HOUSE OF COMMONS
CANADA

# Food Irradiation

## REPORT OF THE STANDING COMMITTEE ON CONSUMER AND CORPORATE AFFAIRS ON THE QUESTION OF FOOD IRRADIATION AND THE LABELLING OF IRRADIATED FOODS



MARY COLLINS, M.P.
CHAIRPERSON

MAY 1987

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*Minutes of Proceedings and Evidence of the Standing Committee on*

# Consumer and Corporate Affairs

*Procès-verbaux et témoignages du Comité permanent de la*

# Consommation et des Corporations

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RESPECTING:

In accordance with its mandate under Standing Order 96(2), an examination of the question of food irradiation and the labelling of irradiated foods.

INCLUDING:

First Report to the House.

CONCERNANT:

En conformité avec son mandat en vertu de l'article 96(2) du Règlement, un examen de la question de l'irradiation des aliments et de l'étiquetage des aliments irradiés.

INCLUANT:

Premier Rapport à la Chambre.

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Second Session of the
Thirty-third Parliament, 1986-87

Deuxième session de la
trente-troisième législature, 1986-87

**THE STANDING COMMITTEE ON CONSUMER AND CORPORATE AFFAIRS**
(Second Session, Thirty-third Parliament)

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## ORDER OF REFERENCE

Wednesday, November 26, 1986

In accordance with its mandate under Standing Order 96(2), the Committee agreed to commence consideration of the issue of food irradiation and the labelling of irradiated foods.

*ATTEST*

Richard Chevrier
*Clerk of the Committee*

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THE STANDING COMMITTEE ON CONSUMER AND CORPORATE AFFAIRS

has the honour to present its

FIRST REPORT

In accordance with its mandate under Standing Order 96(2) your Committee has examined the question of food irradiation and the labelling of irradiated foods.

Pursuant to Standing Order 99(2), the Committee requests that the Government table a comprehensive response to the Report within one hundred and twenty (120) days.

A copy of the relevant Minutes of Proceedings and Evidence of the Standing Committee on Consumer and Corporate Affairs (Issues 2 to 12 of the Second Session, Thirty-third Parliament which includes this Report) is tabled.

Respectfully submitted,

MARY COLLINS,
*Chairperson.*

## ACKNOWLEDGEMENTS

The Committee could not have completed its study on the complex and controversial subject of food irradiation and the labelling of irradiated foods without the cooperation and support of several people. All of the witnesses who accepted, sometimes on very short notice, to appear before the Committee deserve our gratitude.

Our acknowledgements also to Robert Milko and Margaret Smith from the Research Branch of the Library of Parliament for their expertise.

In addition, the Committee wishes to express its appreciation for the logistic and administrative support provided by Richard Chevrier, Clerk of the Committee.

Finally, the Committee would like to recognize the valuable cooperation of the staff from the Committees and Private Legislation Directorate, the Translation Bureau of the Secretary of State and the other services of the House of Commons.

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## Introduction

The possibility of using ionizing radiation to preserve and sterilize food* has received considerable attention since the Second World War, but only of late has there been a strong resurgence of interest. This method of treatment, commonly called food irradiation, can be achieved by exposing food to ionizing energy generated by X-rays,* high-speed electrons from an electron accelerator or gamma rays* emitted by the decay of radioactive isotopes such as Cobalt-60 ($Co^{60}$) or Cesium-137. Depending on the dose* of radiation applied and the type of food exposed, irradiation can extend shelf life, reduce the use of chemicals for preservation and pest control, and reduce or eliminate certain food-borne microorganisms and pathogenic bacteria. (see Appendix II)

The potential benefits of irradiating food are not devoid of potential risks and, not unexpectedly, a large number of concerns have been expressed. For some, questions about the safety and the nutritional value of irradiated foods are predominant concerns. For others, environmental and occupational safety risks associated with the operation of irradiation facilities are important issues. There is also a general concern about the labelling of irradiated foods; how should the consumer be informed?

In general, decisions on whether to proceed when factors are many and complex require analyses of both the potential benefits and the potential risks. Since the Standing Committee believes that the safety of the consumer should not be compromised, it was necessary to first examine the safety and wholesomeness of irradiated foods. Realizing that conclusive evidence might not be available to indicate whether irradiated foods are either unequivocally safe or harmful, we also examined other issues germane to food irradiation. We felt that these examinations would assist in determining whether the benefits of food irradiation outweigh the risks, or vice versa. The conclusions from this analysis influenced the direction of our recommendations respecting many of the other related issues.

Given the renewed interest and public concern about food irradiation, the Standing Committee felt that a study of this subject was warranted. Committee hearings began on November 26, 1986. From then until March 11, 1987, public hearings were held during which 26 representations were heard.

We believe that our recommendations will assist the Government in revising the regulations respecting the control of food irradiation and the labelling of irradiated foods, help clarify questions about the safety and wholesomeness of irradiated foods and contribute to an increase in public awareness about food irradiation.

## Background Information

In Canada, food irradiation is currently regulated as a food additive under the *Food and Drug Regulations*. Irradiation is permitted for potatoes and onions as an antisprouting agent, for wheat, flour and whole wheat flour for deinfestation purposes, and for whole or ground spices and dehydrated seasonings to reduce the microbial load. Although irradiation has been allowed for selected food items in Canada since 1960, apart from a short period during the mid-1960s when irradiation was used to inhibit

* Words identified by the asterisk * are defined in the Glossary of Terms (Appendix I).

sprouting in potatoes, food irradiation has not been, nor is it now being carried out commercially in this country. Throughout the world, food irradiation has not gained widespread commercial use and irradiated foods currently constitute less than one-tenth of one percent of all foodstuffs.

A number of factors have contributed to an increased interest in irradiation as a method of food preservation. First, a decision in 1980 by a Joint Expert FAO/IAEA/WHO* Committee stated that foods irradiated at an overall average absorbed dose of radiation up to 10 kilograys (kGy)* presented no toxicological hazard. Following this, food irradiation was approved and standardized by the Codex Alimentarius Commission*. Added to these factors is the growing concern about the safety of chemicals used to preserve and deinfest certain foods, (ethylene dibromide was banned in 1984).

In 1983, the Department of National Health and Welfare proposed changes to the regulation of food irradiation in Canada. (see Appendix III) These proposals would control irradiation as a food process rather than as a food additive and would require tests to establish the safety of irradiated foods (toxicological tests) only where the overall average absorbed dose of radiation exceeds 10 kGy. The Department of Consumer and Corporate Affairs concurrently issued proposals for the labelling of irradiated foods. Since 1983, no further action has been taken by Health and Welfare Canada to implement its proposed changes, although the Department of Consumer and Corporate Affairs issued new labelling proposals in November 1985. (see Appendix IV)

# CHAPTER 1

# Wholesomeness and Safety of Irradiated Foods

The concern that has been expressed about the safety of ingesting irradiated foods appears to be derived from the negative perception of nuclear safety, particularly when nuclear technology is associated with food; a fundamental of life. To a considerable degree this association has been strengthened since the Chernobyl accident in 1986 that resulted in widespread radioactive contamination of food. But in fact, regardless of this perception, demonstrating the safety and wholesomeness of irradiated food when regulated as a food additive, is mandatory.

Public awareness of the safety and wholesomeness of foods is increasing and concern about how additives, processing and pesticide residues can erode the nutritional quality of foods and adversely affect human health is becoming more widespread. As evidence of this phenomenon, the Grocery Products Manufacturers of Canada's research on approaches to retailers and consumers regarding food irradiation has noted that food safety is a prime concern of the consumer. The Standing Committee is of the view that these concerns are warranted and that the safety and wholesomeness of foods must take precedence over other benefits food technologies may offer. The introduction of any food technology or additive must therefore, be assessed first on the basis of concern for the safety of the consumer. Care should be taken not to repeat past situations where certain additives which were once considered safe, were subsequently found to be harmful.

Wholesomeness of food that has been treated with ionizing energy (in this case irradiated) has been defined by the Council for Agricultural Science and Technology (CAST) in its 1986 study *Ionizing Energy in Food Processing and Pest Control* to mean that harmful microorganisms and microbial toxins are absent in the food, that the ionizing energy has produced no measurable toxic effects or radioactivity and that the food presents no significant nutritional deficiency when compared with the same food that has not been treated with ionizing energy or that has been processed by well-established conventional methods. The Standing Committee concurs with and uses this definition throughout this report.

Since food irradiation is not a new technology, various toxicological studies of irradiated foods have been conducted over the years. Toxicology as a science, however, has been evolving over time as the understanding of health and toxic response grows. As a consequence, the methods and results of studies from even ten years ago might now have less credibility when examined by current standards. Frequently during the

Committee's hearings witnesses who were opposed to food irradiation cited the U.S. Federal Register (Vol. 51, no. 75 of 18 April 1986) that discussed the recent USFDA* ruling on food irradiation. According to the Federal Register, of 441 toxicity studies on irradiated foods that the USFDA reviewed, only five were "considered by agency reviewers to be properly conducted, fully adequate by 1980 toxicological standards, and able to stand alone in the support of safety." Is this enough? Concern also exists about extrapolating results from toxicological tests performed on laboratory animals to the human situation, but this is not a new concern. Testing irradiated foods, however, does present some unique difficulties in designing toxicological tests (see Appendix V).

There has also been considerable controversy with respect to the interpretation of the results of the most comprehensive series of toxicological studies yet performed on irradiated foods; studies of a design that would be required to demonstrate the toxicological safety of most food additives that were not yet approved for the market. In order to clear up this grey area of controversy the Standing Committee hired on contract, a team of expert independent toxicologists to evaluate these comprehensive, yet controversial Raltech studies and some of the more widely discussed smaller studies that showed adverse or toxic effects. After careful evaluation and consideration, it appears that the jury is still out. Evaluation of the Raltech studies performed by Cantox Inc. for the Standing Committee indicated that many of the studies had methodological deficiencies or unusual or unexplained effects which make it difficult to demonstrate unequivocal safety. Based on its evaluation, Cantox concluded that "unless the benefits are significant, it would be prudent to resolve the remaining questions [respecting food irradiation] before proceeding with widespread application of the technology". In light of the results of the Cantox evaluations and the many additional concerns which will be outlined subsequently in this report:

1) **The Standing Committee recommends that the irradiation of food by any form of ionizing energy continue to be regulated as a food additive, and be restricted to those foods and doses presently approved by the existing regulations until an in-depth scientific assessment of health implications and further toxicological studies indicate that no significant adverse health effects would be expected to be found by the ingestion of irradiated foods. Notwithstanding the foregoing, it is recommended that the irradiation of wheat no longer be permitted until the specific safety questions addressed in other recommendations in this report are resolved.**

Retaining the status of food irradiation as an additive rather than a process helps ensure that appropriate toxicological testing is undertaken. As a process, the requirements for toxicological testing would be reduced.

The Cantox review indicated that:

> "the assessment of the safety of consuming irradiated foods is not a simple task ... . In the case of irradiated foods, the test material is a complex food, rather than a unique chemical entity *per se*. Consequently, it cannot simply be added to adequate diets in incrementally increasing amounts to study a range of exposure levels bracketing the human experience. Negative results with high exposure levels would, [however,] increase general confidence in the assessment of potential adverse effects. If additional studies were conducted to address some of the deficiencies noted in the studies reviewed, the design of such studies should address issues such as the incidence of chromosomal aberrations, the effects of irradiation on different food stuffs (e.g., meats and cereals) and the effects of irradiation on the nutritional value of foods. Simply repeating animal feeding studies using standard designs would not resolve the questions that remain unanswered."

Methodologies to conduct toxicological studies are readily available and such studies should be conducted to conform with the best current standards. Additionally, we feel that they should address questions which may be specific to irradiated foods. Therefore:

2) **The Standing Committee recommends that the Minister of National Health and Welfare in consultation with other interested federal government departments and agencies, and representatives of consumer groups strike a consultative panel to be composed of theoretical and analytical physicists, chemists, nutritionists, toxicologists and consumer group representatives to conduct an in-depth, integrated analysis to provide further insight into potential biochemical and physiological problems that might arise from irradiating various foods at varying doses. The information obtained from this analysis should be used to provide the basis for developing protocols for tests to determine, more fully, the wholesomeness of irradiated foods.**

Toxicological studies are expensive, perhaps $12 million for a complete series. Questions have been raised regarding who is responsible for conducting the studies and who is responsible for the burden of proof of safety. As precedents have been set on these issues in relation to food additives, pesticides and new chemicals, the Standing Committee is of the view that the costs and burden of proof should remain with the proponents and those hoping to benefit economically from food irradiation. In the case of food irradiation there is potentially some overlap in responsibility, for if Atomic Energy of Canada Limited (AECL)* was to produce, sell and supply materials for irradiators, then the Government of Canada through a Crown Corporation may benefit to some degree. If and when an application is made to irradiate a specific food, however, it will be more evident who else may benefit and thus be ultimately responsible for conducting the appropriate tests and proving safety.

After the consultative panel has recommended protocols for specific baseline studies, it will be necessary to conduct these studies before toxicological tests are carried out by an applicant who may be seeking approval to irradiate specific foods. Therefore:

3) **The Standing Committee recommends that baseline studies as suggested by the consultative panel, be conducted with funding from the Federal Government. Emphasis should be placed on conducting tests on wheat and chicken as recommended elsewhere in this report. Funding for the toxicological tests required to support an application to irradiate specific foods is to be the responsibility of the applicant.**

The Standing Committee recognizes that decisions with respect to the safety of irradiated foods presently rests with the Minister of National Health and Welfare. We believe that efforts should be undertaken to ensure that decisions are made in concert with the approval of consumers and in consultation with other bodies offering responsible, constructive input. In particular, the consultative panel struck in Recommendation 2 would be well equipped to assist in reviewing the adequacy of irradiated food safety studies: Therefore:

4) **The Standing Committee recommends that the consultative panel act as an advisory body to the Minister of National Health and Welfare regarding applications for approval to irradiate foods.**

We recognize that there are a number of distinct issues associated with the wholesomeness of irradiated foods and are devoting the remainder of this Chapter to a discussion of many of these.

## (i) Toxicology

### a) Polyploidy

One of the most controversial irradiation studies involved the feeding of irradiated wheat to malnourished children in India (see Appendix V). There has been considerable debate about the interpretation of the results of these studies which indicated an increase in polyploidy* in circulating blood cells (a chromosomal abnormality poorly understood, but of possible serious health concern). For reasons which will be clarified in the following sections it is possible that this adverse effect might be transient and associated with recently irradiated wheat only. Until the scientific questions surrounding the potential effects of ingesting recently irradiated wheat are clarified, wheat should not be irradiated in Canada as indicated in Recommendation 1. It also appears that further studies are necessary to verify the results of these controversial irradiated wheat studies. Therefore:

5) **The Standing Committee recommends that further feeding studies (not on humans) be conducted to determine if the effects from eating irradiated wheat as indicated by earlier studies do in fact occur.**

If polyploidy does occur from ingesting irradiated wheat, it is possible that other irradiated grains of similar moisture content could induce a similar effect. Therefore:

6) **The Standing Committee recommends that if increased polyploidy or other toxic responses are further shown to result from ingesting irradiated wheat, then similar studies should be conducted on other grains which might be candidates for irradiation. If there is an adverse effect and it is dependent on the period of time between irradiating and ingestion, then this relationship should be established.**

### b) Induced Radioactivity

One of the initial questions that arises when considering food irradiation is the possibility of inducing radioactivity. The general understanding, however, is that no measurable radioactivity (thousands of times less than that already occurring in food) would be induced in food by the various sources of ionizing energy, if their energy levels are within those legally permitted for irradiating food. In fact, induced radioactivity was of little concern to the witnesses, although the possibility of inducing radioactivity with accelerated electrons that have energy levels greater than 10 million electron volts (MeV) was expressed as a "concern", particularly with imported irradiated foods.

Gamma rays from Cobalt-60 have a relatively low average energy level compared to other high energy gamma emitters and have little probability of inducing radioactivity. As this is the most likely source of ionizing energy for irradiating food in Canada in the near future,induced radioactivity may be of little concern. As well, X-rays below 5 MeV, and accelerated electrons below 10 MeV will not induce measurable radioactivity, but there would be cause for concern if higher energy levels were used. Discussions with physicists and a review of the literature,however, have indicated that some concerns might exist with electron accelerators when used with specific packaging materials (see Technological Considerations Section). Interestingly, there was no mention of X-rays during the hearings.

### c) Free Radicals and Radiolytic Products

Considerable concern has been expressed about the formation and action of free radicals* (unstable molecular products) in foods that have been irradiated, and about the possible generation of unique radiolytic products (URP's* — products resulting from the chemical decomposition of food that are unique to treatment with ionizing energy). Without becoming involved in a technical discussion, free radicals cause the ionization of molecules, which among others things, can contribute to the production of cancer by their disruptive effect on molecular DNA*. But it is these properties of free radicals which, in part, make irradiation effective in the control of microorganisms.

As indicated by the irradiated wheat study, the potential for direct consumption of free radicals appears to warrant further investigation. The short-life of a free radical in a moist substance could be much longer in a hard, less permeable substance that has a low moisture content. According to the 1986 "Report on the Safety and Wholesomeness of Irradiated Foods" by the U.K. Advisory Committee on Irradiated and Novel Foods (ACINF)* free radicals can remain in bone for several years. It is therefore possible that free radicals caused the polyploidy effect from ingesting freshly irradiated wheat. These possibilities pose difficult scientific questions which require further investigation, therefore:

7) **The Standing Committee recommends that the consultative panel (see Recommendation 2) select researchers and/or research institutes to conduct studies to determine the life of free radicals in various foods that may be irradiated (e.g. dried and hardened spices, wheat and other grains).**

Based on the evidence presented and a review of the literature, it appears that the debate continues over the possible indirect effect of free radicals, that is, whether they contribute to the production of radiolytic products that are unique to irradiation. One side of the debate maintains that the radiolytic products formed by cooking and thermal processing such as canning are no different from those produced by ionizing energy. The other side suggests that ionizing energy produces chemical reactions (molecular bond disruptions) and compounds that are less predictable than those produced by thermal processing. According to the latter argument the number of these compounds (URP's) and their identities would be difficult if not impossible to measure. The consultative panel (Recommendation 2) could examine this debate in further detail.

It is known that some radiolytic compounds produced by cooking and thermal processing are suspected human carcinogens* and that these same products can be produced by ionization. During the hearings there was little concern expressed about such similarities. Emphasis, however, was placed on the potential differences between the radiolytic compounds produced by ionizing energy and thermal processes. For example, what are the potential products that result from the irradiation of pesticide residues in or on foods? Although proponents of food irradiation indicate post-harvest application of pesticides could be reduced by the use of food irradiation it is unlikely pre-harvest application would be affected. Therefore:

8) **The Standing Committee recommends an investigation be conducted into the products that may be produced by irradiating pesticide residues. Such an examination should include irradiating the more widely applied classes of pesticides in isolated conditions and on fruits and vegetables.**

## (ii) Microbial Ecology

In normal situations low levels of bacteria can be found on food even when the food is fresh and appears to be in prime condition. With time, certain types of bacteria increase in numbers, degrading the food and producing odours and off-tastes that indicate the food is no longer fit for consumption. As well, there is normally a balance between these relatively harmless bacteria and those that are pathogenic or toxin producing. These latter bacteria, however, are normally found in low enough numbers that no adverse health effects would be encountered on eating fresh food.

There has been substantial concern expressed that irradiating foods causes changes in this usual pattern of microbial ecology. Despite the fact that the Joint Expert FAO/IAEA/WHO Committee (with a disclaimer) indicated no toxicological problems should be posed with foods irradiated up to 10 kGy, the concern regarding shifts in microbial ecology in foods appears to be warranted. Various microorganisms, such as bacteria, are affected differently by irradiation than by thermal processing. Normally on heating, bacteria are destroyed in a relatively uniform manner. With irradiation this is not necessarily the case. At doses greater than 1 kGy but below 10 kGy, bacteria that normally cause degradation and decomposition of older food are killed. Other potentially toxic bacteria or pathogens, however, may not be destroyed. The potential therefore exists for the toxic bacteria to flourish in the absence of competing bacteria that would normally indicate the poor quality of a food.

### a) *Clostridium Botulinum*

An often cited example of the selective reduction of microorganisms is *Clostridium botulinum*, the bacteria that causes botulism food poisoning. Spores of *C. botulinum* would resist irradiation above 10 kGy, and, particularly if irradiated under anaerobic conditions (absence of oxygen), could flourish and produce their fatal toxin. At the same time, there would be no indication that the food had spoiled because other bacteria would have been eliminated by this dose. In the United States,this concern was accepted by the USFDA in its recent decision to limit doses of irradiation to a ceiling of 1 kGy for fresh foods. One food scientist, a witness at the Standing Committee's hearings, noted that the science of thermal processing has a "probability" built into it — with canning there is a very high probability that no spores of *C. botulinum* will survive. Since irradiation presents new problems that make probability predictions more difficult, more stringent microbial safety testing and other controls may be required. It would thus seem prudent to restrict irradiation to less than 1 kGy to reduce these microbiological concerns if Recommendation 1 of this report is not heeded. Therefore:

9) **If the control of food irradiation is to proceed on the basis of establishing a maximum overall average absorbed dose below which no toxicological testing is required, the Standing Committee recommends that the maximum overall absorbed average dose should be restricted to 1 kGy except for specifically approved situations. This level would reduce the health threat of pathogenic and toxin producing bacteria such as *C. botulinum*.**

### b) *Salmonella*

Another issue falling under the rubric of microbial ecology is the potential for irradiation to select for resistant strains of microorganisms. This phenomenon, particularly in rapidly reproducing and quickly mutating organisms is readily

demonstrable and has been observed between insects and pesticides, and between bacteria and antibiotics. In fact, *Salmonella* have shown a remarkable ability to adapt to antibiotics and develop resistant strains. It is likely that irradiation would provide a similar if not accentuated selection pressure for the development of resistant *Salmonella* strains.

A large percentage of poultry is infected by *Salmonella* and the amount of food poisoning resulting from this bacteria is also estimated to be quite high. As a result, poultry has been indicated as a prime candidate for irradiation. At this point, it should be noted that relatively rough extrapolations have indicated that *Salmonella* may have contributed to approximately 750 deaths in Canada in 1985, but actual statistics attributed only 28 deaths to *Salmonella* from 1983 to 1985. Which figures may be more accurate is unknown at this time, but *Salmonella* contamination is a major source of food poisoning and a significant public health concern in Canada and elsewhere.

Irradiation, however, may not be the most cost-effective method of eradicating *Salmonella* from poultry. A study by Ron Krystynak, published in Agriculture Canada's *Food Market Commentary* in 1986 indicated that irradiation of packaged poultry ranked sixth out of eleven in cost-effectiveness as a control procedure for *Salmonella*. This is behind education of homemakers and the food service sector to prevent cross-contamination, use of chlorine dioxide in chill water in poultry packing houses, and measures to clean up the poultry processing industry. According to another food scientist, who feels that food irradiation has a place in the market as a processing method, it is possible that using irradiation to eradicate *Salmonella* on marketed poultry may give consumers a false sense of security and promote poorer food handling techniques.

Although irradiating packaged poultry can eradicate *Salmonella* from that product, it will not deal with *Salmonella* in a holistic context. *Salmonella* has its roots in the farmyard and in poultry processing plants. Irradiating poultry after it has been packaged for sale to consumers will not eliminate the source of the problem because farmyards and processing plants will continue to be contaminated. As well, *Salmonella* is not limited to poultry and can be found in other animal-based foods. Even with irradiated poultry, direct consumption of these other contaminated products and cross-contamination because of improper handling techniques by processors, shippers, consumers and commercial food establishments would perpetuate the *Salmonella* problem, but at a reduced level of incidence. Accordingly:

**10) The Standing Committee recommends that methods more cost-effective than irradiation be pursued to contend with the *Salmonella* problem in Canada. This should include the establishment of a comprehensive public education program to promote proper and safe handling techniques for poultry. This program should be jointly formulated and funded by the Government and the poultry industry. As well, further studies on the wholesomeness of irradiated chicken should be conducted as indicated in Recommendation 3.**

Another microbiological problem brought to the attention of the Standing Committee was that, as indicated in some scientific studies, irradiation can increase the production of extremely toxic aflatoxins by specific fungi. Aflatoxins can be found on nuts and grains and flourish in warm, humid conditions particularly during storage and shipping. Although these conditions are less frequently encountered in Canada they are a serious concern for other countries which could import Canadian grain that would later be irradiated. The aflatoxin question requires further investigation. Therefore:

**11) The Standing Committee recommends that the Department of Agriculture, in concert with academic microbiologists, and the consultative panel (Recommendation 2) investigate the production of aflatoxins after irradiation. Experiments should attempt to ascertain which fungal species (if any) increase production after irradiation and if mutant strains are produced as is suggested in the scientific literature. In the first instance, studies should be conducted using methods similar to the original aflatoxin studies and then further studies should be conducted under natural conditions where competitor organisms would be present.**

## (iii) Nutritional Degradation and Organoleptic Quality

When foods are irradiated a certain degree of nutritional degradation and organoleptic* deterioration occurs. It is beyond the scope of this report to discuss all aspects of these questions and to outline the various processing methods that might be used to reduce these problems.

It appears, however, that organoleptic deterioration may be a self-imposed limitation on irradiating certain foods. Some foods, because of their composition, undergo a deterioration of organoleptic qualities when specific doses are surpassed. For example, with poultry where a dose of 3-8 kGy would be needed to destroy *Salmonella*, there is substantial deterioration of smell and taste. Although specific conditions while irradiating, for example freezing, may reduce the organoleptic deterioration, a higher dose may consequently be required to accomplish the intended effect. Such a scenario is not limited to poultry as other meats can also encounter texture and colour problems on irradiating.

Undoubtedly one of the major concerns associated with the irradiation of food is the deterioration of essential nutrients, in particular, vitamins. Some have suggested that nutrient degradation resulting from irradiation is no greater — some claim less — than that produced by thermal processing, cooking or freezing. Others contend that nutrient degradation from irradiation is additional to losses that would take place when a product is cooked. Generally, this latter argument is true and many variations of processing and cooking methods can be envisioned in series, all having some added effects. In particular, there is concern for loss of some key vitamins, E, C and thiamine (among others) and for effects on fats which may interfere with the absorption and utilization of other dietary constituents. Another major problem is the production of hyperoxides which can reduce the concentration of essential fatty acids and fat soluble vitamins.

It is recognized that both the amount of nutritional degradation and the dose of radiation may be limited by concurrent changes in organoleptic qualities. Once again, it appears that by employing somewhat complex environmental conditions while irradiating (freezing to -20°C, vacuum packaging, and others) many of the nutritional concerns could be reduced or eliminated. If some or all of these techniques must be employed in conjunction with irradiation, costs could become prohibitive or place a further burden on consumers. In some situations, these other methods may be effective alone.

Specific cases can be debated, but the concern for nutritional degradation appears to be quite legitimate. Since many of the mechanisms that lead to nutrient degradation are complex and because foods of high nutritional quality are desirable, a product-by-product examination at specific doses of radiation would best indicate if nutrient loss is

significant. Undertaking these examinations would be a tremendous task, but if food irradiation were to proceed we feel this would offer the best assurance of nutritional quality. Therefore:

12) **The Standing Committee recommends that investigations be conducted on the effect of irradiation on the nutritional degradation of the foods for which irradiation is presently permitted. Investigations into the nutritional degradation of other foods should also be conducted before they are approved for irradiation.**

## (iv) Additional Health and Safety Concerns

As this report indicates, one can find opinions on both sides of the debate about the safety of irradiated foods. On this point the Standing Committee has determined that there are still unanswered questions regarding safety which warrant further toxicological studies. Although it is realized that such studies would involve multigeneration, reproductive, chronic toxicity, cancer, genetic and other studies, questions remain regarding the limitations of toxicological testing. Is it developed enough to determine long-term low-level consumption effects that could build up in the population? Perhaps only time will tell. Therefore, we would like to reiterate our position limiting the use of irradiation on food until further toxicological tests clarify such questions. In particular:

13) **The Standing Committee recommends that in addition to other toxicological tests that need be conducted, emphasis should be placed on tests to examine the long-term chronic effects (if any) of ingesting irradiated foods.**

If food irradiation was to expand, it is possible that some sub-groups of the population could consume a higher proportion of irradiated foods than others. The long-term retention of records relating to irradiation would facilitate future epidemiological studies to determine whether chronic effects in humans occur. This point, including recommendations, will be further addressed in Chapter 4.

An issue which did not receive attention from witnesses but which the Standing Committee believes to be of importance is the irradiation of animal feed. In general, additives to various animal feeds can be indirectly ingested by humans through their consumption of the animal. Concerns about the effect of additives in animal feeds are growing as researchers discover links between human health and substances ingested by animals. These concerns may also apply in situations where animals which have been fed irradiated animal feed form part of the human diet.

Irradiating animal feed of any kind, including pet food, raises further questions given the uncertainty surrounding the wholesomness of irradiated foods. It would, therefore, seem prudent to restrict the irradiation of all animal feed in the same manner as is proposed in Recommendation 1 of this report.

# CHAPTER 2

# The Labelling of Irradiated Foods

## (i) Form of Labelling

The Standing Committee believes that the right to be informed about the nature and quality of food and to exercise meaningful choices when selecting food products is of prime importance to consumers. This becomes particularly significant as public concern about the safety of food products grows and as evidence of the harmful effects of substances that were once thought to be safe comes to light. Labelling food ingredients is one method of providing information to consumers so that informed choices can be made.

The labelling of irradiated foods may be seen by some as an adjunct to the proposal to classify food irradiation as a food process. Labelling, however, should be viewed as a matter which is distinct from the regulatory status of food irradiation. As irradiation is now permitted for a selected number of food items, labelling requirements for these uses should be addressed irrespective of potential future applications.

Since the *Food and Drug Regulations* define "any source of radiation" as a food additive, irradiated foods must be labelled. The current regulations respecting the labelling of irradiated flour and whole wheat flour require that where these products have been treated with gamma radiation from a Cobalt-60 source, the label must carry a statement to the effect that they have been processed or treated with ionizing radiation. No labelling format, however, is indicated. The labels of irradiated spices, potatoes, onions and wheat must also indicate that these products have been irradiated, but again there would appear to be no standard format for such labelling. As well, imported irradiated foods must be limited to those specified in the existing regulations and labelled accordingly.

Classifying irradiation as a food additive ensures that foods treated with ionizing radiation will be labelled. Classifying it as a process, however, eliminates the mandatory labelling requirements. At present, some food processes require labelling to indicate their use while others do not. For example, foods which are canned or frozen are not labelled to indicate these processing methods — the use of either being evident from the nature of the container or the product. On the other hand, pasteurization, a process the use of which is not evident to consumers of milk, is indicated on the label of milk containers. Food irradiation is analogous to pasteurization in that the consumer has no tangible means of determining whether a food has been irradiated. In the

absence of a label, a consumer would likely believe that an irradiated food has not been subjected to any kind of treatment. Furthermore, there are presently no reliable tests which can be carried out to identify irradiated foods or to establish the dose of radiation employed.

The inability to identify irradiated foods makes the labelling of these products imperative. Testimony heard by the Standing Committee has overwhemingly favoured the labelling of all irradiated foods regardless of the regulatory status of irradiation. We strongly support this position and believe that it is in the best interests of both the consumer and the food industry that labelling be provided. Accordingly:

**14) The Standing Committee recommends that all irradiated foods, both domestically produced and imported, be fully labelled as outlined in recommendations 15, 17, 18, 19, 20 and 21 regardless of whether food irradiation continues to be classified as a food additive as recommended by this Standing Committee, or as a food process.**

In 1983 the Department of Consumer and Corporate Affairs issued recommendations for labelling irradiated foods concurrently with the Department of National Health and Welfare's proposed regulations for the control of food irradiation. In November 1985, the Department issued revised labelling proposals which, in essence, called for the use of a symbol only to identify irradiated foods. (Communiqué 50, Appendix IV)

The Standing Committee has heard a great deal of evidence on the form and content of the labelling requirements for irradiated foods. Although the principle of labelling irradiated foods has been supported by virtually all witnesses, divergent views have been expressed on the manner in which irradiated foods should be identified. Some witnesses favour the use of a symbol only while others contend that a symbol must be accompanied by some form of explanatory wording. Opinions on the form of wording vary. Based upon the view that consumers might be misled or needlessly alarmed by any direct reference to words which may associate irradiation with radioactivity, use of the acronym RADURA or the words "ionizing energy treated" has been suggested. Others feel that this acronym is misleading and that the words "ionizing energy treated" are euphemistic and confusing. Several witnesses provided the Standing Committee with suggested formats for labelling and one witness recommended that the dose of radiation applied to a food be indicated on the label.

The Standing Committee favours a labelling scheme which is both simple and direct — one that will identify irradiated products and provide information to consumers without misleading or confusing them. We believe that this is best accomplished by using both a symbol and a form of explanatory wording. Explanatory wording would provide information to the consumer, and when used in conjunction with a symbol, would assist in educating the consumer that the wording and the symbol are synonymous. As the symbol illustrated below is being increasingly used to identify irradiated foods internationally, using this symbol with appropriate wording should be effective. Therefore:

**15) The Standing Committee recommends that all prepackaged irradiated foods shall bear the following symbol,**

**along with the word "irradiated".**

The symbol contained in Recommendation 15 has been adopted by a number of countries to label irradiated foods. We understand that the Codex Committee on Food Labelling is currently entertaining a proposal which would make this symbol an international identification mark for irradiated foods. The Standing Committee believes that it is important for consumers to have a uniform method of recognizing irradiated foods particularly if their availability becomes widespread. Therefore:

16) **The Standing Committee recommends that efforts be made to establish a uniform method of labelling irradiated foods on an international level.**

We are also concerned that the recommended form of labelling be deployed on prepackaged products in a clear and readily visible manner. In particular, the size and colour of the symbol and wording must allow for easy identification. On examination of various packaged food products it became evident to the Standing Committee that the size requirements prescribed by Section 14 of the Consumer Packaging and Labelling Regulations might not facilitate recognition. Contrary to Communiqué 50's suggestion that the symbol be green, a colour which seems to impart a form of approval of irradiated foods, we feel that it should be the same colour as the labelling of other ingredients which appear on a package. This would avoid any bias that may be suggested by the colour green and ensure that the colour of the symbol would contrast with a package's background colour scheme. Therefore:

17) **The Standing Committee recommends that the symbol and the wording be positioned on the principal display panel of all prepackaged irradiated foods in a minimum size of 4.8 millimeters (3/16 inch), but otherwise in accordance with the size prescribed by the Consumer Packaging and Labelling Regulations (section 14).**

18) **The Standing Committee recommends that the symbol and the wording be the same colour as that of the other ingredient labelling which appears on a prepackaged product that contains irradiated food.**

### a) Irradiated Ingredients

The Department of Consumer and Corporate Affairs' labelling proposal applies to the so-called "first generation foods", foods which are irradiated and sold with no further processing. Their application to irradiated ingredients is limited. An irradiated ingredient would be labelled only when it is the characterizing constituent of the food and has its common name in the finished product, for example, beef stew made from irradiated beef. A product such as Irish stew, whose ingredients may be irradiated beef, potatoes and vegetables, would not have to be labelled. The Standing Committee is concerned that this proposal for labelling irradiated ingredients could be open to abuse by creating product names designed to circumvent these suggested labelling requirements. In view of this possibility:

19) **The Standing Committee recommends that all irradiated ingredients be labelled in a clear and readily visible manner as set out in Appendix VI of this report. This recommended form of labelling is to be positioned on the principal display panel of all prepackaged products as set out in recommendation 17. The colour shall be as prescribed in recommendation 18.**

### b) Bulk Foods

Communiqué 50's labelling proposals require that irradiated foods sold from bulk containers at the retail level display the mandatory labelling declaration on a poster

immediately on or adjacent to the food. The Standing Committee concurs with the principle of labelling bulk irradiated foods. However, we do have some concern about the manner in which the labelling might be displayed. To be effective, the label must be displayed prominently and in a manner that is readily visible to consumers. Therefore:

20) **The Standing Committee recommends that irradiated foods sold from bulk containers at the retail level display the recommended symbol and wording on a poster, card, counter sign or other method of display on or immediately adjacent to the food in a conspicuous and prominent manner. The symbol and wording, shall be at least two-thirds the size of the print or other symbol displaying the product name on the poster, card, counter sign or other method of display and shall be no smaller than 17.5 mm (11/16 of an inch). All bulk irradiated foods must be labelled accordingly regardless of whether the product name is displayed. The symbol and wording shall be displayed in a colour which contrasts with the background colour of the poster, card, counter sign or other method of display.**

### c) Invoices and Bills of Lading

The Department of Consumer and Corporate Affairs' labelling proposals do not address the reirradiation of foods. The current United States regulations, on the other hand, stipulate that the labels, invoices or bills of lading for a food, any portion of which is irradiated, contain a statement indicating that the product has been irradiated and not to irradiate it again. This applies when a product is shipped to a food manufacturer for further processing, labelling or packaging. The Standing Committee believes that the reirradiation of foods warrants comment and regulatory action. We agree with the following comments on reirradiation contained at pp. 13392-13393 of the Federal Register Vol. 51 no. 75, April 18, 1986:

> An irradiated food that is properly packaged and stored should not require further irradiation to be marketable. Irradiation is not a sustitute for good sanitation practices.
>
> Where a food is irradiated more than once, the cumulative radiation dose cannot exceed the maximum allowable dose prescribed. The determination of whether those foods that are irradiated more than once are in compliance with the dosage requirements would be virtually impossible. Records from different irradiation facilities would likely not be available for inspection simultaneously.
>
> Labelling requirements may be difficult to comply with. Labelling at the wholesale level would have to ensure that the maximum cumulative dose absorbed by a food does not exceed the prescribed maximum. The label would also have to indicate the dose at which a previously irradiated food was treated.

Therefore:

21) **The Standing Committee recommends that the reirradiation of foods not be permitted. The Standing Committee further recommends that the label and invoices or bills of lading of all irradiated foods bear the symbol prescribed in Recommendation 15 and the statement "Irradiated — do not irradiate again".**

## (ii) Consumer Information and Education

One of the factors prompting this study was the need to increase public awareness about food irradiation. Labelling irradiated foods can contribute to consumer awareness, but merely placing a label on an irradiated food may not be sufficient. The consumer must be made aware of the meaning of the label and have access to information about food irradiation. Should irradiated foods become available in Canada, some form of public education will be necessary.

Testimony before the Standing Committee has supported the need for public education, but who should be responsibile for educating consumers is unclear. Some have suggested that education should be the government's task while others believe that it should be the responsibility of the food industry. Since there are divergent views on the safety and nutritional value of irradiated foods it is of utmost importance that any information provided to consumers address food irradiation in a clear unbiased manner.

Various government agencies have a role to play in food irradiation, for example, Agriculture Canada with food inspection and research, the Department of Consumer and Corporate Affairs with labelling and the Department of National Health and Welfare with food safety. The Standing Committee feels that while government agencies and departments should avoid promoting food irradiation, they could play an important role in educating and providing factual information to consumers. Such information might include scientific data, information on irradiation technology and the nutritional value of irradiated foods, and other relevant information. The Standing Committee believes that a food irradiation information program would also benefit from input from both proponents and opponents of food irradiation. Therefore:

22) **The Standing Committee recommends that emphasis be placed on providing clear unbiased information on food irradiation to the public. Information pamphlets on food irradiation should be made available to consumers by the Department of Consumer and Corporate Affairs through its regional offices.**

**If irradiated foods become available for consumption in Canada, the Department of Consumer and Corporate Affairs should be responsible for co-ordinating the development of a public information program about food irradiation. Financing for the program should be jointly shared by the Department and producers, manufacturers, and processors involved with food irradiation.**

## (iii) Other Labelling Considerations

At present, there is no requirement that advertisements declare that a food has been irradiated. Communiqué 50 proposes that radio and television advertisements for irradiated foods identify the food has having been irradiated where special claims are being made for the product. For example, if an advertisement for potatoes states that they are less likely to sprout, and the potatoes have been irradiated, the advertisement must declare that irradiation has been used; if no claims about improvements resulting from irradiation are made, then no mention of irradiation is required. The Communiqué does not deal with advertising in the printed media which is a particular concern since this is the predominant forum for advertising foods. In the absence of specific claims, it would appear that a consumer would not be informed that a product has been irradiated until reading the product label at the point of purchase. We have some concern that these advertising proposals may not provide adequate information to

the consumer. Further consideration by the Department of Consumer and Corporate Affairs may be warranted.

The Standing Committee is aware that irradiated foods could be served at commercial establishments that sell prepared food with no requirement for labelling. It is also apparent that food consumption at commercial establishments is increasing, and if there is no indication of which foods have been irradiated, the effectiveness of any labelling requirements would be somewhat compromised.

Commercial food establishments, like other businesses, are subject to basic regulatory requirements that they not provide information to the public that is misleading or inaccurate. The Standing Committee recognizes that requiring these establishments to adhere to product labelling regulations is a matter fraught with complexities, and that enforcing such regulations may be both difficult and expensive. If the availability of irradiated foods becomes widespread in Canada, the Department may wish to examine the feasibility of undertaking regulatory action in this area or establishing a voluntary compliance program whereby commercial food establishments would agree to identify irradiated foods and ingredients.

Although the Standing Committee has not heard evidence regarding the labelling of alcoholic beverages in its proceedings on food irradiation, we have on previous occasions heard from witnesses who called for ingredient labelling for alcoholic beverages. Alcoholic beverages are currently exempt from the ingredient labelling requirements prescribed under the *Food and Drugs Act*. Because of this exemption there would appear to be no requirement to identify any irradiated ingredient which may be contained in an alcoholic beverage. The absence of labelling requirements for alcoholic beverages may be of concern if grains and other ingredients commonly found in these beverages are approved for irradiation in a number of countries. It may be appropriate for the Department of Consumer and Corporate Affairs to examine the practicability of requiring, the labelling of irradiated ingredients in alcoholic beverages if the use of such ingredients becomes widespread.

# CHAPTER 3

# Technological Considerations

## (i) Differences in Methods of Irradiation

Technological questions arise with respect to the differences and effectiveness of the three methods currently proposed for irradiating foods in Canada. Most of the testimony heard was related to gamma irradiation from Cobalt-60, some comments addressed electron accelerators, but little or no mention was made of X-rays. The Standing Committee recognizes that the latter two methods raise fewer concerns regarding the transportation and disposal of radioactive wastes when compared to the Cobalt-60 method. These methods, however, have their own limitations and potential for concern.

The induction of radioactivity using energy levels above 10 MeV with any irradiation method has already been discussed, but there also appears to be some possibility of exceeding the predetermined dosage with electron accelerators. This is possible because a relatively short period of exposure to electrons with energy as high as 10 MeV (the level permitted with electron accelerators) produces an adequate dosage. Therefore, controls to ensure the exact timing of exposure are critical. In addition, because accelerated electrons have a very shallow penetration ability, careful monitoring of the dose received will be necessary to ensure that the required effect of irradiation is obtained.

On examination of the Raltech toxicology studies, a question arose regarding accelerated electrons and X-rays. In these studies chicken irradiated with accelerated electrons at 10 MeV was vacuum packaged in plastic that was lined with thin foil. Theoretically, the chicken was irradiated by X-rays produced by the electrons encountering the foil. The energy level the chicken would have received could be calculated or measured, but because X-rays can induce radioactivity at lower levels than accelerated electrons, the potential exists for the energy level to have been high enough to induce some radioactivity (albeit perhaps short-lived). In view of this:

**23) The Standing Committee recommends that if food irradiation is to proceed on a wider scale, theoretical and analytical studies should be performed to determine whether X-rays capable of inducing radioactivity are produced when food is irradiated in packaging materials lined in foil. If so, proper precautions should be taken to ensure that foods with induced radioactivity are not presented for consumption.**

## (ii) Monitoring and Inspection

The monitoring and inspection of irradiated foods presents some unique problems. Among these are how to determine whether a food has been irradiated, the standardization and placement of dosimeters* in each lot of food and the inspection of irradiation facilities.

As stated elsewhere in this report, there would not appear to be any reliable test for identifying irradiated foods or for establishing the dose of radiation used. There is some concern that irradiated products, particularly spices, are now being imported into Canada contrary to current regulations. If these products are not labelled, inspectors have no means of determining whether they have been irradiated. The lack of detection procedures presents particular problems for food inspectors who will have to rely on product labelling and the accuracy of the records kept by irradiation facilities and food importers to identify irradiated foods. In particular, gaining access to foreign records may be difficult.

Tests to identify irradiated foods are apparently under development. One witness presented documentation indicating that a sensitive crystallization test could be used to distinguish between irradiated and non-irradiated fruits and vegetables. Although this method has not been widely addressed, it may have the potential to alleviate some identification problems. The Standing Committee believes that special attention should be given to developing a means of identifying irradiated foods and the radiation dose used. Accordingly:

**24) The Standing Committee recommends that the sensitive crystallization test for identifying irradiated fruits and vegetables be further investigated.**

**25) The Standing Committee recommends that research be conducted by Agriculture Canada to develop tests which will identify irradiated foods and the radiation dose used.**

The radiation dose received by a food depends on a number of factors: the type of radiation source, the position of the food in relation to the source, and the length of time that the food is exposed to the radiation source. The dose of radiation absorbed by a food is not uniform throughout the whole food — one portion of a food may receive a higher dose than another. For this reason the radiation dose is normally expressed as the overall average dose, that is, the average of all doses measured at various points in a food. (for further discussion see Chapter 4) Controlling average dose may be a particular concern when electron accelerators are used because a timing error of a few seconds may result in foods being exposed to high levels of radiation.

Since irradiated foods will likely be available on the food export market, it is important that instruments and methods used to measure and record dosage information be uniform. Standardization is essential if the documentation accompanying exported foods is to be meaningful to import inspectors. The "Codex Recommended International Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods," outlines general parameters regarding dosimetry and treatment control. The Standing Committee understands that codes for the placement and use of dosimeters and the standardization of dosimeters have now been agreed upon. Although these standards have been created, countries are not required to implement them and efforts should be focused on encouraging their use. Therefore:

**26) The Standing Committee recommends that emphasis be placed on encouraging countries to adopt uniform standards respecting dosimeters and their placement in each lot of food.**

In general, non-irradiated foods available for sale in Canada, whether domestically produced or imported, must comply with established Canadian standards and inspections are carried out to ensure that these standards are met. In the case of certain products, meat for example, Canada has entered into arrangements with a number of countries which permit both Canadian inspectors to inspect meat processing plants located in these countries and foreign inspectors to examine Canadian facilities. Testimony suggested that a uniform international inspection system be devised for irradiated foods. The Standing Committee understands that the IAEA will be giving accreditation to irradiation facilities when they are established. Because an ongoing system of inspection is not included in the accreditation procedure, accreditation alone may not be enough. We believe that uniform standards for food irradiation facilities and an international inspection system would further ensure the quality of domestically produced and imported irradiated foods. Therefore:

27) **The Standing Committee recommends that once uniform international standards for irradiated foods have been implemented, an international inspection system be developed to ensure that irradiated foods comply with such standards.**

## (iii) Occupational and Environmental Concerns

Questions were raised before the Standing Committee with respect to the environmental impact of broadening the regulations controlling food irradiation. These concerns cover three areas: (1) safety of workers in food irradiation plants, (2) storage and disposal of radioactive waste and (3) transportation of radioactive materials. Although it is beyond the scope of this report to examine these questions in depth, the Standing Committee feels that some comment on each of these subjects is warranted.

A number of witnesses expressed concern about the hazards to workers employed in irradiation facilities. Among these are exposure to ionizing radiation and exposure to toxic substances that may form in the atmosphere of the irradiation area of the facility. According to AECL the design and construction of irradiation plants provide for a shielded area to adequately contain the radiation source. The Atomic Energy Control Board (AECB)* sets the standards for the amount of radiation exposure permitted for plant operating personnel. It also licences irradiation facilities and periodically monitors their operation. At the present time there are commercial irradiation facilities operating in Canada. These plants, although not irradiating food products, sterilize medical supplies and other materials using gamma radiation produced by Cobalt-60. The standards applicable to these irradiation facilities would also apply to those irradiating foods.

The Standing Committee recognizes that worker safety is a concern. We believe that all necessary precautions should be taken by plant manufacturers, operators and regulatory agencies to ensure both the safe operation and the safety of workers in food irradiation facilities. In particular, plant operators should develop and maintain practices which will minimize worker exposure to radiation.

Some witnesses expressed concern that an increased use of radioactive materials will lead to a corresponding increase in problems relating to the disposal of radioactive waste material. As indicated elsewhere in this report, three sources of ionizing energy are being considered for food irradiation: accelerated electrons, X-rays and radioactive isotopes such as Cobalt-60 or Cesium-137. The disposal of radioactive waste material is a concern mainly with respect to irradiation facilities using the radioactive isotopes

Cobalt-60 or Cesium-137, although there will probably be some low level nuclear waste generated by the other sources. AECL does not view the disposal of waste Cobalt-60 as presenting any special problems since it is possible to regenerate the spent isotope for further use. The Standing Committee believes that disposal of spent radioactive isotopes from food irradiation facilities may be a matter of concern if the number of irradiation facilities using radioactive isotopes as an energy source increases. Isotope suppliers such as AECL can assist in alleviating this problem by regenerating Cobalt-60 for further use. Therefore:

**28) The Standing Committee recommends that AECL take all necessary steps to emphasize the regeneration of spent Cobalt-60 to reduce levels of radioactive waste materials.**

A number of witnesses expressed concern about the safety of transporting radioactive materials. They suggested that implementing regulations which broaden the use of food irradiation would lead to increased amounts of radioactive material being transported in Canada. The Standing Committee acknowledges that increased transportation of radioactive materials may be a concern. However, sufficient evidence was not heard regarding projected increases in the amount of radioactive isotopes that may be transported and the methods of transport used to comment further on this issue. It should be noted, however, that concern for increased transportation is most relevant to the use of Cobalt-60 rather than X-rays or electron accelerators.

## (iv) Food Irradiation: Export and the Third World

We are presently suggesting a limitation on the irradiation of foods for domestic use based on our perceptions of the risks and benefits as outlined in this report. We are aware, however, that the expansion of food irradiation on the international scene may increase the demand for the importation of irradiated foods by other countries. Notwithstanding this potential demand, we feel that the same cautious stance we are suggesting for the use of food irradiation in Canada should apply to the export of irradiated foods from Canada. Should other countries determine that for their purposes the benefits to be derived from irradiation surpass the risks, then they can irradiate Canadian food products on or after importation.

The Standing Committee has heard considerable evidence with respect to the application of food irradiation technology in the context of the Third World. Although this matter is outside the scope of this study, we feel that it is appropriate to make some comments.

Proponents of food irradiation believe that it may have significant benefits for Third World countries. They maintain that irradiation may help these countries attain food self-sufficiency and facilitate their export trade by reducing the amount of food spoilage. Others see food irradiation as an attempt to provide a "technological fix" to problems which require more complex solutions. The following have been cited as reasons why the technology may not be appropriate in some situations: the inapplicability of irradiating foods in countries with decentralized food systems, the possible recontamination of food after irradiation because of improper handling techniques and inadequate storage, the difficulties with moving food to and from irradiation plants because of poor transportation and distribution networks, and ill-defined regulatory frameworks for protecting the public and workers from hazardous substances. One witness questioned the rationale for encouraging Third World countries to invest large sums of money in food irradiation technology without comparing its value with other less capital intensive methods of food preservation and storage.

Where a few staple foods constitute a large percentage of the diet, irradiating even one of those staples may present special problems both in terms of the effect of irradiation on nutrient content and the long-term effect of consuming substantial amounts of irradiated foods. The ACINF study noted that foods that make a significant contribution to dietary nutrient intake should be thoroughly studied. For this reason, it recommended that further investigation be carried out on irradiated potatoes because potatoes are a major source of vitamin C and thiamine in the British diet. Such studies are perhaps even more relevant to the Third World where a few staples may form an even larger portion of the diet. Therefore:

29) **The Standing Committee recommends that special emphasis be placed on investigating the effect of irradiation on the nutritional value of foods which constitute a large portion of a diet.**

AECL is a leading manufacturer and supplier of irradiation equipment to the Third World. The Canadian International Development Agency (CIDA)* may also be providing financial assistance to some developing countries wishing to purchase food irradiators. A recent example of this is a CIDA aid package which will enable Thailand to purchase an AECL-designed facility. The Standing Committee understands that financial aid to other countries is under consideration. Testimony indicated that agencies such as CIDA are not obliged to make their intention to finance projects such as food irradiation facilities public in the Third World; nor are they required to publicize details of plans, environmental assessments or other studies dealing with worker health and safety. There appears to be no forum for public comment on proposals for these types of projects. The Standing Committee feels that public participation in matters which can affect a country's food supply is essential and efforts should be made to encourage such participation.

## (v) Commercial Aspects of Food Irradiation

Changing the regulatory framework to facilitate food irradiation will not ensure its commercial viability. Food industry representatives appearing before the Standing Committee felt that regulatory change would increase the likelihood of imported irradiated foods being available for consumption in Canada. Domestic production, on the other hand, would not occur until sufficient consumer demand has been established.

The commercial viability of food irradiation is dependent on several factors. Among these are the capital and operating costs of irradiation facilities, the market potential for irradiated products, (partially governed by consumer acceptance), and the existence of lower cost alternatives which provide similar benefits. At present, food irradiation on a commercial scale is taking place in some 11 countries. At least 32 countries have approved collectively over 40 food items or groups of related foods for consumption either on a conditional or unconditional basis. The fact that there are some commercial applications of food irradiation indicates that there may be some profitable uses for the technology.

Food irradiation technology requires a substantial capital outlay. The capital cost (excluding land) of a small irradiator is approximately $1 million while a large, automatic irradiator may cost as much as $4 million. Operating costs can also be significant — one study estimated that they might range from $600,000 to $1.2 million for the first year of operation depending upon the size of the irradiator. These high capital and operating costs are likely to preclude many companies from setting up irradiation facilities. In Canada, the establishment of a few strategically located contract irradiators may be the most plausible scenario.

The food industry sees some commercial potential for food irradiation in Canada. Possible applications include irradiating imported tropical fruit to extend shelf life, strawberries to delay mold growth, spices for deinfestation purposes, and poultry to eliminate *Salmonella* bacteria. Irradiation treatment may also prove to be a useful substitute for chemical fumigants. Consumer acceptance of irradiated foods, however, will be critical to the commercial viability of food irradiation. Factors such as perceptions about the safety, wholesomeness and nutritional value of irradiated foods and the cost of these products are likely to determine the degree of consumer acceptance.

Although the cost of irradiating foods in relation to the benefits to be derived from irradiation will be an important factor in the level of acceptance of irradiation by industry and consumers, there appears to be few studies which examine these factors. One study by Ron Krystynak, referred to elsewhere in the report, examined irradiation as a potential method for eliminating *Salmonella* contamination in poultry. Irradiating packaged poultry in Canada at a 3-8 kGy dose would eliminate *Salmonella* from this product at an estimated annual cost of $13.8 million. The Krystynak study, however, suggests that there are more cost effective methods than irradiation for dealing with *Salmonella*. These types of analyses conducted on a product-by-product basis would provide considerable data on the cost-effectiveness of irradiation.

Questions have been raised about the need for irradiating food when other less controversial methods of food preservation are readily available or are currently being developed (for example controlled atmospheric packaging). Given the variety of food products currently available in Canada, the widespread use of other processing techniques, and our highly refined food transportation and distribution networks, irradiating food may not be necessary. This is not to say that there are not other applications of irradiation technology. At present large quantities of disposable medical supplies are sterilized by exposure to radiation. Other potential applications include the sterilization of cosmetics and the treatment of waste-water sludge. However, until the concerns expressed and questions asked in this report regarding the safety of irradiated foods are answered, the widespread application of the technology to food does not seem appropriate. As the irradiation of food is not yet commercially established in Canada, a decision not to broaden its application should not present substantial hardship to any existing sector of the economy.

# CHAPTER 4

# Comments and Recommendations Regarding Health and Welfare Canada Information Letter No. 651 — Control of Food Irradiation

The Standing Committee recognizes that the proposed revisions to the regulations for the control of food irradiation as outlined in Information Letter no. 651 (see Appendix III) are not binding. Above all, we wish to emphasize that, because of the need for more substantial evidence relating to the wholesomeness of irradiated foods, Recommendation 1 takes precedence over the ensuing discussion and recommendations. However, in the event that revisions are made to the regulations to facilitate the use of food irradiation, the Standing Committee has the following suggestions and recommendations.

30) **The Standing Committee recommends that in the event that the regulations controlling food irradiation are amended, irradiation should continue to be classified as a food additive and be governed by all the controls and requirements for testing food additives. As well, because of the many unique qualities that may be imparted by irradiation, toxicological testing should be required for each food at the dosage at which it is proposed to be treated if above the 1 kGy level as outlined in Recommendation 9.**

It is possible that food irradiation may be classified as a process not as a food additive. Earlier in this report, we expressed our concern that classifying food irradiation as a process may weaken the controls and toxicological testing requirements presently required. Therefore:

31) **The Standing Committee recommends that if food irradiation is classified as a process rather than as a food additive, regulations be drafted that would require controls and toxicological testing as stringent as would be required for food additives.**

Section B. 27.005 of the proposed regulations requires manufacturers who sell irradiated foods and importers of irradiated foods to keep on their respective premises for at least two years certain records respecting the irradiation of foods. It would appear that there are three lines of reasoning for requiring that specific records be retained by manufacturers and importers: (a) for inspection of a facility's records, (b) to facilitate recall of a product from the shelves in the event of problems and (c) to

assist in epidemiological types of studies. If this is to assist in epidemiological studies, as was suggested as a reasonable concept by various witnesses, then the retention of records for a two year period would be totally inadequate. A period of 15 to 20 years would be needed for the gathering of information to determine if there was a subgroup of the population with a high consumption rate of irradiated foods (or a particular food type) and if they were experiencing adverse health effects from long-term consumption. It would seem appropriate for the Department of National Health and Welfare to acquire such records after the expiration of this two year period to ensure that they are retained for a sufficient period of time to conduct such epidemiological studies. Accordingly:

32) **The Standing Committee recommends that immediately upon the expiration of the two year period during which manufacturers and importers are required to retain records in accordance with Section B. 27.005 of the proposed food irradiation regulations, such manufacturers and importers be required to present those records to the Health Protection Branch for retention by the Branch for a further period of twenty years.**

There are also certain terms, wording and requirements in the proposed regulations which the Standing Committee feels could be clarified or expanded upon. For example, some of the problems inherent in measuring the dosage a food receives have been briefly discussed. The following two paragraphs from the ACINF report present reasons for the further specification of dosimetry* that the Committee recommends be incorporated into new regulations:

> Distribution of Dose Throughout Irradiated Foods
>
> 11. Radiation plants are designed to give as uniform a dose as practicable throughout a food item. However, the fundamental properties of radiation and the detailed geometry of the radiation source make some non-uniformity of dose unavoidable, and this is exacerbated by the fact that food items may be of irregular shape, and may vary in density and composition. Thus a package of food exposed to a radiation source receives a range of doses for which a minimum, a maximum and an average dose can be determined. The average dose may not always be the arithmetic mean of the maximum and minimum doses. This illustrates the need in most cases for the average dose to be measured during a calibration run, using dosimeters randomly distributed throughout the food and not merely on the surface and at the centre. The arithmetic mean of all such dosimeter readings is designated the "overall average dose".
>
> 12. The degree of non-uniformity of dose within an irradiated sample may be expressed as the ratio between the maximum and minimum doses occurring in that sample. The value of this ratio will depend upon the characteristics of the irradiation plant and the material being irradiated, but its value will usually not be more than 2.0, while a ratio of 1.5 is a more typical figure. This means that, for a sample receiving an overall average dose of 10 kGy, the dose received by different parts of the sample would usually vary between 8 and 12 kGy, though in some circumstances the dose might vary between 6.5 and 13 kGy.

Elsewhere in this report we discussed why specific processing conditions (level of oxygen content, temperature, and others) may be necessary when irradiating certain foods to reduce nutrient degradation and prevent deterioration of a food's organoleptic quality. The proposed regulations require that the recommended conditions for storage and shipment after irradiation be specified. They do not, however, require specification of conditions during irradiation. It would seem appropriate that an applicant seeking approval to irradiate a food be required to specify the conditions during irradiation

since these conditions may have an effect on the dose of radiation employed, among other things.

To strengthen the proposed regulations for the control of food irradiation the Standing Committee recommends as follows:

33) **The Standing Committee recommends, that if the regulations respecting food irradiation are changed, the following amendments be made to the proposed regulations:**

1) **In subsection B.27.004.(c) more specific locations for the placement of dosimeters in each lot of food should be required and some minimum standards declared.**

2) **In subsection B.27.004(f) recommended processing conditions during irradiation should be specified.**

# RECOMMENDATIONS

1) **The Standing Committee recommends that the irradiation of food by any form of ionizing energy continue to be regulated as a food additive, and be restricted to those foods and doses presently approved by the existing regulations until an in-depth scientific assessment of health implications and further toxicological studies indicate that no significant adverse health effects would be expected to be found by the ingestion of irradiated foods. Notwithstanding the foregoing, it is recommended that the irradiation of wheat no longer be permitted until the specific safety questions addressed in other recommendations in this report are resolved.**

2) **The Standing Committee recommends that the Minister of National Health and Welfare in consultation with other interested federal government departments and agencies, and representatives of consumer groups strike a consultative panel to be composed of theoretical and analytical physicists, chemists, nutritionists, toxicologists and consumer group representatives to conduct an in-depth, integrated analysis to provide further insight into potential biochemical and physiological problems that might arise from irradiating various foods at varying doses. The information obtained from this analysis should be used to provide the basis for developing protocols for tests to determine, more fully, the wholesomeness of irradiated foods.**

3) **The Standing Committee recommends that baseline studies as suggested by the consultative panel, be conducted with funding from the Federal Government. Emphasis should be placed on conducting tests on wheat and chicken as recommended elsewhere in this report. Funding for the toxicological tests required to support an application to irradiate specific foods is to be the responsibility of the applicant.**

4) **The Standing Committee recommends that the consultative panel act as an advisory body to the Minister of National Health and Welfare regarding applications for approval to irradiate foods.**

5) **The Standing Committee recommends that further feeding studies (not on humans) be conducted to determine if the effects from eating irradiated wheat as indicated by earlier studies do in fact occur.**

6) **The Standing Committee recommends that if increased polyploidy or other toxic responses are further shown to result from ingesting irradiated wheat, then similar studies should be conducted on other grains which might be candidates for irradiation. If there is an adverse effect and it is dependent on the period of time between irradiating and ingestion, then this relationship should be established.**

7) **The Standing Committee recommends that the consultative panel (see Recommendation 2) select researchers and/or research institutes to conduct studies to determine the life of free radicals in various foods that may be irradiated (e.g. dried and hardened spices, wheat and other grains).**

8) **The Standing Committee recommends an investigation be conducted into the products that may be produced by irradiating pesticide residues. Such an examination should include irradiating the more widely applied classes of pesticides in isolated conditions and on fruits and vegetables.**

9) **If the control of food irradiation is to proceed on the basis of establishing a maximum overall average absorbed dose below which no toxicological testing is required, the Standing Committee recommends that the maximum overall absorbed average dose should be restricted to 1 kGy except for specifically approved situations. This level would reduce the health threat of pathogenic and toxin producing bacteria such as *C. botulinum*.**

10) **The Standing Committee recommends that methods more cost-effective than irradiation be pursued to contend with the *Salmonella* problem in Canada. This should include the establishment of a comprehensive public education program to promote proper and safe handling techniques for poultry. This program should be jointly formulated and funded by the Government and the poultry industry. As well, further studies on the wholesomeness of irradiated chicken should be conducted as indicated in Recommendation 3.**

11) **The Standing Committee recommends that the Department of Agriculture, in concert with academic microbiologists, and the consultative panel (Recommendation 2) investigate the production of aflatoxins after irradiation. Experiments should attempt to ascertain which fungal species (if any) increase production after irradiation and if mutant strains are produced as is suggested in the scientific literature. In the first instance, studies should be conducted using methods similar to the original aflatoxin studies and then further studies should be conducted under natural conditions where competitor organisms would be present.**

12) **The Standing Committee recommends that investigations be conducted on the effect of irradiation on the nutritional degradation of the foods for which irradiation is presently permitted. Investigations into the nutritional degradation of other foods should also be conducted before they are approved for irradiation.**

13) **The Standing Committee recommends that in addition to other toxicological tests that need be conducted, emphasis should be placed on tests to examine the long-term chronic effects (if any) of ingesting irradiated foods.**

14) **The Standing Committee recommends that all irradiated foods, both domestically produced and imported, be fully labelled as outlined in recommendations 15, 17, 18, 19, 20 and 21 regardless of whether food irradiation continues to be classified as a food additive as recommended by this Standing Committee, or as a food process.**

15) **The Standing Committee recommends that all prepackaged irradiated foods shall bear the following symbol,**

**along with the word "irradiated".**

16) **The Standing Committee recommends that efforts be made to establish a uniform method of labelling irradiated foods on an international level.**

17) **The Standing Committee recommends that the symbol and the wording be positioned on the principal display panel of all prepackaged irradiated foods**

in a minimum size of 4.8 millimeters (3/16 inch), but otherwise in accordance with the size prescribed by the Consumer Packaging and Labelling Regulations (section 14).

18) The Standing Committee recommends that the symbol and the wording be the same colour as that of the other ingredient labelling which appears on a prepackaged product that contains irradiated food.

19) The Standing Committee recommends that all irradiated ingredients be labelled in a clear and readily visible manner as set out in Appendix VI of this report. This recommended form of labelling is to be positioned on the principal display panel of all prepackaged products as set out in recommendation 17. The colour shall be as prescribed in recommendation 18.

20) The Standing Committee recommends that irradiated foods sold from bulk containers at the retail level display the recommended symbol and wording on a poster, card, counter sign or other method of display on or immediately adjacent to the food in a conspicuous and prominent manner. The symbol and wording, shall be at least two-thirds the size of the print or other symbol displaying the product name on the poster, card, counter sign or other method of display and shall be no smaller than 17.5 mm (11/16 of an inch). All bulk irradiated foods must be labelled accordingly regardless of whether the product name is displayed. The symbol and wording shall be displayed in a colour which contrasts with the background colour of the poster, card, counter sign or other method of display.

21) The Standing Committee recommends that the reirradiation of foods not be permitted. The Standing Committee further recommends that the label and invoices or bills of lading of all irradiated foods bear the symbol prescribed in Recommendation 15 and the statement "Irradiated - do not irradiate again".

22) The Standing Committee recommends that emphasis be placed on providing clear unbiased information on food irradiation to the public. Information pamphlets on food irradiation should be made available to consumers by the Department of Consumer and Corporate Affairs through its regional offices.

If irradiated foods become available for consumption in Canada, the Department of Consumer and Corporate Affairs should be responsible for co-ordinating the development of a public information program about food irradiation. Financing for the program should be jointly shared by the Department and producers, manufacturers, and processors involved with food irradiation.

23) The Standing Committee recommends that if food irradiation is to proceed on a wider scale, theoretical and analytical studies should be performed to determine whether X-rays capable of inducing radioactivity are produced when food is irradiated in packaging materials lined in foil. If so, proper precautions should be taken to ensure that foods with induced radioactivity are not presented for consumption.

24) The Standing Committee recommends that the sensitive crystallization test for identifying irradiated fruits and vegetables be further investigated.

25) **The Standing Committee recommends that research be conducted by Agriculture Canada to develop tests which will identify irradiated foods and the radiation dose used.**

26) **The Standing Committee recommends that emphasis be placed on encouraging countries to adopt uniform standards respecting dosimeters and their placement in each lot of food.**

27) **The Standing Committee recommends that once uniform international standards for irradiated foods have been implemented, an international inspection system be developed to ensure that irradiated foods comply with such standards.**

28) **The Standing Committee recommends that AECL take all necessary steps to emphasize the regeneration of spent Cobalt-60 to reduce levels of radioactive waste materials.**

29) **The Standing Committee recommends that special emphasis be placed on investigating the effect of irradiation on the nutritional value of foods which constitute a large portion of a diet.**

30) **The Standing Committee recommends that in the event that the regulations controlling food irradiation are amended, irradiation should continue to be classified as a food additive and be governed by all the controls and requirements for testing food additives. As well, because of the many unique qualities that may be imparted by irradiation, toxicological testing should be required for each food at the dosage at which it is proposed to be treated if above the 1 kGy level as outlined in Recommendation 9.**

31) **The Standing Committee recommends that if food irradiation is classified as a process rather than as a food additive, regulations be drafted that would require controls and toxicological testing as stringent as would be required for food additives.**

32) **The Standing Committee recommends that immediately upon the expiration of the two year period during which manufacturers and importers are required to retain records in accordance with Section B. 27.005 of the proposed food irradiation regulations, such manufacturers and importers be required to present those records to the Health Protection Branch for retention by the Branch for a further period of twenty years.**

33) **The Standing Committee recommends, that if the regulations respecting food irradiation are changed, the following amendments be made to the proposed regulations:**

    1) **In subsection B.27.004.(c) more specific locations for the placement of dosimeters in each lot of food should be required and some minimum standards declared.**

    2) **In subsection B.27.004(f) recommended processing conditions during irradiation should be specified.**

# APPENDIX I

## Glossary of Terms

**ACINF** — Advisory Committee on Irradiated and Novel Foods. This committee was established in 1982 to advise the Health and Agriculture Ministers of Great Britain and the Head of the Department of Health and Social Services for Northern Ireland on irradiated foods.

**AECB** — Atomic Energy Control Board.

**AECL** — Atomic Energy of Canada Limited.

**Aflatoxin** — Any of several carcinogenic toxins produced by molds (e.g. *Asperillus flavus*) especially in stored agricultural crops.

**Carcinogen** — A substance or agent capable of producing or inciting cancer.

**CIDA** — Canadian International Development Agency.

**Codex Alimentarius Commission** — A joint FAO/WHO body established in 1962 to protect consumers, facilitate international trade and assist developing countries. Its principal concern is the establishment of international food standards and codes of practice with the object of having them accepted worldwide.

**DNA** — Deoxyribose nucleic acid: molecules in the nucleus of cells which contain the genetic programme.

**Dose** — A dose of radiation is the amount of ionizing energy absorbed by a material.

**Dosimeter** — An instrument used for measuring dose.

**Dosimetry** — The process of measuring dose.

**Electron** — A negatively charged particle found in all atoms.

**FAO** — United Nations Food and Agriculture Organization.

**Food** — Food is defined by the section 2 of the *Food and Drugs Act* to include ... any article manufactured, sold or represented for use as food or drink for man, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.

**Free radical** — Unstable and highly reactive molecular entities with an unpaired electron in the outer orbit of an atom that are believed to behave as co-carcinogens. They can be formed by the cleavage of a molecule upon reaction with another reactive chemical entity or by the direct absorption of high energy (for example from a gamma ray).

**Gamma ray** — A unit of electromagnetic radiation having a short wave-length and high energy that is produced by the disintegration of certain radioactive isotopes.

**IAEA** — International Atomic Energy Agency.

**Kilogray** — 1000 Grays; which are units of dose measurement. The gray (Gy) is defined as the dose equivalent to the absorption of 1 joule of energy per kilogram of matter through which the radiation passes. Food irradiation doses are commonly measured in kilograys (kGy).

**Organoleptic** — Relating to the taste, aroma and texture of a food.

**Polyploidy** — A condition where cells contain more than two full sets of homologous chromosomes (genetic material).

**Radiolytic product** — Chemical products produced by the decomposition of molecules as a result of exposure to ionizing energy.

**URP** — Unique Radiolytic Product.

**USFDA** — United States Food and Drug Administration.

**WHO** — World Health Organization.

**X-rays** — Short wave-length electromagnetic radiation usually produced by striking a metal target with high speed electrons.

# APPENDIX II

## Potential Applications of Food Irradiation*

| Type of Food | Radiation Dose in kGy | Effect of Treatment |
|---|---|---|
| Meat, poultry, fish, shellfish, some vegetables, baked goods, prepared foods | 20-70 | Sterilization. Treated product can be stored at room temperature without spoilage. Treated product is safe for hospital patients who require micro-biologically sterile diets. |
| Spices and other seasonings | 8-30 | Reduces number of microorganisms and insects. Replaces chemicals used for this purpose. |
| Meat, poultry, fish | 1-10 | Delays spoilage by reducing the number of microorganisms in the fresh, refrigerated product. Kills some types of food poison bacteria. |
| Strawberries and some other fruits | 1-4 | Extends shelf life by delaying mold growth. |
| Grain, fruit, vegetables, and other foods subject to insect infestation | 0.1-1 | Kills insects or prevents them from reproducing. Could partially replace fumigants used for this purpose. |
| Bananas, avocados, mangos, papayas, guavas, and certain other non-citrus fruits | 0.25-0.35 | Delays ripening. |

* American Council on Science and Health, *Irradiated Foods*, 2nd ed., July 1985, p. 6-7.

| | | |
|---|---|---|
| Potatoes, onions, garlic | 0.05-0.15 | Inhibits sprouting. |
| Pork | 0.08-0.15 | Inactivates trichinae. |
| Grain, dehydrated vegetables, other foods | Various doses | Desirable physical and chemical changes. |

# APPENDIX III

## Health and Welfare Canada
## Information Letter No. 651

# Information Letter / Lettre de renseignements

Health Protection Branch / Direction générale de la protection de la santé


July 28, 1983 I.L. No. 651

TO: All Interested Parties

SUBJECT: Proposed Revised Regulations for the Control of Food Irradiation

In Canada, irradiation of food is presently regulated under the Food Additive Tables of Division 16, Food and Drug Regulations. Provision exists under Table VIII for the use of "gamma radiation from a Cobalt-60 source" in (1) potatoes and onions as an antisprouting agent, the level of use not to exceed 15 000 rads (i.e., 0.15 kGy), and in (2) wheat, flour and whole wheat flour for deinfestation purposes, the level of use not to exceed 75 000 rads (i.e., 0.75 kGy).

Currently, there is renewed international interest in this process as outlined in the recommendations of the 1981 Report of the Joint FAO/IAEA/WHO* Expert Committee(1). In addition, as a member of the Codex Alimentarius Commission, Canada has an obligation to consider, with a view to adoption, international recommendations dealing with irradiation of food(2). Therefore, the existing regulatory mechanism for controlling food irradiation was re-examined with a view towards assessing its adequacy in terms of consumer protection and harmonization with international standards. As a result, it is proposed that food irradiation no longer be controlled under the food additive provisions in Division 16 of the Food and Drug Regulations. Rather, it is proposed to control irradiation as a food process in new regulations. This change would also facilitate submissions respecting new uses of irradiation

* Food and Agricultural Organization/International Atomic Energy Agency/World Health Organization

Le 28 juillet 1983 L.R. N° 651

À: Tous les intéressés

OBJET: Projet de révision des règlements concernant le contrôle de l'irradiation des aliments

Au Canada, l'irradiation des aliments est actuellement réglementée en vertu des tableaux sur les additifs alimentaires du Titre 16 du Règlement sur les aliments et drogues. On trouve, au Tableau VIII dudit Titre, des dispositions régissant l'utilisation de "radiations gamma d'une source de cobalt-60" dans (1) les pommes de terre et les oignons, pour empêcher de germer, en quantité n'excédant pas 15 000 rads (c'est-à-dire 0,15 kGy), et (2) dans le blé, la farine et la farine de blé entier, contre l'infestation, en quantité n'excédant pas 75 000 rads (c'est-à-dire 0,75 kGy).

Comme il est mentionné dans les recommandations du Rapport du Comité mixte AIEA/FAO/OMS* d'experts(1), paru en 1981, on constate actuellement, à l'échelle internationale, un renouvellement d'intérêt en regard de ce procédé. En outre, à titre de membre de la Commission du Codex Alimentarius, le Canada se doit de considérer, en vue d'une adoption éventuelle, les recommandations formulées à l'échelle internationale concernant l'irradiation des aliments(2). On a donc examiné de nouveau les mécanismes actuels de réglementation de l'irradiation des aliments afin d'évaluer leur suffisance, d'une part en ce qui a trait à la protection des consommateurs et, d'autre part, à leurs possibilités d'harmonisation avec des normes internationales. Par conséquent, il est proposé que l'irradiation des aliments ne soit désormais plus régie par les dispositions sur les additifs alimentaires apparaissant au Titre 16 du Règlement sur les

* Food and Agricultural Organization/Agence internationale de l'Energie atomique/Organisation mondiale de la Santé

for the purposes of increasing the quality, safety and shelf-life of foods.

The Health Protection Branch intends to recommend to the Minister that a new Division entitled Food Irradiation be established under Part B of the Food and Drug Regulations. This new Division, tentatively designated as Division 27, will contain revised regulatory requirements appropriate to the use of radiation in the treatment of foods. The proposed new Regulations appear as an Annex to this letter.

Of particular note is the fact that the Joint FAO/IAEA/WHO Expert Committee stated that toxicological testing of foods irradiated below 10 kGy is no longer required. All studies carried out to date on a large number of individual foods have produced no evidence of adverse effects as a result of irradiation below this dosage level. Based on these considerations, the Health Protection Branch proposes that the requirement for tests to establish safety of irradiated foods will thus be necessary only when the overall average absorbed dose exceeds the 10 kGy value. It should also be emphasized that no radioactivity whatsoever is imparted to a food product that is irradiated with the sources of ionizing radiation mentioned in the draft regulations.

Comments on the above and on the proposed regulations should be sent within 90 days of the date of this letter to:

Chief, Food Regulatory Affairs Division,
Food Directorate,
Health Protection Branch,
Department of National Health and Welfare,
Ottawa, Ontario.
K1A 0L2

aliments et drogues. On se propose plutôt d'élaborer de nouveaux règlements visant à contrôler l'irradiation des aliments en tant que mode de traitement distinct. Cette modification aurait également l'avantage de faciliter le dépôt de présentations pour de nouvelles utilisations de l'irradiation visant à améliorer la qualité, la salubrité et la durée de conservation des aliments.

La Direction générale de la protection de la santé compte recommander au Ministre l'incorporation d'un nouveau titre, intitulé "Irradiation des aliments" à la partie B du Règlement sur les aliments et drogues. Ce nouveau titre, provisoirement désigné sous le nom de Titre 27, précisera les exigences réglementaires révisées s'appliquant à l'usage des rayonnements dans le traitement des aliments. On trouvera le texte du nouveau règlement projeté annexé à la présente Lettre.

Il est particulièrement important de noter que le Comité mixte AIEA/FAO/OMS d'experts a déclaré qu'il n'est désormais plus nécessaire de soumettre à des épreuves toxicologiques les aliments irradiés à l'aide d'une dose inférieure à 10 kGy. Toutes les études effectuées jusqu'à ce jour sur un grand nombre d'aliments n'ont en effet pu démontrer d'effet indésirable résultant de l'irradiation à des niveaux inférieurs à cette dose. Considérant ce qui précède, la Direction générale de la protection de la santé propose de ne soumettre à des épreuves destinées à établir leur innocuité que les seuls aliments irradiés à l'aide d'une dose globale moyenne absorbée supérieure à 10 kGy. Il convient également de préciser qu'aucune forme de radioactivité n'est transmise à une denrée alimentaire irradiée à l'aide des sources de rayonnements ionisants mentionnés dans le projet de règlement.

Faire parvenir tout commentaire sur le règlement projeté dans les 90 jours suivant la date de parution de la présente Lettre au:

Chef de la politique de réglementation
Direction des aliments
Direction générale de la protection de la santé
Ministère de la Santé nationale et du
Bien-être social
Ottawa (Ontario)
K1A 0L2

Le Sous-ministre adjoint,

for A.B. Morrison, Ph.D.,
Assistant Deputy Minister

## REFERENCES


(1) WHO. Geneva, 1981. "Wholesomeness of Irradiated Food". Report of a Joint FAO/IAEA/WHO Expert Committee. WHO Technical Report Series No. 659.

(2) FAO/WHO. Rome 1981. "Revised Draft Recommended International General Standard for Irradiated Foods and Revised Draft Recommended International Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods". Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission. Document No. CX/FA 82/14.


## BIBLIOGRAPHIE


(1) Salubrité des aliments irradiés, Rapport d'un Comité mixte AIEA/FAO/OMS d'experts, Série de Rapports techniques de l'OMS, n° 659, OMS, Genève, 1981.

(2) Projet révisé - Norme générale internationale recommandée pour les aliments irradiés et Projet révisé - Code d'usage international recommandé pour l'exploitation des installations de traitement des aliments par irradiation. Programme mixte de la FAO et de l'OMS sur les normes alimentaires, Commission du Codex Alimentarius, document n° CX/FA 82/14, Rome, 1981.

ANNEX

PROPOSED FORMAT OF NEW DIVISION TO CONTROL FOOD IRRADIATION
DIVISION 27

Food Irradiation

B.27.001. In this Division, the term "ionizing radiation" shall refer to radiation from the following sources:

a) gamma-radiation from a Cobalt-60 or Cesium-137 source;

b) X-rays generated from machine sources operated at or below an energy level of 5 MeV; and

c) electrons generated from machine sources operated at or below an energy level of 10 MeV.

B.27.002. No person shall sell a food which has been subjected to any treatment with ionizing radiation, except as prescribed by these regulations.

B.27.003. These regulations do not apply to foods exposed to radiation doses imparted by measuring instruments used for purposes of weight determination, bulk solids estimation, measurement of total solids in liquids and other such inspection procedures.

B.27.004. A request that a food be added to or a change made in the Table to this Division shall be accompanied by a submission to the Director in a form, manner, and content satisfactory to him and shall include:

ANNEXE

FORMULATION PROPOSÉE DU NOUVEAU TITRE SUR LE CONTRÔLE DE L'IRRADIATION DES ALIMENTS
TITRE 27

Irradiation des aliments

B.27.001. Dans le présent Titre, le terme "rayonnement ionisant" désigne des rayonnements provenant des sources suivantes:

a) rayons gamma provenant d'une source de cobalt-60 ou de césium-137

b) rayons X provenant d'appareils radiogènes fonctionnant à un niveau d'énergie égal ou inférieur à 5 MeV; et

c) électrons provenant d'appareils radiogènes fonctionnant à un niveau d'énergie égal ou inférieur à 10 MeV.

B.27.002. Il est interdit de vendre un aliment qui a été soumis à tout traitement aux rayonnements ionisants, sauf dans les cas prévus au présent règlement.

B.27.003. Le présent règlement ne s'applique pas aux aliments exposés à des doses de rayonnements transmis par des instruments de mesure utilisés dans le but d'en déterminer le poids, d'en estimer le volume des solides, de mesurer la proportion totale de solides dans un liquide ainsi que pour d'autres fins d'inspection similaires.

B.27.004. Toute demande visant à faire ajouter un aliment au tableau du présent Titre, ou à faire modifier ce dernier devra être accompagnée d'une présentation au Directeur, selon une forme, une manière et un contenu jugés satisfaisants par ce dernier, et comprendra:

a) information on the isotopes to be used, the dosages to be used, the frequency of dosage, and the purpose for which the radiation is proposed;

b) experimental data indicating that the radiation dose proposed accomplishes the intended technical effect and does not exceed the amount reasonably required to accomplish this technical effect;

c) information on the nature of the dosimeter, frequency of the dosimetry on the product, and data pertaining to the dosimetry and phantoms used with a view to assuring that the dosimetry readings adequately reflect the dose absorbed by the food during exposure;

d) data which would indicate the effects, if any, on the nutritional quality of the food under the irradiation conditions proposed;

e) data establishing that the irradiated food has not been significantly altered in chemical or physical characteristics to render the material unfit for human consumption;

f) the recommended conditions of storage and/or shipment (time, temperature, packaging, etc.) of the food subjected to the irradiation process when compared with a similar food not irradiated;

g) in the case of an individual food item proposed to be irradiated above a 10 kGy overall average absorbed dose, detailed reports of tests made to establish the safety of the food under the conditions of such treatment; and

a) des renseignements sur les isotopes qui seront utilisés, les dosages qui seront employés, la fréquence des dosages et les fins auxquelles on destine l'utilisation des rayonnements;

b) des données expérimentales indiquant que la dose de rayonnements projetée produira l'effet technique escompté et n'excédera pas le niveau normalement requis pour produire cet effet technique;

c) des renseignements quant à la nature du dosimètre, à la fréquence des mesures dosimétriques, ainsi que des données relatives à la dosimétrie et aux fantômes utilisés dans le but de s'assurer que les lectures dosimétriques reflètent avec précision la dose absorbée par l'aliment durant l'exposition;

d) des données portant, s'il y a lieu, sur la qualité nutritionnelle de l'aliment soumis aux conditions d'irradiation projetées;

e) des données établissant que les caractéristiques chimiques ou physiques de l'aliment irradié n'ont pas été modifiées de façon à le rendre impropre à la consommation humaine;

f) une description des conditions recommandées pour la conservation et l'expédition (temps, température, conditionnement, etc.) de l'aliment soumis au traitement d'irradiation, par comparaison à un aliment semblable qui n'a pas été irradié;

g) dans le cas d'un aliment particulier qui doit être irradié à l'aide d'une dose globale moyenne absorbée supérieure à 10 kGy, des rapports détaillés des épreuves effectuées pour établir l'innocuité de l'aliment visé dans de telles conditions de traitement; et

h) such other data as the Director may require.

B.27.005. (1) A manufacturer who sells a food treated with ionizing radiation shall keep on the premises for at least two years from the time of irradiation a record of:

a) the food treated;

b) the purpose of the treatment;

c) the date of the treatment, quantity treated, and lot numbers of the treated food;

d) the dose absorbed by the food;

e) the type of ionizing radiation source; and

f) an indication whether or not the product has been irradiated previously and if so, details of such treatment.

(2) Any person who imports a food to be offered for sale in Canada which has been treated by ionizing radiation shall keep on his premises a record of the information required under Subsection (1), for at least two years from the date of import.

B.27.006. Subject to the conditions prescribed in Columns I, II, and IV, the foods named in Column I of the following Table may be irradiated:

h) toute autre donnée dont le Directeur pourrait faire la demande.

B.27.005. (1) Tout fabricant qui vend un aliment traité à l'aide de rayonnements ionisants doit conserver, pour une période d'au moins deux ans à partir de la date d'irradiation, un registre contenant les renseignements suivants:

a) l'aliment traité;

b) le but visé par le traitement;

c) la date du traitement, la quantité de l'aliment traitée et les numéros de lots des aliments traités;

d) la dose absorbée par l'aliment;

e) la nature de la source de rayonnements ionisants; et

f) une indication permettant de savoir si le produit a déjà été irradié précédemment et, dans l'affirmative, tous les détails du traitement.

(2) Toute personne qui importe, aux fins de mise en vente au Canada, un aliment qui a été traité à l'aide de rayonnements ionisants doit conserver un registre de tous les renseignements requis, pour une période d'au moins deux ans à partir de la date d'entrée, en vertu du paragraphe (1).

B.27.006. Sous réserve des conditions prescrites aux Colonnes II, III et IV, les aliments dont le nom apparaît dans la Colonne I du tableau suivant peuvent être irradiés:

TABLE / TABLEAU

| Item No./<br>Poste N° | Column I/<br>Colonne I | Column II/<br>Colonne II | Column III/<br>Colonne III | Column IV/<br>Colonne IV |
|---|---|---|---|---|
| | Food/<br>Aliment | Permitted Sources of Radiation/<br>Sources permises de rayonnements | Purpose of Irradiation/<br>But de l'irradiation | Maximum Overall Average Absorbed Dose/<br>Dose moyenne maximale absorbée |
| 1. | Potatoes (Solanum tuberosum L.)/<br>Pommes de terre (Solanum tuberosum L.) | Cobalt-60 | To inhibit sprouting during storage/<br>Inhibition de la germination durant la conservation | 0.15 kGy/<br>0,15 kGy |
| 2. | Onions (Allium cepa)/<br>Oignons (Allium cepa) | Cobalt-60 | To inhibit sprouting during storage/<br>Inhibition de la germination durant la conservation | 0.15 kGy/<br>0,15 kGy |
| 3. | Wheat, Flour, Whole Wheat Flour (Triticum sp.)/<br>Blé, farine, farine de blé entier (Triticum sp.) | Cobalt-60 | To control insect infestation in stored product/<br>Prévention de l'infestation par des insectes dans le produit entreposé | 0.75 kGy/<br>0,75 kGy |

# APPENDIX IV

## Consumer and Corporate Affairs Canada
## Communiqué 50

Consumer and Corporate Affairs Canada
Consommation et Corporations Canada
Consumer Affairs
Consommation

November 22, 1985

G7075-2-50

COMMUNIQUÉ NO. 50

To: Consumer associations, food manufacturers, importers, retailers, advertisers, embassies, provincial and other federal agencies

Re: Labelling of irradiated foods

In July 1983, the Bureau of Consumer Affairs issued Communiqué No. 39 to solicit comments and suggestions on the various labelling options that could be considered for irradiated foods and foods manufactured with irradiated ingredients.

Analysis of the 43 responses received to that communiqué indicated clearly that consumers and those expressing consumer interests have a firm desire for irradiated products and those made with irradiated ingredients to be identified by some distinctive means, while industry generally recommended that such products not be singled out and subjected to a special labelling requirement.

As a result of the diversity of responses received to the communiqué and in view of the Department's commitment to ensure that the consumers' freedom of choice be retained in the marketplace, subsequent deliberations were held with a select group of consumer and industry representatives to formulate a recommendation that would be satisfactory to both industry and consumers and form the basis for a labelling requirement to be incorporated in the Food and Drug Regulations.

In addition to analyzing the responses to Communiqué No. 39, the group reviewed the status of international proposals for standards under the Codex Alimentarius Commission and noted that both wholly treated foods and foods containing irradiated ingredients are to be identified on product labels; however, the form and manner of the identification are not specifically prescribed. A review of the current status of regulations in the U.S.A. revealed that a decision on labelling had not been reached, although it was anticipated that some form of labelling identification would likely be required. The importance of co-ordinating the Canadian and U.S.A. positions was stressed in view of the need to eliminate non-tariff trade barriers that could inhibit free trade considerations now under discussion.

Canada

CCA-2340 (12-84)

The following recommendations are now being proposed for general consideration:

1. The symbol shown below is to be used as the distinctive identification mark to be applied on all prepackaged irradiated foods.

GREEN

2. The term RADURA[1/] is to accompany the symbol when separate claims for the process are made on the label. In lieu of the term RADURA, the acronyms I.E.T. and T.R.I. have been suggested for the statements "ionizing energy treated" and "traité aux rayons ionisants". Please indicate your preference.

3. The symbol is to be positioned on the principal display panel of all prepackaged irradiated foods in letters of at least the same height as that prescribed by the Consumer Packaging and Labelling Regulations (section 14) for the numerical portion of the net quantity declaration.

4. Irradiated ingredients used in the manufacturing of another food will be identified when an ingredient which has been irradiated is the characterizing constituent of the food and has its common name incorporated in the name of the finished product (i.e. Chicken Stew made with Irradiated Chicken, or Potato Chips made with Irradiated Potatoes). The symbol will accompany the ingredient in the listing of ingredients and will be shown in a clear and readily visible manner.

5. Where such foods are sold from bulk containers at the retail level, all mandatory labelling declarations will appear on a poster immediately on or adjacent to the food.

6. The aformentioned labelling requirements would not preclude the showing of other pertinent information on irradiated products.

7. When irradiated foods or foods which have been made with irradiated ingredients are advertised on radio or television, identification of the treatment process will be required to substantiate any claims being made for the product.

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1/ RADURA is an acronym used in several countries to accompany the symbol identified in item 1. It is believed to be derived from the statement "Durability enhanced by radiation".

The information programme to familiarize consumers with the identification mark will be initiated by the industry sector with technical support to come from various government agencies.

The above labelling provisions would become effective coincident with the effective date of the amendment to the Food and Drug Regulations, by Health and Welfare Canada, which will make the food irradiation treatment a process rather than a food additive.

Comments regarding the above proposal should be directed to Mr. C. G. Sheppard, Chief, Manufactured Food Division, Consumer Products Branch, Consumer and Corporate Affairs Canada, Place du Portage, Phase 1, 16th Floor, Zone 2, 50 Victoria Street, Hull, Quebec, K1A 0C9, no later than January 31, 1986.

Please note that comments submitted in response to this communiqué will be subject to the provision of the Access to Information Act. If you feel that the comments you are providing constitute confidential information, please add a note to this effect. Should an official request for information on any responses be received, you will be provided with notification of any intention to disclose information and will have an opportunity to provide reasons which could justify refusing disclosure.

Ralph H. McKay
Director
Consumer Products Branch
Bureau of Consumer Affairs

K. Francoeur Hendriks
Kathleen Francoeur Hendriks
Assistant Deputy Minister
Bureau of Consumer Affairs

# APPENDIX V

# Executive Summary of Toxicologists' Report CANTOX INC.

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## EXECUTIVE SUMMARY

Several different types of studies of the potential adverse effects of irradiated foods were reviewed, including teratogenicity studies, chronic toxicity, reproductive performance and cancer studies, genotoxicity/mutagenicity studies and publications from the scientific literature. A brief summary of these reviews is presented, followed by the general conclusions and opinions of the reviewers.

### Teratogenicity Studies

Studies of the teratogenic potential of consuming diets containing up to 70% irradiated chicken meat were conducted in rabbits, rats, mice and hamsters. None of these studies demonstrated any evidence of teratogenic or developmental effects associated with irradiated chicken meat, however, these conclusions have to be considered in the light of the overall power of such tests as discussed below.

Positive control groups were conducted with each study, using thalidomide (rabbit study) or retinoic acid (mouse, rat and hamster study) as positive test compounds. Teratogenic effects were observed in the positive control groups. Based on the small numbers of animals used in the studies it would have been possible to detect teratogenic responses from agents between 3 and 100 times less potent than the positive control substances used. Therefore, the data indicate that it is unlikely that the irradiated chicken meat contained potent teratogens. On the other hand, the existence of weak teratogenic activity, or low levels of more potent teratogens would not likely have been detected by the studies conducted.

### Chronic Toxicity, Reproductive Performance and Cancer Studies

Studies of the above parameters using Sprague-Dawley rats, CD-1 mice and beagle dogs were reviewed.

Sprague-Dawley rats fed diets containing 35% irradiated chicken meat for 39 weeks did not show any adverse effects that correlated with their diet. The termination of the study at 39 weeks due to lactation failure in the basal diet control group,

however, precluded any assessment of potential longer-term toxic effects, reproductive effects or carcinogenicity that may be associated with feeding diets containing irradiated chicken meat.

The CD-1 mouse study was seriously flawed through the contamination of the diets with urine and feces from the test animals, lack of data on feed intake, and inadequate data on serum chemistry in the $F_0$ generation. The problem of contamination of the diets with urine and feces was most serious in the groups fed chicken meat diets because the higher moisture content of these diets promoted greater bacterial growth. These flaws in the study preclude an unequivocal conclusion that no adverse effects were associated with feeding irradiated chicken meat to mice.

No major problems were identified regarding the design or conduct of the beagle dog study. Mean body weights of dogs fed diets containing 35% gamma irradiated chicken meat were significantly lower than those from the group fed frozen chicken meat. This effect is likely a reflection of the higher incidence of excessive weight gain and obesity observed in the group fed the diets of frozen chicken meat. This effect was not considered biologically significant, since there was no significant difference in body weights among groups fed diets of electron irradiated, or gamma irradiated or thermally processed chicken meat. No other observed effects were correlated with feeding irradiated chicken meat. From this study it would appear that no adverse effects were associated with feeding irradiated chicken meat at 35% of the diet to dogs for three years.

## Genotoxicity/Mutagenicity Studies

The genotoxicity/mutagenicity studies reviewed included a dominant lethal study in mice, a heritable translocation study in mice, a lethal mutation study in fruit flies, and mutagenicity studies in bacteria.

A major technical problem with the dominant lethal study (i.e., the lack of response in the positive control group), limits the interpretation of the data obtained. The reason for the lack of response in the positive controls was not known. The incidence of pre-implantation embryo deaths in the negative control populations were within normal ranges. Within the constraints of an inadequate positive control group, the results of the study indicated that there were no dominant lethal effects of feeding irradiated chicken to mice.

The heritable translocation study conducted in CD-1 mice was seriously flawed by the loss of data from the poor quality of microscopic slide preparation. This deficit in the study precludes the drawing of any conclusions from the results reported.

No increase in lethal mutations was observed in the offspring of fruit flies reared on chicken meat. There was a significant decrease in the number of offspring in cultures containing irradiated chicken meat. The information available suggested that this effect may have been related to malnutrition of the fruit flies, however, the phenomena was not adequately explained and its biological significance cannot be conclusively assessed. In addition, the decreased survival of the fruit flies cultured on irradiated chicken meat may have biased the selection of specimens for mutagenicity assessment resulting in resistant offspring being studied.

There was no evidence of mutagenicity of any of the extracts from the meat samples in any test conducted on bacteria. However, these studies did not rule out the possibility that there may have been mutagens trapped in the chicken meat and fat

which would not have been extracted by simple water extraction. Additional extractions using acidic, basic and organic solvents would have increased the confidence in the data.

**Published Scientific Papers on Irradiated Foods**

Several scientific publications were reviewed that reported an increased incidence of numerical chromosomal aberrations (e.g., polyploidy) in rats, mice, monkeys and children consuming diets made from irradiated wheat. It appears that feeding irradiated diets for six weeks did not increase the incidence of polyploidy whereas exposure periods greater than six weeks were associated with an increase in the incidence of polyploidy.

It has been suggested that the increased incidence of polyploidy observed was an artifact due to the low (0%) incidence observed in the control populations. However, if the background incidence of polyploidy was about 0.2% in the positive studies rather than zero (0%), it would appear that a significant increase in polyploidy would still be observed in the animals exposed to freshly irradiated wheat for periods exceeding six weeks.

The biological significance of an increase in polyploidy is not fully understood. Polyploidy refers to a condition where cells contain more than two full sets of homologous chromosomes. A certain background incidence of polyploidy is common in tissues such as the liver, bone marrow, neural tissue and muscle, and in certain insects and plants. The incidence of polyploidy has been shown to increase with aging and exposure to ionizing radiation (e.g., X-rays). Agents that interfere with microtubule functions in certain cell types (e.g., metahalone) have been shown to induce polyploidy. No information was available on the possible mechanism of polyploid induction following feeding irradiated wheat.

Scientific publications were also reviewed on the potential effects of exposure to irradiated food on mutations in *Drosophila melanogaster*, rats and mice, and general systemic effects in rats. No effect was observed on the incidence of sex-linked recessive lethal mutations in *Drosophila melanogaster* exposed to irradiated onion powder, and irradiated ham and beef. However, it appears that the irradiated foods used in these studies were stored for periods exceeding 10 months. Therefore, these studies do not address the potential mutagenic effects of freshly irradiated foods in fruit flies.

Two scientific publications reported that the incidence of dominant lethal mutations was increased in rats and mice exposed to diets made from irradiated foods. In one study, no distinction was made between pre-implantation and post-implantation embryo deaths, consequently it is not possible to fully evaluate whether the effects reported were clearly dominant lethal mutations, or increased embryo deaths due to other factors (e.g., malnutrition, embryo toxicity).

The second study reported an increased incidence of dominant lethal effects, likely related to the increased incidence of chromosomal aberrations observed in the treated animals. However, the level of irradiation used in this study was 5000 krad, more than 60 times that used in other studies, consequently, a much greater opportunity was available for the production of undesirable products in the food. Therefore, the significance of these observations at lower levels of food irradiation is questionable.

Studies were available including that feeding irradiated fish to rats did not markedly affect growth or development over three generations, however, effects were

observed on various metabolic and reproductive parameters. The data available were inadequate to evaluate the potential causes or significance of these observations. In addition, the level of irradiation used in these studies was higher (600 krads) than in most other studies (about 75 krads).

One study reported an increased incidence of kidney lesions in rats fed irradiated diets, however, the information provided in the publication was inadequate to evaluate the significance or relevance of the results reported.

## General Conclusions and Opinions

Although there are deficiencies in several of the studies of the potential adverse biological effects associated with irradiated meats, the general impression is that no life-threatening adverse effects would be expected from consuming such products. In the case of other irradiated foods (e.g., wheat), several studies demonstrated undesirable or adverse biological effects in various test systems. These effects ranged from evidence of mutations and chromosomal damage in mice and rats, to increased incidence of cytogenetic effects in children (e.g., increased polyploidy). Most of these studies reporting potential adverse effects were conducted in the same region of the world by the same research group. No adequate independent studies to confirm or refute these observations were available for review.

The information for review in these studies on irradiated wheat was inadequate to fully evaluate and assess the data. Nonetheless, no serious flaws were evident in the studies and the possibility must be addressed that the effects observed were genuine. There are several possible explanations for the different results observed:

i) Differences may exist in the food materials irradiated from different regions of the world (e.g., differences in chemical contaminants, molds, etc.). Such differences would not, however, negate the effects observed on test systems exposed to irradiated foods within a given region.

ii) Different food may respond to irradiation in different ways. Although beyond the scope of this review to address this point, the possibility that free radicals formed during the irradiation process may persist for longer periods of time in certain foods would be expected. The decomposition of free radicals is facilitated in the presence of free water. Therefore, free radicals may persist longer in dry foods (e.g., wheat) than high moisture foods (e.g., chicken meat). This hypothesis is supported by the observation that the adverse effects observed from feeding irradiated wheat markedly diminished 20 weeks after the initial irradiation. No information was found to further assess this question.

iii) The biological significance of certain of the adverse effects observed remains unclear. The occurrence of chromosomal aberrations, and mutations should certainly be considered as undesired effects. On the other hand, the biological significance of an increase in the incidence of effects such as polyploidy is much less clear. Some scientists indicate that polyploid states of cells may be an advantage to survival, particularly for non-proliferating cell types. Others indicate that polyploidy is part of the aging process. Whichever is the case, it seems clear that a significant increase in polyploidy is an effect correlated with exposure to irradiated foods.

The assessment of the safety of consuming irradiated foods is not a simple task. It is doubtful if the overall quality of the information available on the assessment of the potential adverse effects of irradiated foods would be considered adequate to demonstrate the safety of general substances intended for widespread human consumption. Yet, one should not be left with the impression that the laboratories conducting the studies reviewed had low standards or inadequate capabilities. In the case of irradiated foods, the test material is a complex food, rather than a unique chemical entity *per se*. Consequently, it cannot simply be added to adequate diets in incrementally increasing amounts to study a range of exposure levels bracketing the human experience. Negative results with high exposure levels would increase general confidence in the assessment of potential adverse effects. It is conceivable that irradiated foods could make up a substantial portion of the human diet if the technology is widely applied. Therefore, the actual test conditions studied (e.g., up to 70% of the diet as irradiated chicken meat) does not represent an excessive exposure situation vis-à-vis humans. Further, there does not appear to be an obvious method of increasing experimental exposures beyond those projected for humans in order to facilitate the assessment of potential adverse effects. If additional studies were conducted to address some of the deficiencies noted in the studies reviewed, the design of such studies should address issues such as the incidence of chromosomal aberrations, the effects of irradiation on different food stuffs (e.g., meats and cereals) and the effects of irradiation on the nutritional value of foods. Simply repeating animal feeding studies using standard designs would not resolve the questions that remain unanswered.

Based on the information reviewed, the author is of the opinion that it is doubtful that life-threatening effects would be expected from consuming irradiated foods. However, there are some data indicating unusual and unexplained effects from irradiated foods in some test systems. Therefore, the decision to proceed with widespread utilization of food irradiation procedures as a method of preserving foods should be based on weighing the benefits derived from such usage against the potential risks associated with the effects observed. Unless the benefits are significant, it would be prudent to resolve the remaining questions before proceeding with widespread application of the technology.

# APPENDIX VI

## Recommended Labelling Format — Irradiated Ingredients

Sample label:

INGREDIENTS: CHICKEN, POTATOES, CARROTS, ONIONS, FLOUR, PALM OIL, MILK POWDER, SUGAR, SALT, SPICES.

IRRADIATED 

POTATOES, ONIONS, FLOUR, SPICES

minimum size 4.8 millimeters (3/16 inch)

otherwise, same size as labelling requirements prescribed by Section 14 of the Consumer Packaging and Labelling Regulations

As noted all irradiated ingredients must be listed separately under the word "IRRADIATED" accompanied by the symbol. Other specifications are outlined in Recommendations 17 and 18.

# APPENDIX VII

## Witnesses and Submissions

| Issue No. | Date | Organizations and Witnesses |
|---|---|---|
| 2 | Wednesday, November 26, 1986 | **Department of Health and Welfare:**<br>S.W. Gunner, Director General, Food Directorate. |
| 3 | Wednesday, December 3, 1986 | **Department of Consumer and Corporate Affairs:**<br>G.F. Reasbeck, Acting Director, Consumer Products Branch;<br>C.G. Sheppard, Chief, Manufactured Food Division.<br>**Science Council of Canada:**<br>Susan Mills, Research Officer. |
| 4 | Thursday, December 11, 1986 | **Atomic Energy of Canada Radiochemical Company:**<br>Paul O'Neill, President;<br>Frank Fraser, Vice-President, Industrial Irradiation Division;<br>Bruce Wilson, Director of Marketing, Industrial Irradiation Division;<br>Yves Doyle, Senior Physicist, Industrial Irradiation Division. |
| 5 | Thursday, January 22, 1987 | **Institut Armand-Frappier:**<br>Aurèle Beaulnes, Director General;<br>Marcel Gagnon, Director, "Centre de recherche en sciences appliquées à l'alimentation". |

| | | |
|---|---|---|
| 6 | Thursday, January 29, 1987 | **Canadian Advisory Committee on Food Irradiation:**<br>Yvan Jacques, Assistant Deputy Minister, International Programs, Agriculture Canada;<br>Norman Tape, Director, Food Research Centre, Agriculture Canada;<br>Madhu R. Sahasrabudhe, Assistant Director, Food Research Centre, Agriculture Canada;<br>Jim De Graaf, Coordinator, Market Development Division, Agriculture Canada.<br>**Consumers' Association of Canada:**<br>Marilyn G. Young, Chairman, National Food Committee. |
| 7 | Thursday, February 5, 1987 | **Canadian Coalition for Nuclear Responsibility:**<br>Gordon Edwards, President.<br>**Energy Probe:**<br>David Poch, Lawyer;<br>Patricia Adams, Executive Director of Probe International. |
| 8 | Thursday, February 12, 1987 | **Pollution Probe Foundation:**<br>Colin Isaacs, Executive Director;<br>Linda Pim, Consultant. |
| 9 | Thursday, February 19, 1987 | **University of Toronto:**<br>Venket Rao, Professor of Nutrition.<br>**Université Laval, Québec:**<br>François Castaigne, Professor, Department of Food Science and Technology. |
| 10 | Friday, March 6, 1987<br>Public Hearings in Vancouver, British Columbia | **Food Irradiation Alert Group:**<br>Lila Parker;<br>Carey Linde.<br>**Health Action Network Society:**<br>Bonnie Gosse;<br>Judith Cross.<br>**Mothers Against Nuke Food:**<br>Inge Hanle;<br>Thelma McAdam. |

**Canadian Coalition Against Food Irradiation:**

Russell Beach;

Michael Weiner;

Joseph Roberts.

**University of British Columbia:**

John Van der Stoep;

Brent Skura.

**Society Promoting Environmental Conservation:**

Dorothy Beach;

Thelma McAdam.

**Canadian Healing Exchange Association:**

Ronald Main.

**Canadian Health Food Association:**

Croft Woodruff.

**North West Bio-Dynamic Agriculture Society:**

F.U. Vondruska.

**Association of Naturopathic Physicians of British Columbia:**

Stefan Kuprowsky;

Philip Kempling.

11 Wednesday, March 11, 1987

**Association of Concerned Citizens for Preventive Medicine:**

Ron J. Dugas, President.

**Nuclear Awareness Project:**

Irene Kock, President.

**Grocery Products Manufacturers of Canada:**

Donald M. Jarvis, Vice-President, Government Relations and Ottawa Operations;

Shelagh Kerr, Director, Scientific Affairs;

Dick Shantz, Director of Technical Services for the Thomas J. Lipton Company.

**Canadian Natural Hygiene Society:**

Julia Hattori.

# OTHER BRIEFS SUBMITTED TO THE COMMITTEE

"Association des opposants à l'irradiation des aliments"

Consumers United to Stop Food Irradiation

Dr. Tim Lang, London Food Commission, London, United Kingdom

"Les ami-e-s de la terre du Québec"

The Concerned Citizens of Manitoba

# MINUTES OF PROCEEDINGS

Tuesday, March 31, 1987
(14)

The Standing Committee on Consumer and Corporate Affairs met *in camera* at 9:42 o'clock a.m., this day, in room 306, West Block, the Chairperson, Mary Collins, presiding.

*Members of the Committee present*: Mary Collins, Jennifer Cossitt, David Orlikow, Peter Peterson.

*Acting Member present*: Charles Caccia for Dave Dingwall.

*In attendance*: *From the Research Branch, Library of Parliament*: Robert Milko, Research Officer; Margaret Smith, Research Officer.

Charles Caccia moved,—That the Committee authorize the reimbursement of $173.96 to the researcher of the Committee, Robert Milko, for the fees he incurred with Micromedia Limited for the duplicating of the microfiches that are used for the review of toxicological studies on food irradiation.

Charles Caccia moved,—That the Committee reimburse the travelling and living expenses of the following witnesses that have already appeared before the Committee: *From the Nuclear Awareness Project*: Mrs. Irene Kock. *From the Canadian Natural Hygiene Society*: Mrs. Julia Hattori.

Peter Peterson moved,—That the Committee print 1,000 copies in addition to the 550 already published of Issue No. 10 for the meeting of March 6, 1987.

Peter Peterson moved,—That the transcripts of *in camera* meetings be kept as confidential documents by the staff of the Committee for a period of three months after the meetings, after which the transcripts will be disposed of.

In accordance with its mandate under Standing Order 96(2), the Committee commenced consideration of a draft Report on the question of food irradiation and the labelling of irradiated foods.

At 10:30 o'clock a.m., the Committee adjourned to the call of the Chair.

Thursday, April 2, 1987
(15)

The Standing Committee on Consumer and Corporate Affairs met *in camera* at 9:06 o'clock a.m., this day, in room 306, West Block, the Chairperson, Mary Collins, presiding.

*Members of the Committee present*: Mary Collins, Jennifer Cossitt, Peter Peterson.

*Acting Member present*: Rob Nicholson for Bob Horner.

*In attendance*: *From the Research Branch, Library of Parliament*: Robert Milko, Research Officer; Margaret Smith, Research Officer.

The Committee resumed consideration of a Draft Report on the subject of food irradiation and the labelling of irradiated foods.

At 10:35 o'clock a.m., the Committee adjourned to the call of the Chair.

Tuesday, April 7, 1987
(16)

The Standing Committee on Consumer and Corporate Affairs met *in camera* at 9:40 o'clock a.m., this day, in room 208, West Block, the Chairperson, Mary Collins, presiding.

*Members of the Committee present*: Mary Collins, Jennifer Cossitt, Bob Horner, Guy Ricard.

*Acting Member present*: Vic Althouse for David Orlikow, Jack Scowen for Peter Peterson.

*In attendance*: *From the Research Branch, Library of Parliament*: Robert Milko, Research Officer; Margaret Smith, Research Officer.

The Committee resumed consideration of a Draft Report on the subject of food irradiation and the labelling of irradiated foods.

At 11:00 o'clock a.m., the Committee adjourned to the call of the Chair.

Thursday, April 9, 1987
(17)

The Standing Committee on Consumer and Corporate Affairs met *in camera* at 10:09 o'clock a.m., this day, in room 307, West Block, the Chairperson, Mary Collins, presiding.

*Members of the Committee present*: Mary Collins, Bob Horner, Peter Peterson.

*Acting Member present*: Vic Althouse for David Orlikow.

*In attendance*: *From the Research Branch, Library of Parliament*: Robert Milko, Research Officer; Margaret Smith, Research Officer.

The Committee resumed consideration of a Draft Report on the subject of food irradiation and the labelling of irradiated foods.

It was agreed,—That the executive summary of the report submitted by Cantox Inc. be printed as an appendix to the Report to the House.

At 11:38 o'clock a.m., the Committee adjourned to the call of the Chair.

Tuesday, April 14, 1987
(18)

The Standing Committee on Consumer and Corporate Affairs met *in camera* at 9:40 o'clock a.m., this day, in room 208, West Block, the Chairperson, Mary Collins, presiding.

*Members of the Committee present*: Mary Collins, Jennifer Cossitt, Peter Peterson, Guy Ricard.

*Acting Member present*: Vic Althouse for David Orlikow, Mel Gass for Bob Horner.

*In attendance*: *From the Research Branch, Library of Parliament*: Robert Milko, Research Officer; Margaret Smith, Research Officer.

The Committee resumed consideration of a Draft Report on the subject of food irradiation and the labelling of irradiated foods.

The Committee agreed to pay an additional amount of $2,096.50 to Cantox Inc. for extra consulting time to evaluate toxicity studies on irradiated foods.

At 12:30 o'clock p.m., the Committee adjourned to the call of the Chair.

Tuesday, April 28, 1987
(19)

The Standing Committee on Consumer and Corporate Affairs met *in camera* at 9:42 o'clock a.m., this day, in room 208, West Block, the Chairperson, Mary Collins, presiding.

*Members of the Committee present*: Mary Collins, Jennifer Cossitt, Peter Peterson, Guy Ricard.

*Acting Member present*: Vic Althouse for David Orlikow.

*In attendance*: *From the Research Branch, Library of Parliament*: Margaret Smith, Research Officer.

The Committee resumed consideration of a Draft Report on the subject of food irradiation and the labelling of irradiated foods.

Moved by Jennifer Cossitt,—That the draft report, as amended, be adopted as the Committee's First Report to the House and that the Chairperson be authorized to make such typographical and editorial changes as may be necessary without changing the substance of the draft report and that the Chairperson be instructed to present the said report to the House.

Moved by Guy Ricard,—That the Committee print 3,000 copies of its First Report to the House in tumble bilingual format with a distinctive cover.

Moved by Vic Althouse,—That pursuant to Standing Order 99(2), the Committee request that the Government table, within 120 days, a comprehensive response to its First Report.

Moved by Jennifer Cossitt,—That, notwithstanding the motion adopted on February 12, 1987, the Committee pay an additional amount of $2,342.16 to Cantox Inc. for extra consulting time to evaluate toxicity studies on irradiated foods and that a total amount of $12,342.16 be paid by the Committee to Cantox Inc. for their final report submitted on March 31, 1987.

At 10:42 o'clock a.m., the Committee adjourned to the call of the Chair.

Richard Chevrier,
*Clerk of the Committee.*