

FOOD IRRADIATION REGULATION IN CANADA

Comments on Regulatory Proposals in
the Canada Gazette, Part I, June 4, 1988, hereby
issued jointly to:

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last page of brief.

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I INTRODUCTION

The purpose of these comments is to respond to the draft regulations and accompanying "regulatory impact analysis statements" published by Health and Welfare Canada (re: pre-clearance and regulatory compliance requirements for irradiated foods) and Consumer and Corporate Affairs Canada (re: labelling of irradiated foods) in the Canada Gazette on June 4, 1988.

Reference will also be made to Information Letter No. 746 of the Health Protection Branch of Health and Welfare Canada, published on the same date. We also take this opportunity to comment, where relevant to the proposed regulations, on the Comprehensive Government Response to the Report on Food Irradiation (May 1988) of the Parliamentary Standing Committee on Consumer and Corporate Affairs, which the government issued on September 10, 1988.

The premise from which we are working in offering these comments is three-fold:

(1) The need for food irradiation technology, whether within Canada or internationally, has not been adequately demonstrated. Food irradiation is an expensive technique which cannot compete with other, currently used methods of preserving food. It is no more an answer to the global food crisis than any other food preservation method. If anything, it is less of an answer.

(2) Even if need were adequately established, we nevertheless believe that the safety -- toxicological, microbiological and nutritional -- of irradiated foods has not been shown conclusively enough to warrant commercial sale of such products. We also believe that food irradiation facilities pose an unacceptable occupational risk to workers (as evidenced by accidents that have occurred in the United States and elsewhere), and that transportation and disposal of the radioactive substances used in many food irradiators pose unacceptable environmental and public health risks.

(3) Even if the safety of irradiated foods were adequately established, the lack of a widely applicable test to detect whether a food has been irradiated severely limits the efficacy of any scheme to label such foods. The potential for consumer deception and/or actual fraud are great; there have already been such cases in European countries, as reported to the Standing Committee in a brief from the London Food Commission.

Given the premise stated above, and until the three issues raised are resolved to the satisfaction of the public, we recommend a total moratorium on the irradiation of food in Canada; on the import into, or export from Canada of irradiated foods; and on the export of food irradiation equipment and supplies to other countries by Atomic Energy of Canada Limited and/or the Canadian International Development Agency.

We believe that the Comprehensive Government Response to the Report of the Standing Committee on Consumer and Corporate Affairs, and these draft regulations, show a profound disrespect for the due process of the Parliamentary Committee. That all-party committee unanimously supported a "go-slow" approach to food irradiation, urging more research into the technology's safety, after hearing from all sides of the food irradiation question -- consumer groups, environmental groups, university scientists, government departments and agencies, and the food irradiation/nuclear industry.

The justification for the proposals to amend the food irradiation regulations under the Food and Drugs Act is that there has been "renewed domestic and international interest in this process" (1). We suggest that the interest in the process has come not from the food industry, not from Canadian consumers or from consumers in other countries, but from agencies which would reap special benefits from an expanded market in irradiated foods, for example Atomic Energy of Canada Limited and the International Atomic Energy Agency.

The Focus Canada public opinion poll, published by the Environics Research Group Ltd. earlier this year, found that approximately 75 percent of those surveyed opposed food irradiation (2). Irradiation proponents assert that ignorance and misinformation generate such public mistrust of food irradiation. However, we have found that while consumers tend to have a fairly immediate and natural aversion to the idea of subjecting food to large doses of radiation, as they learn more, particularly that there are controversies over issues of need, safety and detection, their opposition to food irradiation tends to intensify. If a market for irradiated foods in this country does not exist, then food processors and retailers will not be making any use of whatever new regulations are passed. It appears that the rush to amend the regulations is proceeding at the expense of adequate investigations into the very issues that consumers are concerned about: need, safety and detection. There is, in fact, no need to hurry the approval of this controversial technology.

**II SAFETY OF IRRADIATED FOODS: COMMENTS ON PRE-CLEARANCE
AND REGULATORY COMPLIANCE REQUIREMENTS
(Health and Welfare Canada)**

(a) Food Irradiation: Additive or Process?: We disagree with the removal of food irradiation from the food additive tables for three reasons:

(i) This move eliminates the requirement for toxicological testing at any radiation dose; the proposed regulations will require such testing only "where the Director so requests" (B.27.005f).

~~(ii) This move eliminates the requirement for labelling of irradiated foods and food ingredients regardless of their percentage in the food (see Part III~~

below), since the processes to which a food has been subjected need not be indicated on food labels, according to the Food and Drugs Act and Regulations.

(iii) This move eliminates the requirement under the food additive regulations that there be a method to detect the food additive. One could argue that food irradiation is to be classified as a food process precisely because there is no broadly applicable detection test. As the Comprehensive Government Response stated, "While efforts in this regard will continue, the prospects of developing a test to detect irradiation of foods are considered very remote." (3)

While we agree that the proposed regulations are more "specific" than the current ones covering food irradiation, we disagree that in re-classifying irradiation as a process, the government is able to "enhance control over it" (4). Our comments on labelling (Part III below) bear out our concern in this regard.

We believe that the government has provided insufficient rationale to justify the change from additive to process. "Harmonization" with international practices is not an adequate justification, since other aspects of the proposed regulations do not necessarily harmonize with international practice -- see (b). Although some countries have enacted regulations, there are still many countries which have decided not to push ahead with food irradiation.

(b) Safety Testing Requirements: The 1983 regulatory proposals (Health Protection Branch Information Letter No. 651, July 31, 1983) would have required safety tests only if foods were to be irradiated at doses over 10 kilograys (kGy). We are pleased to see that in the new proposed regulations, safety tests will be required "where the Director so requests," which will mean that Health and Welfare Canada can "require the generation of toxicological data under conditions of any proposed dose, where such data are not presently available." (5) We understand that the 1983 draft regulations would actually have prohibited the government from requiring safety tests for any foods to be irradiated at less than 10 kGy. Now, in allowing a requirement for tests at any radiation dosage, Canada is stepping back, even if only gingerly, from the international position that no safety tests are ever needed below a dose of 10 kGy. This is the position stated by the Joint Expert Committee on Food Irradiation (JECFI) of the World Health Organization, the Food and Agriculture Organization and the International Atomic Energy Agency.

However, this discretionary power opens up two new concerns:

(i) Because there is no mention of the 10-kGy dosage level anywhere in the draft regulations, it is conceivable that the government could waive the requirement for safety tests at any dosage level, even over 10 kGy.

(ii) The Director may require safety tests "where such data are not presently available." Who will decide whether adequate data are already available? Non-government, non-industry scientists and organizations will apparently have no input to such decisions. These sources may believe that current data do not support safety, while the government may believe otherwise. We are therefore disappointed that in the Comprehensive Government Response, the Parliamentary Committee's proposal for a consultative panel on matters

relating to the safety of irradiated foods was rejected. (6) Similarly, clause B.27.005e requires petitioners to provide "data that the irradiated food has not been significantly altered in chemical, physical, or microbiological characteristics to render the food unfit for human consumption." Without a consultative panel, it would appear that only the Health Protection Branch will decide what are "significant" alterations in the food's characteristics.

(c) Detection Tests, Re-Irradiation and Record-Keeping: "The Branch [Health Protection Branch] agrees that a food already irradiated up to a maximum absorbed dose should not be re-irradiated and that a mechanism be developed to achieve this end." (7) However, there is no valid test to detect whether a food has been irradiated, let alone at what dose it has been irradiated. Therefore, the sought-after "mechanism" to prohibit re-irradiation of a food treated at its maximum absorbed dose is simply the record-keeping spelled out in clause B.27.004 of the draft regulations. We submit that such record-keeping will be impractical and open to disregard and abuse. It is certainly not a suitable substitute for a detection test. Therefore, we recommend that no re-irradiation of or food ingredients food be permitted. Furthermore, as stated in our basic premise above, food irradiation should not be permitted at all, if only because there is no broadly applicable detection test.

In the event that the regulations do permit re-irradiation of foods, there should be an amendment to clause B.27.004 to state explicitly that there may be no re-irradiation of food that, according to records, has already received its maximum permitted absorbed dose; also, that there be no re-irradiation of a food treated at less than the maximum dose except at such a dosage that the maximum permitted absorbed dose is not exceeded in a cumulative way by the re-irradiation. We note that at present, it is only in the labelling regulations, under the jurisdiction of Consumer and Corporate Affairs, that there is any reference to the prior radiation dose which would prohibit re-irradiation (B.01.035[7]). Restrictions on re-irradiation are important because of the increased opportunities for chemical, microbiological and nutritional degradation of a food that is subject to further radiation treatment.

* * *

We wish to address some additional topics in Information Letter 746 and in the Comprehensive Government Response:

(d) International Acceptance of Food Irradiation: The government continues to rely on the opinions of organizations that have endorsed food irradiation as a safe and necessary technology. These include the Joint Expert Committee on Food Irradiation of the WHO/FAO/IAEA; the United Kingdom Advisory Committee on Irradiated and Novel Foods; and the United States Council for Agricultural Science and Technology.

The government does not even acknowledge the positions taken by other organizations and governments which have expressed serious reservations about irradiated foods. These include: (i) the Canadian Medical Association (8); (ii) the British Medical Association; (iii) the International Organization of Consumer Unions, which, at its conference in Madrid in September 1987, called for a global moratorium on any further food irradiation until issues related to nutrition, safety, labelling and detection were resolved; (iv) and the

British junior Minister of Health Edwina Currie, who in February 1988, announced that she would uphold the United Kingdom ban on irradiated foods at least until a detection test is available.

(e) Peer Review of Food Irradiation Safety Tests: The government relies for safety determinations on the 1981 report of the FAO/WHO/IAEA Joint Expert Committee on Food Irradiation. What disturbs us is the source of the data upon which that committee reached its conclusions. We have tallied the references for that document by examining a companion volume entitled "Summaries of Data Considered by the Joint FAO/WHO/IAEA Expert Committee on the Wholesomeness of Irradiated Food"(9). We found that of the 221 references in that document, 142, or 64%, are listed as either unpublished reports or are printed in publications of atomic energy agencies, food irradiation projects, or government departments. Only 79, or 36%, are published in what are, or appear to be, peer-reviewed scientific journals.

In light of the ongoing international controversy and our concerns about the integrity of the JECFI data base, the government's stated intent of "enhancing control over" food irradiation is undermined, since we believe the government is relying upon an inadequate information base to demonstrate safety. For the same reason, the commitment to a case-by-case examination of new applications for irradiation is undermined by statements that Health and Welfare Canada will consider the existing data base and if it is found satisfactory, will not investigate further. It is precisely this existing data base that is controversial. In addition, the commitment not to necessarily recommend "across-the-board" clearances for foods treated at less than 10 kGy is undermined by the fact that Health and Welfare Canada may, in fact, recommend such clearances after consulting the JECFI data base.

We therefore agree with the caucus committee of the government (Labour) party in Australia, which, with concerns similar to ours, in April 1988 recommended to Australian Minister of Health Dr. Neal Blewett that he urge the World Health Organization to re-open its investigations into the safety of irradiated foods. It is expected that Dr. Blewett will accept the caucus recommendation when the Australian Parliament reconvenes at the end of August 1988 (10).

Similarly, in rebutting the 1975 findings (published in a peer-reviewed scientific journal) of polyploidy in malnourished children fed irradiated wheat at the National Institute of Nutrition in India, Information Letter No. 746 (Health Protection Branch) uses, among other references, the work of A. Brynjolfsson published in the Food Irradiation Newsletter of the International Atomic Energy Agency. The fact remains, as the Parliamentary Committee's toxicology consultants (Cantox Inc.) also found, that no formal refutation of the findings of the NIN workers has ever been published in a peer-reviewed scientific journal.

While we are pleased to know that Health and Welfare Canada places more weight on peer-reviewed studies and often communicates directly with the authors of scientific studies regardless of where they are published, we believe that it is improper to rely for any significant decisions about food irradiation regulations on material not published in peer-reviewed journals. We believe that safety studies published only under the auspices of the International Atomic Energy Agency or other atomic energy agencies should not be used as the

sole source of information in evaluating the safety of any particular irradiated food. Perhaps such studies should even be dismissed out of hand. (f) The Parliamentary Committee's Toxicology Report: The Standing Committee on Consumer and Corporate Affairs retained Cantox Inc. to perform a literature review of key food irradiation safety studies. Cantox concluded as follows:

"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."(11)

Yet the Comprehensive Government Response relegates the Cantox report to one short paragraph:

"...The special toxicological review undertaken by Cantox was carried out in a very short time-frame which would not permit an in-depth assessment of all the detailed data. Furthermore, their review was based on only a very small number of studies and did not take into account the larger number of available studies which comprise the total data base on food irradiation. The Standing Committee indicated that on the basis of the Cantox review certain effects noted in some of the studies made it difficult to demonstrate unequivocal safety." (12)

We believe that the government's response in this case is completely inadequate, since it provides no details of the perceived deficiencies of the Cantox report. The government should not proceed further with its regulations until it has shown more scientific respect for the work of Cantox Inc. by publishing a thorough rebuttal of the Cantox report prepared for the Standing Committee, so that the public may understand the basis for Health and Welfare Canada's disagreement with Cantox.

(g) A Consultative Panel: We reiterate our disappointment that the government has rejected the Standing Committee's recommendation for a consultative panel to help assess the safety of irradiated foods. Consumer mistrust of food irradiation is sufficiently high that we believe the government does not benefit from statements that it has all the expertise. While we do not doubt the scientific integrity of Health and Welfare Canada scientists, we find distasteful the arrogance of the Comprehensive Government Response to the Standing Committee when it states:

"There are within the Health Protection Branch numerous professional chemists, nutritionists, microbiologists and toxicologists who carry out evaluation and scientific research activities These scientists have consulted with scientific colleagues, including physicists within the government, Crown agencies and in the international community. Thus establishment of such a panel in this instance is not warranted." (13)

This statement appears to conflict with the statement that "the Branch [Health Protection Branch] has a responsibility to consider relevant scientific data

from any available source." (14)

As noted above with respect to future safety testing during the case-by-case consideration of foods to be approved for irradiation, members of the public should be granted substantive input to such decision-making. Under circumstances of controversy and emerging research, the non-government, non-industry community have unique and valuable perspectives to bring to the discussion.

III LABELLING IRRADIATED FOODS

(Consumer and Corporate Affairs Canada)

We preface our comments here by reiterating that labelling is only a secondary issue in our view, given our basic premise that there should be a moratorium on food irradiation at this time. We note also that labelling offers little protection to the consumer when there is no test to detect whether a food has or has not been irradiated. There is nothing to stop a food manufacturer from selling an irradiated food as unirradiated, or vice versa. However, should irradiated foods be offered for sale and labeled as such, we have the following concerns:

(a) Full Labelling: It is clear that Health and Welfare Canada lost its bid to have full labelling of foods containing irradiated ingredients. The Health Protection Branch states that it "supports the need to label all irradiated foods" and that "this Department has always supported the need for appropriate labelling of irradiated foods in order that they can be recognized in the marketplace." (15) Discussions with Health and Welfare Canada have confirmed that the Department would have preferred labelling even when an ingredient comprises less than 10% of the food, but that Consumer and Corporate Affairs Canada is the final arbiter on labelling.

(b) The Ten Percent Rule: We are pleased that the draft Canadian labelling regulations are better than those in the United States, where no irradiated ingredients are required to be listed; only entire foods that are irradiated are so labeled. However, the proposed Canadian labelling exemption for irradiated ingredients that comprise less than 10% of a food is arbitrary, and does not fulfill the consumer's right to know what has been done to food. The 10% rule violates the Consumer and Corporate Affairs mandate "to ensure the protection of the consumers' right to be informed and to enable them to exercise an effective choice between irradiated and non-irradiated foods" (15).

For example, a food could contain 45% irradiated ingredients, comprised of five ingredients each present at nine percent of the food product, and therefore escape labelling entirely. We recommend that all irradiated ingredients, at any percentage in the food product, be listed.

We disagree with the regulatory impact analysis statement that the proposal to label all ingredients has to be "rejected in view of attendant cost implications and the technical difficulties which would be imposed on industry." (17)

~~One argument put forward for not requiring labelling of minor ingredients (less than 10% of the food) is that food processors would have the added cost~~

of printing multiple sets of labels, since at some times these ingredients would be irradiated while at other times they would not. This type of "problem" is resolved in the consumer's favour in other, similar instances related to food additives. For example, a butter label typically states "may contain colour" so that the creamery need not stock two sets of labels. Therefore, the regulations should be amended such that after any ingredient that is sometimes used in irradiated form, the words "(may be irradiated)" are inserted.

In any case, product labels are changed regularly for advertising and promotional purposes. Surely the cost of label changes can be similarly absorbed to satisfy the consumer's right to know what has been done to the food.

(c) Wording on Labels: We are pleased that Canada would use the words "treated with radiation," "treated by irradiation," or "irradiated." However, our concern is that this clear and direct wording is jeopardized by the phrase "or a written statement that has the same meaning" (clause B.01.035[3]). We understand that this latter phrase was deemed necessary in order to accommodate irradiated foods imported from countries which may use different wording in their legislation. However, we think it is important to guard against the kind of obfuscation which we saw in earlier labelling proposals, when descriptions incomprehensible to the consumer, such as "radurized" and "ionized energy processed", were suggested. We therefore recommend that any foods sold in Canada must use the wording stated clearly in the draft regulation, and nothing else.

(d) No "Sunset" Clauses: We are pleased that the draft regulations do not contain a clause similar to that adopted in the United States whereby wording on the labels of irradiated foods would disappear two years after the regulations were promulgated, leaving only the international symbol on the label. Although the United States "sunset" clause has been extended another two years until 1990, we are concerned about irradiated foods coming into Canada from the United States after that date. We urge the Canadian government to recommend to the U.S. Food and Drug Administration that it drop the "sunset" clause entirely.

(e) Labelling to Prohibit Re-Irradiation: Because we believe that re-irradiation should not be permitted at all (see Part II above), we therefore recommend that B.01.035(7) be amended to read: "The label attached to a shipping container containing any food ... that has been irradiated ... shall carry ... the statement 'Do not irradiate again'."

IV OTHER CONCERNS

In this final section, we wish to address issues that have not been the subject of the regulatory impact analysis statements in the Canada Gazette (June 4, 1988).

(a) International Issues: We do not think that the Comprehensive Government Response to the Report of the Standing Committee on Consumer and Corporate Affairs is anywhere near "comprehensive." It appears to have received the input only of Health and Welfare Canada, Consumer and Corporate Affairs Canada and perhaps Agriculture Canada. But it makes absolutely no reference to the two other government agencies which have pivotal roles in the marketing of

food irradiators internationally -- namely, Atomic Energy of Canada Limited (which reports to the Minister of Energy, Mines and Resources) and the Canadian International Development Agency (which reports to the Minister of External Relations and International Development).

Nor do we think that Health and Welfare Canada has recognized that a significant impediment to the export of Canadian food irradiators is the absence of domestic regulations governing food irradiation and, of course, the actual consumption of irradiated food in Canada. As Susan Mills of the Science Council of Canada stated before the Parliamentary Standing Committee on Consumer and Corporate Affairs:

"... The problem of the guinea pig syndrome does certainly arise in the question of when, for instance, a consultant ... goes out to a country and asks Thailand how it would like to buy a Canadian irradiator, and they ask if we use it. We answer that we do not use it, and they ask how we know if Canadians will accept it. We tell them we have not passed the regulations yet, and they ask why we are giving it to them if we do not use it ourselves. So that is one part of the guinea pig syndrome. The other is that they agree to buy it, but they want to make sure we will accept back the product they irradiate."(18)

The export market for food irradiators is apparently a government priority. On CBC Radio's "The Food Show" in March 1988, it was reported that the federal Cabinet had given a directive to the Canadian International Development Agency to make food irradiation projects a priority.(19) It therefore appears to us that an important impetus behind the proposed regulations governing food irradiation domestically is to make it easier for AECL to tap an international market for food irradiators.

We are very concerned that Health and Welfare Canada does not see the relevance of international issues to the development of domestic regulations. On page 39 of Information Letter No. 746 is the following statement:

"Technical and cultural applicability of food irradiation in developing countries is not related to the development of Canadian regulations regarding food irradiation, which deal with the sale of imported or domestic irradiated food in Canada."

It is true that the draft regulations do not govern the irradiation of food and the consumption of irradiated food in developing countries. However, it appears that an important *raison d'etre* behind the draft regulations is, indeed, to win the confidence of potential Third World buyers of Canadian irradiation technology. This is not a legitimate *raison d'etre* for prematurely pushing new regulations on Canadian consumers, in the face of so many unanswered questions about food irradiation. Neither is it a legitimate way to win the confidence of Third World purchasers, who, for the most part, will have neither their own regulations governing irradiated food nor the ability to enforce them.

Indeed, it is shameful that agencies of the Crown are so eagerly selling or, as is the case with CIDA, giving away, food irradiators to countries where ~~regulations for protection of consumers, the environment and workers are so~~ weak, and where there has been no formal public debate, review or scrutiny of this technology. CIDA does not insist that the public in the recipient Third

World country be informed of or participate in the decision to irradiate food. Documents such as environmental assessments are treated as confidential by CIDA. The Canadian public, which has shown such an intense concern about food irradiation, would be outraged to learn that the rights of consumers in other countries to know about the food they consume are being so flagrantly abused by Canadian agencies.

(b) Occupational and Environmental Concerns: While there is a passing reference in the Health Protection Branch Information Letter No. 746 (pp. 35-36) to the transportation, use and disposal of nuclear materials related to food irradiation, neither the Comprehensive Government Response nor any of the documents released on June 4, 1988 adequately address this issue. While the Information Letter states that occupational exposure "would also be a concern to provincial and federal departments of labour and to the Health Protection Branch", no regulatory impact analysis statement has been prepared by these agencies.

Moreover, given the Cantox caution that the risks and benefits of food irradiation be weighed, the lack of any estimate in the government's response of occupational health costs and risks is glaring.

We note that, perhaps unintentionally, the draft regulations from Health and Welfare Canada do address the occupational and environmental concerns. Clause B.27.005(f) states that the Director may request "data establishing that the proposed irradiation is safe under the conditions proposed for the irradiation." If the Department means this clause to relate only to the safety of the food, and not also, as we would recommend, to occupational and environmental safety as well, then the regulations should be more explicit in this regard.

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14. Information Letter No. 746, p. 13.
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16. Canada Gazette, Part I, June 4, 1988, p. 2180.
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19. "The Food Show." CBC Radio, March 13, 1988.

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