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--- PREPUBLICATION NOTICE ---

SCC MEETING OF November 20, 2002

WILL APPEAR IN THE PART I OF THE CANADA GAZETTE OF  
NOVEMBER 23, 2002

FOOD AND DRUGS AMENDMENTS - PROPOSAL

PROJECT N° 1094 (FOOD IRRADIATION)

**REGULATORY IMPACT ANALYSIS STATEMENT**

*(This statement is not part of the Regulations)*

**Description**

Treatment of foods with ionizing radiation, called food irradiation, is one process which can be used during food production to reduce bacterial load and hence improve food safety, prevent spoilage and control insect infestation in food commodities. Provisions currently exist in the *Food and Drug Regulations* for the use of the irradiation process on a limited number of foods. The Table to Division 26 of the Regulations lists the foods that can be irradiated and the respective purpose and conditions of use for each product. At the present time, food irradiation is permitted on potatoes and onions to inhibit sprouting during storage; on wheat, flour, and whole wheat flour to control insect infestation during storage; and on whole or ground spices and dehydrated seasoning preparations to reduce microbial load.

Before the irradiation process can be applied to other food products, a thorough review must be conducted by Health Canada to establish the chemical, toxicological and microbiological safety and the nutritional quality of the proposed uses. If the safety of the new areas of use is confirmed, the treatment can only begin once the Regulations have been appropriately amended and the new uses listed in the Table to Division 26.

Requests for additions to the Table to Division 26 can be presented to Health Canada for evaluation and review. The information and data that must be included in a submission are prescribed in the Regulations. Submissions must present the purpose and complete technical details on the proposed use of the irradiation process, minimum and maximum absorbed dosages, efficacy data, process equipment and methodology, effects on nutritional quality of the food, evidence of maintenance of the chemical, physical or microbiological characteristics and safety of the food, recommended conditions of storage and shipment, and other processes that may be applied to the food before or after the proposed irradiation.

By regulation, all prepackaged food products that have been irradiated must carry a statement "treated with radiation", "treated by irradiation" or "irradiated" and display the international symbol identifying irradiated foods, the radura, on the principal display panel of their label. When an irradiated food is not sold in prepackaged form, a sign displaying the radura symbol must be located next to the point of sale of the food.

Health Canada has received several submissions to irradiate fresh and frozen ground beef, fresh and frozen poultry, and prepackaged fresh, frozen, prepared and dried shrimp and prawns to control pathogens, reduce microbial load and to extend durable shelf life. A submission has also been presented to irradiate mangoes as a disinfestation treatment to control fruit flies and the mango seed weevil.

Scientists in Health Canada have reviewed the data provided in the submission, as well as those found in numerous other scientific literature sources, in order to determine whether these new proposed uses of the food irradiation process met regulatory requirements for safety and effectiveness. It has been concluded that:

- S the consumption of the irradiated foods would not result in any risk to the health of the consumer;
- S the irradiation of the foods would not result in destruction or loss of nutrients in a food recognized as a significant source of those nutrients in the diet; and
- S the proposed uses of food irradiation could be beneficial through improved safety of the food products resulting from enhanced control of pathogens or reduction in insect infestation.

Therefore, Health Canada proposes to recommend amendments to the Table to Division 26 of the Regulations to permit the new applications of the food irradiation process as listed above. For chicken, ground beef, shrimp and prawns, the permitted sources of irradiation would be Cobalt-60, Cesium-137, electrons from machine sources operated at or below an energy level of 10 Millions of electron-Volts (MeV) or x-rays generated from a machine source operated at or below an energy level of 5 MeV. For mangoes, the permitted source of irradiation would be Cobalt-60.

#### **International Environment**

During the 1980s, a Joint Food and Agriculture Organization (FAO)/International Atomic Energy Agency (IAEA)/World Health Organization (WHO) Expert Committee on Food Irradiation (JECFI) of the United Nations reviewed the safety of the food irradiation. This review supported the adoption of a General Standard for Irradiated Foods by the Joint FAO/WHO Food Standards Programme, the Codex Alimentarius Commission, in 1983. This document addresses the various aspects of the food irradiation process, namely: general process requirements; hygiene of irradiated foods; technological requirements; re-irradiation; labelling; and methods of sampling and analysis. The Codex General Standard for Irradiated Foods states that, as one of the technological requirements for irradiating food, irradiation should not be used by the food industry as a substitute for good manufacturing practices. Information on the Codex General Standard for Irradiated Foods can be found at <ftp://ftp.fao.org/codex/alinorm01/al0112ae.pdf>.

In the United States (US), the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA) have given clearance for the use of irradiation on a wider range of foods than is permitted or proposed in Canada. The approved areas of use in the US include the areas of use covered in the Canadian regulatory proposal with the exception of shrimps and prawns. Consideration is being given by the US government to new proposed uses of the food irradiation for control of food borne pathogens in crustaceans and processed crustaceans. At the present time, irradiation of shrimp, crustaceans and other seafood products is not yet approved. Further details on the status of food irradiation in the United States can be found at [http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr179\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr179_01.html).

Australia and New Zealand have a regulatory approach similar to that of Canada and require that each specific application for irradiation or re-

irradiation be approved by the Australia New Zealand Food Authority (ANZFA) on the basis of a demonstrated food safety or technological need. Public comment was solicited in October 2000 for the first proposed applications of the food irradiation process to herbs, spices, nuts, oilseeds and tea. On September 13, 2001, these countries approved irradiation of herbs, spices and herbal teas.

In the European Union (EU), food irradiation is controlled through two Directives. The Directive 1999/2/EC covers general and technical aspects for carrying out irradiation, labelling of irradiated foods and conditions for authorizing food irradiation, including a requirement that it must not be used as a substitute for hygiene and health practices, or for good manufacturing or agricultural practices. In addition, the Directive 1999/3/EC seeks to establish a Community list of food and food ingredients treated with ionizing radiation. So far, the list of products authorized for irradiation within the whole EU contains only a single entry: "dried aromatic herbs, spices and vegetable seasonings". The EU Directorate General Health and Consumer Protection has undertaken open discussions with consumer organizations, stakeholders and other interested parties as an initial step towards expanding the list. Further details can be found at [http://europa.eu.int/comm/food/fs/sfp/fi\\_index\\_en.html](http://europa.eu.int/comm/food/fs/sfp/fi_index_en.html).

### **Alternatives Considered**

Only those foods listed in the Table to Division 26 of the Regulations may be irradiated and offered for sale in Canada. Under the Regulations, provision for new uses of the food irradiation process can only be accommodated by regulatory amendment. Maintaining the status quo was rejected as this would preclude the use of the food irradiation process which has been shown to be both safe and effective for the foods covered by this proposal.

### **Benefits and Costs**

As the proposed new applications of the food irradiation process would remain optional, the actual benefits and costs of the use of this process cannot be determined. It has been recognized by national and international bodies, such as the WHO and the FAO, that the food irradiation process is one method of reducing levels of pathogenic bacteria, other microorganisms and parasites that cause food borne illness and disease. Irradiation of poultry would destroy any *Salmonella*, a microorganism commonly associated with food borne disease and poultry. Irradiation would also destroy *E.coli* O157, if present in ground beef. While not common, illness caused by *E.coli* O157 has frequently been related to ground beef and can be very severe in some cases. The proposed new uses of food irradiation could contribute to a reduction in disease incidence and consequently result in an associated reduction in public and personal health costs.

Treatment with ionizing radiation can also improve the quality of foods by controlling insect infestations and microbial contamination after harvesting. This is of particular benefit with foods originating in warmer climates, such as mangoes, where insect infestation and microbial loads become problematic when the food must travel considerable distances before distribution and sale to consumers or for use in manufactured food products. Therefore, irradiation has the potential to assist industry in enhancing the safety and quality of food products.

Both consumers and industry are likely to benefit from the longer durable shelf life of irradiated foods as a result of the reduction of spoilage bacteria in these foods. In the case of the irradiation of refrigerated fresh chicken, the durable life was found to be in the range of 14 to 22 days, a period two to three times that of non-irradiated fresh chicken. This extended durable life would be expected to reduce product wastage and disposal costs of "spoiled" food at retail and consumer levels.

The costs of installing, operating and monitoring food irradiation facilities are substantial and may be offset by any overall lowering of processing costs and other benefits such as a reduction of product wastage due to pathogen contamination. Furthermore, if the price of the product is increased as a result of the application of the irradiation process, the economic benefits resulting from reduced costs related to longer durable shelf life and reduced spoilage along the distribution chain may also be less apparent to the consumer.

It is anticipated that there would be costs to the Canadian Food Inspection Agency (CFIA) to develop compliance and enforcement activities as a result of these additional applications of food irradiation. Monitoring of labelling of additional irradiated products or of new promotional label statements may also require CFIA resources for the conduct of surveillance and compliance programs.

### **Consultation**

Prior to the prepublication of these proposed amendments in the *Canada Gazette*, Part I, Health Canada conducted consultation with the affected industries and other Departments of the Federal Government. More precisely, Health Canada consulted with the Canadian Produce Marketing Board, the Canadian Meat Council, the Canadian Poultry and Egg Processors Council, the Canadian Turkey Marketing Agency, the Fisheries Council of Canada, Agriculture and Agri-Food Canada and the CFIA.

The comments from industry stakeholders and the CFIA were generally supportive of the proposal and can be summarized as follows: a recommendation that irradiation be approved by Health Canada for all red meat products; the need for proposed regulations to prevent post-irradiation contamination of irradiated foods; and "Best before date" issues related to the implementation of the irradiation process by the food industry.

Health Canada's responses to these comments are outlined below.

### **Extension of food irradiation application to all red meat products**

The evaluated data are adequate only for the application of the food irradiation process to ground beef products. Accordingly, Health Canada is not in a position to extend the proposed regulations to include all red meat products.

### **The need for proposed regulations to prevent post-irradiation contamination of irradiated foods**

Health Canada agrees that the post-irradiation handling of foods will be important in avoiding the recontamination of the irradiated foods with pathogenic organisms. Health Canada will develop guidelines, in collaboration with the CFIA, for the handling of irradiated foods.

### **"Best Before Date" related to the implementation of the food irradiation process by the food industry**

While the issue of "Best Before Date" is new when applied to irradiated poultry, shrimp and prawns and ground beef products, it is not a new issue as there is a regulatory requirement at present for a "Best Before Date" for these foods when they have not been irradiated and certain prepackaged foods that have a shelf life of less than 90 days. This issue will be the subject of discussions between the CFIA, Health Canada and the industry. These discussions can take place after the proposed amendments are prepublished in the *Canada Gazette*, Part I.

## Public Environment

Health Canada recognizes that public opinion and perceptions of food irradiation will play an important role in consumer response to the proposed regulatory amendments. When Health Canada proposed amendments to the *Food and Drug Regulations* in the 1980's with respect to food irradiation, the level of interest and attention was high. In response to the concerns, the Standing Committee on Consumer and Corporate Affairs examined the issues of food irradiation and the labelling of irradiated foods. The current regulatory provisions which require premarket review for each food product and use of irradiation, as well as mandatory labelling, were promulgated in 1989.

In Spring 2000, a National Angus Reid Poll, commissioned by Agriculture and Agri-food Canada, revealed that:

- S Canadians would likely approach irradiated foods with caution because of uncertainty about their safety;
- S when given a brief description of the process, 51% thought that irradiation was a good idea and 42% thought that it was a bad idea;
- S 54% said they would not buy food treated with irradiation because of safety concerns, while 43% said they would buy such food because it would make it safer from harmful bacteria and slow down spoilage;
- S 93% of the respondents thought information on food irradiation for the consumer was important.

In addition to the results of an Angus Reid Poll on food irradiation, Health Canada felt it was important to obtain feedback on the general knowledge of consumers regarding the application of irradiation technology to food. A series of focus groups were organized in March 2001 to determine attitudes of Canadians towards food irradiation. Eight focus groups were conducted between March 6-8, 2001, in Halifax, Toronto, Montreal and Red Deer (two focus groups in each city). The results of the focus groups indicated that:

- S the majority of people were neutral or negative in their predisposition to irradiated foods; however, they expressed a desire for more information;
- S a variety of concerns were identified including long-term impact on health, loss of nutritional value, labelling, unease with the technology, and lack of information;
- S many participants expressing concerns grouped food irradiation in with other food technology issues such as genetic modification;
- S there was general acceptance that new food technologies are here to stay and that irradiation has a positive role to play in reducing illness related to *E. coli* or other pathogens in some foods;
- S the participants wanted information from a variety of sources, including the government, and would be mistrustful of materials that present only positive information.

Upon prepublication of these proposed amendments in the *Canada Gazette*, Part I, Health Canada will conduct a series of information sessions on the proposed amendments in various locations across Canada. In addition, Health Canada will undertake the distribution of information materials on food irradiation. The factual information to be presented in the educational materials and in the information sessions will focus on:

- what "food irradiation" is;
- how food irradiation is used;
- the purpose of this process in the proposed applications;
- the limits of what food irradiation can and cannot do with regard to food safety;
- the regulation of food irradiation in Canada and other countries;
- the significance of any nutritional, chemical or microbiological effects in the proposed food applications;
- the requirements in Canada for labelling of irradiated foods; and
- the ways that consumers could identify irradiated foods in the marketplace.

### **Enforcement and Compliance**

If these proposed amendments are adopted, the CFIA would develop and incorporate appropriate inspection and monitoring activities into ongoing domestic and import inspection programs. In addition, the Canadian Nuclear Safety Commission would include any new food irradiation facilities in its licensing, monitoring and inspection programs.

### **Contact**

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February 25, 2002

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1)<sup>1</sup> of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1094 – Food Irradiation)*.

Interested persons may make representations with respect to the proposed Regulations within 90 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Mr. Ronald Burke, Director, Bureau of Food Regulatory, International & Interagency Affairs, Department of Health, Room 2395, Address Locator 0702C1, Health Protection Building, Tunney's Pasture, Ottawa, Ontario K1A 0L2 (tel.: (613) 957-1828; fax: (613) 941-3537; e-mail: sche-ann@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa,

2002

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Eileen Boyd  
Assistant Clerk of the Privy Council

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<sup>1</sup> S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1094 - FOOD IRRADIATION)

AMENDMENTS

1. The portion of item 3 of the table to Division 26 of Part B of the *Food and Drug Regulations*<sup>1</sup> in column III<sup>2</sup> is replaced by the following:

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Column III	
Item	Purpose of Treatment
3.	To control insect infestation during storage

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2. The portion of item 4 of the table to Division 26 of Part B of the Regulations in column II<sup>2</sup> is replaced by the following:

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Column II	
Item	Permitted Sources of Ionizing Radiation
4.	Cobalt-60, Cesium-137 or electrons generated from a machine source (3 MeV max.)

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3. The table to Division 26 of Part B of the Regulations is amended by adding the following after item 4:

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<sup>1</sup> C.R.C., c. 870

<sup>2</sup> SOR/89-175

Item	Column I Food	Column II Permitted Sources of Ionizing Radiation	Column III Purpose of Treatment	Column IV Permitted Absorbed Dose
5.	Mangoes	Cobalt-60	To control insect infestation during storage and to extend durable life	0.25 kGy min., 1.5 kGy max.
6.	Fresh poultry	Cobalt-60, Cesium-137, X-rays generated from a machine source (5 MeV max.) or electrons generated from a machine source (10 MeV max.)	To control pathogens, reduce microbial load and extend durable life	1.5 kGy min., 3.0 kGy max.
7.	Frozen poultry	Cobalt-60, Cesium-137, X-rays generated from a machine source (5 MeV max.) or electrons generated from a machine source (10 MeV max.)	To control pathogens, reduce microbial load and extend durable life	2.0 kGy min., 5.0 kGy max.

Item	Column I Food	Column II Permitted Sources of Ionizing Radiation	Column III Purpose of Treatment	Column IV Permitted Absorbed Dose
8.	Fresh, prepared or dried shrimp and prawns	Cobalt-60, Cesium-137, X-rays generated from a machine source (5 MeV max.) or electrons generated from a machine source (10 MeV max.)	To control pathogens, reduce microbial load and extend durable life	1.5 kGy min., 3.0 kGy max.
9.	Frozen shrimp and prawns	Cobalt-60, Cesium-137, X-rays generated from a machine source (5 MeV max.) or electrons generated from a machine source (10 MeV max.)	To control pathogens, reduce microbial load and extend durable life	1.5 kGy min., 5.0 kGy max.

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

COMING INTO FORCE

4. These Regulations come into force on the day on which they are registered.