tool to complement and strengthen, not replace, current food safety practices would help prevent foodborne illness outbreaks in the

future. This is in line with the Department's commitment to ensure the continued safety of the Canadian food supply and the health and safety of Canadians and responds to the recommendations of the 2012 Independent Review of the XL Foods Inc. Beef Recall.

Impacts on Industry

Comment: Concerns were raised regarding potential impacts on industry, including: the potential for larger beef packing companies to further gain a competitive advantage over small and medium sized enterprises (SMEs); the potential need for Canadian beef slaughter and processing plants to reduce costs to maintain a competitive advantage over potentially cheaper imports of U.S. irradiated beef, which could result in practices leading to food safety issues; and the potential that ground beef irradiation could decrease Canada's beef exports to major importing partners that do not allow beef irradiation.

Response: Health Canada acknowledges the concerns about the possible impact that the proposal could have on SMEs. However, the objective of this proposal is to improve food safety by allowing the sale in Canada of irradiated fresh and frozen raw ground beef.

Beef slaughterhouses and processing plants, including those using high line speeds are subject to a Hazard Analysis Critical Control Point (HACCP) system that consists of a series of steps designed to minimize bacterial contamination. They must be able to show trained and qualified inspectors from the Canadian Food Inspection Agency (CFIA) that their HACCP system is effective. They are also responsible for the proper handling of beef products according to GMPs. These obligations would continue to apply to all processors and beef slaughterhouses regardless of whether they choose to use irradiation to treat ground beef.

With regards to the potential impact that the proposal could have on beef exports, exported beef must meet the importing country's requirements and this regulation does not change this requirement.

Safety concerns relating to irradiated beef

Comment: A number of concerns were raised about either the safety of irradiated beef or the impact that the practice could have on other safety-related issues. One of these concerns was that food processors may use this technology in place of maintaining sanitary conditions and in place of other existing food safety practices. Another concern was that ground beef irradiation may give consumers a false sense of safety, noting that food safety incidents involving beef continue to occur in the U.S. even though ground beef irradiation has been permitted since 1997. Concern was also raised about the public health risks associated with the production of hydrogen peroxide and cyclobutanones during the irradiation process and the management of radioactive waste.

Response: The evidence demonstrates that the irradiation of ground beef reduces the level of bacteria that may be present. Irradiated ground beef must still be handled, stored and cooked

properly like all other foods. The rules of safe food handling – proper sanitation, packaging, storage and preparation – still need to be followed. Irradiation cannot be used to restore ground beef that is already spoiled.

In addition, there are a number of other food safety strategies that are required regardless of whether irradiation is used. Federally registered beef slaughter and processing establishments are required to have a Hazard Analysis Critical Control Point (HACCP) system and to demonstrate to the CFIA that it is effectively implemented. The HACCP system must include good manufacturing practices, personnel hygiene practices and dressing procedures that prevent the contamination of carcasses and other raw meat products with biological hazards. CFIA inspectors assess the effectiveness of an establishment's HACCP system by reviewing and assessing the written plan, reviewing plant records, observing plant personnel and processes, and sampling and testing carcasses and raw beef products to verify that the establishment's controls are working. Inspectors receive specific training to inspect beef slaughter establishments that use high line speeds.

To minimize the risks posed by pathogenic bacteria such as *E. coli* O157:H7, beef slaughter establishments must also include at least one intervention (such as steam/hot water pasteurization, organic acid sprays, etc.) that has been validated to control *E. coli* O157:H7 on beef carcasses to below the detectable level. In addition, raw meat products derived from beef or veal such as trim, hearts, etc. (known as precursor materials) used to make raw ground beef products must be tested under a robust sampling protocol for the presence of *E. coli* O157:H7. Only precursor materials that are negative for *E. coli* O157:H7 can be used to make ground beef. For slaughter establishments using higher line speeds, the operator must do additional regular sampling to monitor the effectiveness of their system and their processes in order to demonstrate that they are capable of maintaining such line speeds. They must also have corrective action plans should a deviation occur. Irradiation is another technology that will complement and strengthen, not replace, current food safety practices.

Meat processors are required to handle all beef products, including ground beef, according to GMPs and maintain refrigeration of the product at all times in order to minimize the growth of bacteria. When raw ground beef is properly refrigerated and handled, the possibility of toxin production by some specific strains of bacteria in the food is extremely low. Health Canada continues to recommend handling all food with care according to its four key safe food handling messages: refrigerate, separate, clean and cook. Additionally, Health Canada recommends cooking ground beef to a safe internal temperature of 71°C.

When irradiated, the water found in meat can form hydrogen peroxide. However, hydrogen peroxide is relatively unstable and any residues that may remain on the meat after irradiation are expected to break down to water and oxygen during post-irradiation storage.

Alkylcyclobutanones are products referred to as “Unique Radiolytic Products” (URPs) that are derived from fat when irradiated and therefore their presence is directly related to the fat content of the food. These URPs are found in extremely small quantities in irradiated foods, in the order

of parts per billion. The overall weight of evidence indicates that the very low levels of these compounds found in irradiated beef do not pose a risk to human health.

The technologies approved for beef irradiation were selected to ensure radioactive waste would not be produced as a byproduct of food irradiation. Isotope-based irradiators, however, will require radioactive sources to be replaced as they age. For food irradiation, the isotopes involved would be Cobalt-60 and Cesium-137. The exchange of sources of ionizing radiation is performed by qualified service providers licensed by the Canadian Nuclear Safety Commission (CNSC). The used sources are transferred to facilities regulated and licensed by the CNSC.

Used sources and/or radioactive waste produced in Canada are managed safely in specially designed facilities. The CNSC regulates and licenses these facilities in order to protect the health, safety and security of Canadians and the environment. As part of all CNSC-licensed activities in Canada, the waste producers are required to manage waste in a safe and secure manner, which is considered by the CNSC during the review process for any licensed activity or facility.

The transport of nuclear substances, including radioactive waste, is a joint responsibility between the CNSC and Transport Canada. The CNSC issues transport licenses for nuclear substances only once it is convinced that the shipment will be completed safely, without posing risks to the health, safety and security of Canadians and the environment. Recycling radioactive waste is one of the strategies used by the licensee to minimize the volume of radioactive waste. Methods used to reduce, reuse and recycle radioactive waste must always ensure that the health and safety of persons and the environment are protected.

Results of Consultation

Health Canada conducted a thorough analysis of all comments received and has taken into consideration only those which were relevant to this specific regulatory proposal. Given that neither new scientific information nor new issues that had not already been taken into consideration at the time of the CGI publication were submitted during the consultation, Health Canada did not make any changes to the current ground beef regulatory proposal.

As a result, Health Canada has authorized the use of ionizing radiation to treat fresh and frozen raw ground beef and permitted the sale of these products in Canada, as proposed, through publication in *Canada Gazette*, Part II.

Contact Information

For further information on this consultation, please contact the Food Directorate's Bureau of Policy, Intergovernmental and International Affairs.

Additional Resources

- **June 2016:** Frequently Asked Questions Regarding Food Irradiation
- **June 2016:** Proposed Regulatory Amendments for Food Irradiation
- **June 2016:** Technical Summary – Health Canada's Safety Evaluation of Irradiation of Fresh and Frozen Ground Beef