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RESPONSE TO CCA STANDING COMMITTEE ON FOOD IRRADIATION IS TABLED

OTTAWA - Health and Welfare Minister Jake Epp and Consumer and Corporate Affairs Minister Harvie Andre have announced the tabling of the government response to "Food Irradiation", a report of the Standing Committee on Consumer and Corporate Affairs.

Mr. Epp said, "After studying the Standing Committee's recommendations and considering current scientific knowledge about this process, the federal government has outlined its position on food irradiation and labelling which reflects our commitment to ensuring the safe application of this technology and to providing consumers with the choice of irradiated or non-irradiated foods."

Mr. Andre, in endorsing the Standing Committee's recommendations on labelling said, "My department is continuing its work on new regulations to ensure the clear identification of irradiated foods."

Mr. Epp noted that several recommendations from the report are consistent with current and planned government actions related to food irradiation. However, he acknowledged that there are some recommendations the government does not accept in light of research done in Canada and elsewhere over the last 30 years. Such research establishes that the proper application of food irradiation is effective and does not pose a hazard to health.

"Following careful evaluation of the scientific data base," Mr. Epp said, "the government sees no reason to alter current approved uses of food irradiation or to postpone the case-by-case consideration of any future applications."

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Both Ministers indicated the government is proceeding to amend the Food and Drug Regulations pertaining to food irradiation to strengthen premarket review requirements and compliance measures. Regulations for labelling will be established to ensure that consumers can readily identify irradiated foods.

Mr. Epp thanked the Standing Committee and its chairperson, Mary Collins, for its report.

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LABELLING OF IRRADIATED FOODS

Food irradiation -- treating foods with low-level doses of ionizing energy -- is being recognized by the food industry as a potential means of making more of the world's food supply available for human consumption.

The federal government is interested in two aspects of the irradiation process: first, assessing the health risks involved, and regulating the process, which is the responsibility of Health and Welfare Canada; and second, establishing a product labelling scheme to give consumers sufficient information to identify irradiated foods in the marketplace, which is the responsibility of Consumer and Corporate Affairs Canada.

Present Labelling Regulations

Current labelling regulations, which apply to all food additives, require the source of the irradiation treatment to be identified in the list of ingredients on product labels (e.g. Cobalt 60 source). There are additional specific labelling requirements for irradiated flour and whole-wheat flour in the form of a labelling statement to reveal that they have been treated with ionizing radiation (e.g. treated with gamma radiation from a Cobalt 60 source).

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Although the regulations have permitted ionizing irradiation, this process has not gained acceptance in Canada beyond a trial use on potatoes in the 1960s, and no commercial food irradiation facilities are currently operating in Canada. Furthermore, the government is confident that no irradiated products are being imported into Canada. The application of the irradiation technology presents a challenge from a regulatory enforcement point of view. This is because, apart from a labelling declaration, there are no known methods of determining whether a product has been irradiated.

Future Labelling Considerations

Canada is a member of the Codex Alimentarius Commission, and it is in its best interest to co-ordinate to the extent possible with the international recommendations for labelling irradiated foods. The Codex General Standard for the Labelling of Pre-Packaged Foods requires irradiated foods and foods containing irradiated ingredients to be identified on the product label. However, the form and manner of the identification is not specifically prescribed.

Consumer and Corporate Affairs communiqué No. 39, issued in 1983, offered for public comment possible options for labelling irradiated foods and foods containing irradiated ingredients. Consumer representatives have stressed the need for adopting a readily identifiable method of

labelling irradiated foods to protect the consumer's right to be informed and to exercise choice in the selection of foods.

A second communiqué (No. 50) issued in 1985 identified a labelling proposal requiring the international symbol (see Appendix A) to be shown on the label of wholly treated products. Showing a symbol to identify foods subjected to special processing has been used by the Jewish community to distinguish Kosher products from others in the marketplace.

In United States, irradiated foods must be labelled as either "treated with radiation" or "treated by irradiation" in conjunction with the international symbol. In the interest of promoting freer trade with the U.S.A., labelling proposals should be co-ordinated to avoid the creation of a non-tariff trade barrier.

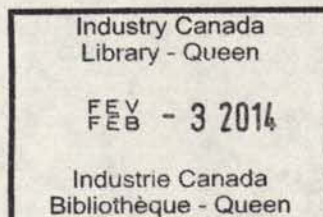
In November 1986, the House of Commons Standing Committee on Consumer and Corporate Affairs undertook to examine food irradiation and the labelling of irradiated foods. In its report of May, 1987, the Committee, headed by Mary Collins, M.P., recommended that all pre-packaged irradiated foods bear the international symbol along with the word "irradiated," and that all irradiated ingredients be labelled in a clear and readily visible manner.

Consumer and Corporate Affairs Canada is developing a labelling proposal which takes into consideration the recommendations of the Standing Committee, the requirements of

trading partners (particularly the United States), and international regulation developments in Codex Alimentarius. A proposal requiring the use of the international symbol, along with a written statement on the product label, has been discussed with representatives of the food industry and the Consumers' Association of Canada, and is scheduled for publication in Part I of the Canada Gazette in the last quarter of 1987.

(Version française
disponible)





Comprehensive Federal Government Response To
REPORT OF THE STANDING COMMITTEE ON CONSUMER AND
CORPORATE AFFAIRS ON THE QUESTION OF FOOD
IRRADIATION AND THE LABELLING OF IRRADIATED FOODS

September 1987

Comprehensive Government Response

to

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

RECOMMENDATION

- 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.

RESPONSE

The proposed regulations outlined in Information Letter No. 651 issued by the Health Protection Branch of the Department of National Health and Welfare were motivated by two key interrelated factors. Firstly, there was renewed domestic and international interest in this process in view of its utility in reducing microbial hazards and extending the shelf-life of food. Secondly, there was a consequent need to have strengthened pre-clearance and compliance requirements specifically applicable to food irradiation in place at an early date to enhance and facilitate control procedures under the Food and Drug Regulations. It was considered that the best way to achieve these ends is to recognize that food irradiation is a process in its own right and control its application to foods under regulations other than the food additive regulations. The new regulatory proposals pertaining to the application of ionizing radiation to food would (1) define and impose constraints upon isotopic, electronic or machine sources used in the process, (2) delineate detailed pre-clearance requirements specifically applicable to the irradiation of food, and (3) enhance the Health Protection Branch's ability to undertake an inspection and compliance program by setting out requirements for record keeping. It should be noted that considering food irradiation under regulations separate from the food additive regulations is not intended to, nor will it, weaken regulatory control or

circumvent labelling of the process. Furthermore, adoption of these new regulations will not result in any across-the-board clearances for irradiation of food. In fact, these regulations ensure that food irradiation will not proceed in an uncontrolled manner.

The Health Protection Branch has considered the position of the Food and Agriculture Organization/International Atomic Energy Agency/World Health Organization Joint Expert Committee on the Wholesomeness of Irradiated Foods elucidated in 1981 whereby it was concluded that ...

"... irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence toxicological testing of foods so treated is no longer required"

The 1983 Health Protection Branch Information Letter (No. 651) in commenting on this position indicated that the absence of evidence of adverse effects as a result of irradiation below this dosage level formed the basis for the proposal of requiring safety tests only when foods were irradiated above 10 kGy. Although there have been no new data to alter this stated position, it was subsequently recognized that a regulatory exclusion for toxicity testing of foods irradiated below 10 kGy does not reflect possible future developments in safety testing/assessment. Thus, while the Health Protection Branch does not intend to alter the position that food irradiation is a process and should be considered as such, and accepts in principle the lack of toxicological hazards for foods irradiated below 10 kGy, the Health Protection Branch will examine each submission on a case-by-case basis to determine if additional or new toxicity testing is required. This will be of particular significance in those instances where a food commodity which is not a member of a class of foodstuffs already subjected to extensive toxicity testing is proposed to be irradiated.

The Department of National Health and Welfare is cognizant of the oft-cited U.S. FDA remark which appeared in its recent (1986) Federal Register document and which was mentioned by the Standing Committee, namely that ...

"Only 5 of the 441 studies reviewed ... 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."

What is not often cited is the follow-up remark made in the same Federal Register article:

"Although most of the studies were generally inadequate by present day standards and could not stand alone to support safety, many contained individual components which, when examined either in isolation or collectively, allowed the conclusion that consumption of foods treated with low levels of irradiation did not appear to cause adverse toxicological effects".

It is important to recognize that these studies were conducted for a myriad of reasons via many different protocols designed for many different purposes. A substantial percentage of these studies were conducted in an era prior to the "standardization" of several types of toxicity testing protocols. Although some of these studies may well be classified as inadequate in light of present standards, the fact remains that the essential findings and interpretations are valid and useful.

In this context, 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.

The nature of toxicology as used in the regulatory process is such that it can never offer guarantees of absolute safety under all circumstances. What can be offered is assurance that under specified conditions there is no evidence to suggest hazard to humans. Under these constraints the Health Protection Branch proposes to manage food irradiation in such a manner that each new use will be subject to intense premarket approval to ensure safety.

Finally, it must be appreciated that not only Health Protection Branch toxicologists, but also scientists and toxicologists from several reputable international organizations such as the United Kingdom Advisory Committee on Irradiated and Novel Foods, the (United States) Council for Agricultural Science and Technology, and the Food and Agriculture Organization/International Atomic Energy Agency/World Health Organization Joint Expert Committee on the Wholesomeness of Irradiated Foods, have attested to the overall safety of foods irradiated at doses that would be used commercially.

With regard to the recommendation concerning the delisting of wheat, this will be dealt with in comments on Recommendations (5) and (6).

RECOMMENDATION

- 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.

RESPONSE

There is some merit in specific cases for the use of ad hoc outside expert consultative panels and the Health Protection Branch of the Department of National Health and Welfare has used such panels in the past (e.g. the Expert Committee on Fibre) where required expertise was not available in the Health Protection Branch. In regards to food irradiation, however, there are within the Health Protection Branch numerous professional chemists, nutritionists, microbiologists and toxicologists who carry out evaluation and scientific research activities. Health Protection Branch scientists in all of these disciplines have been involved in the assessment of food irradiation submissions and in regulatory development. Furthermore, 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.

RECOMMENDATION

- 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.

RESPONSE

Toxicologists within the Health Protection Branch of the Department of National Health and Welfare as well as other national and international organizations such as the U.K. Advisory Committee on Irradiated and Novel Foods, the (U.S.) Council for Agricultural Science and Technology, and the FAO/IAEA/WHO Joint Expert Committee on the Wholesomeness of Irradiated Foods have thoroughly reviewed the toxicological studies available on irradiated wheat and chicken (see responses to Recommendations (1), (5) and (10)). As a result of these reviews, additional toxicological studies for these commodities were not deemed necessary.

Insofar as applications to irradiate specific foods are concerned, the Health Protection Branch position is that funding for any tests required to support such applications is the responsibility of the applicant.

RECOMMENDATION

- 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.

RESPONSE

It is considered that adoption of this suggestion is not warranted for the reason that the Minister of National Health and Welfare has a cadre of experts within the Department whose responsibility it is to advise and administer the Food and Drugs Act and Regulations to protect the health of Canadians. Thus a second advisory body would be redundant.

RECOMMENDATION

- 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.

RESPONSE

The significance of the studies undertaken at the National Institute of Nutrition, Hyderabad, India in connection with the feeding of freshly-irradiated wheat to undernourished Indian children has been assessed by Health Protection Branch toxicologists as well as international scientific bodies. There is general agreement that these studies do not demonstrate a

hazard. This conclusion is based on the fact that:

- (a) Malnourished children are not considered to be the best test subjects available since malnutrition alone is known to induce chromosomal aberrations. Furthermore, the background incidence of chromosomal aberrations among malnourished children may vary because it may be affected by the type and degree of malnutrition. No data on the background incidence of chromosomal aberrations in malnourished Indian children were provided.
- (b) The fact that the study reported increased polyploidy (1.8%) in the lymphocytes of malnourished children fed freshly-irradiated (0.75 kGy) wheat, but not (0.0%) in children fed unirradiated wheat is unusual. Armendarres et al., (1971) reported that malnourished Mexican children (age 1-60 months) exhibited a high incidence of chromosomal aberrations (12-21%) in lymphocytes relative to the background incidence of chromosomal aberrations in lymphocytes of well-fed children (2-4%).

Health Protection Branch toxicologists have noted other work which is of relevance in addressing the polyploidy issue. In particular, Brynjolfsson (1986) has cited the results of eight experiments conducted in China in which foods irradiated from 0.1-8.0 kGy were fed to a total of 439 human volunteers for a 7 to 15 week period. These experiments were reported to reveal no increase in the incidence of polyploidy. In a study by Renner et al. (1982) no chromosomal aberrations, including polyploidy, were observed in the bone marrow of male and female Chinese hamsters fed irradiated cooked chicken (7.0 kGy, stored 5-8 days), dried dates (1.0 kGy) or cooked fish (2.5 kGy, stored 7-10 days) for a period of 6 days. Although an earlier study by Renner (1977) showed that a commercial diet, freshly-irradiated at 30-45 kGy and fed to Chinese hamsters for a period of 1 day or 6 weeks, did increase the incidence of polyploidy cells in the bone marrow 3-5 times that of controls (controls 0.06-0.08% vs treated 0.20-0.32%) the same diet irradiated at dose levels below 20 kGy caused no increase in polyploidy or other chromosomal aberrations.

Based on all of the above considerations, the Health Protection Branch has concluded that there is no evidence to indicate a health hazard from consumption of wheat irradiated up to the maximum absorbed dose permitted in Canada for this commodity (0.75 kGy). Thus, additional studies are not considered necessary.

RECOMMENDATION

- 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.

RESPONSE

As indicated in the response to recommendation 5, Health Protection Branch scientists have concluded that the evidence does not demonstrate any health risk, including polyploidy, to consumers from the ingestion of wheat irradiated up to the permitted dose level. Should the Department receive a request to extend the irradiation process to grains other than wheat, the data base available for that particular commodity would be closely examined with a view to assessing the need for further specialized studies.

RECOMMENDATION

- 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).

RESPONSE

The formation of free radicals is not unique to food irradiation. Indeed, free radicals are formed by other types of physical processing of food such as cooking and canning. Free radicals are generally very short-lived in the presence of moisture and do not persist in foods. Even so-called dry foods such as wheat contain significant amounts of water (15%) and free radicals would not be expected to persist for any appreciable time in such a medium. In fact, in a study by Diehl (1972) whereby starch (the major constituent of wheat) containing 15% moisture was irradiated at a dose of 10 kGy, no free radical activity could be detected within one day of irradiation. Thus, in relation to the existing provisions for wheat and flour the likelihood of there being any free radicals present in food as consumed is extremely remote. Nevertheless, the proposed regulations provide a mechanism whereby additional information on this aspect can be required on a case-by-case basis.

RECOMMENDATION

- 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.

RESPONSE

The total radiolytic product concentrations in various meat products irradiated at a total overall average absorbed dose of about 56 kGy* have been shown to range from 2.1 ppm (parts per million) to 4.8 ppm, with an average of 3.5 ppm. Pesticide residues in foods are extremely low in relation to other macro-constituents. If, for example, a foodstuff contained 10 ppm of a pesticide residue and irradiation of this residue led to formation of 3.5 ppm radiolytic products, then the amount of pesticide radiolytic product could be estimated to be 0.000035 ppm. Since the production of radiolytic products is linearly related to dose and since fruits and vegetables are only likely to be irradiated at doses up to about 1 kGy (55 times lower than the meat studies mentioned above), the predicted level of radiolytic products will be even lower than 0.000035 ppm. The toxicological significance of this level of degradation product would be questionable.

Nonetheless, regulations pertaining to agricultural chemicals, in addition to the Health Protection Branch regulatory proposals on food irradiation, confer authority on the Branch to require further data from petitioners on this issue on a case-by-case basis.

Finally, it should be mentioned that irradiation has been shown in some studies to detoxify substances such as PCB's and gossypol.

*Although this work was carried out at 56 kGy, practical commercial applications of food irradiation would generally be below 10 kGy.

RECOMMENDATION

- 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.

RESPONSE

It would appear that the Standing Committee's 1 kGy toxicological maximum is based on the assumption that C. botulinum spores will grow unabated in food irradiated at 10 kGy due to competitors being eliminated. Indeed, irradiation up to 10 kGy, like other conventional non-sterilizing processing techniques (e.g. pasteurization) will not destroy Clostridium botulinum spores. As is the case following application of these other techniques, proper storage and refrigeration conditions must be employed to ensure against outgrowth of C. botulinum spores. It should also be noted that C. botulinum spores would be capable of outgrowth only, first, if present, and second, under anaerobic conditions such as those encountered in vacuum-packaging or canning.

Notwithstanding the above, Rowley et al. (1983) showed that the use of a 5 kGy irradiation dose delayed by one week over unirradiated control bacon the onset of swollen and toxic pouches of temperature-abused bacon containing C. botulinum spores at a concentration of 2/gram. This low dose of irradiation while not capable of eliminating all microflora present, according to the authors, would reduce the numbers of foodborne pathogens, such as salmonellae and S. aureus 10,000 to 100,000-fold. At a dose of 15 kGy, however, irradiation completely inactivated all microflora present except C. botulinum but the botulinum spores were injured and were unable to produce toxin when incubated at 27°C for 60 days.

Contrary to the opinion of the Standing Committee, it is not a foregone conclusion that a 1 kGy level would reduce the health threat of pathogenic and toxin-producing bacteria such as C. botulinum, especially in products such as shelf-stable preserved meats. The citation by the Standing Committee of the U.S. FDA limiting doses of irradiation to a ceiling of 1 kGy for fresh foods bears no relevance to vacuum-packaged shelf-stable meat products where anaerobic conditions could be envisaged and wherein C. botulinum could be a contaminant. Canned foods would require high doses (i.e. above 50 kGy) of irradiation to provide assurance of microbiological sterilization and such is not presently envisaged by the Department of National Health and Welfare, nor is a discussion of such doses germane to the 1 kGy/10 kGy discussion. (see also response to Recommendation (1)).

The Department of Agriculture has pointed out that an upper limit of 1 kGy would effectively preclude the potential useful application of ionizing radiation for preservation of fresh, refrigerated meats and poultry.

RECOMMENDATION

- 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.

RESPONSE

The Departments of National Health and Welfare and Agriculture accept this recommendation as it relates to safe and effective measures to control Salmonella and educational initiatives to promote proper and safe handling of poultry.

In relation to this recommendation, the Department of Agriculture has indicated that the report of a study undertaken by Krystynak (1986) deals with benefit/cost ratios of various alternative measures of addressing the salmonella issue. In terms of the level of technological effectiveness (i.e. reduction of salmonella), this varies considerably from 5% for consumer education (Curtin, 1984) to 100% for irradiation. If the objective were a mere 5% reduction in salmonella, consumer education is clearly most cost effective. If on the other hand the objective is a 100% reduction (i.e. elimination) of salmonella for poultry, then food irradiation is technologically the most cost effective as it is the only procedure that can totally eliminate salmonella from the final product. It should also be noted that irradiation can play a role in reducing or eliminating other microorganisms of public health concern.

Department of National Health and Welfare toxicologists have reviewed the available data on the toxicology of irradiated chicken and have indicated that the data base provides evidence for the toxicological safety of irradiated chicken. Data would have to include data relating to microbiological efficacy, effects of radiation on packaging materials, effects of radiation on the nutritional quality of raw and ready-to-serve chicken, and details of any chemical, physical or microbiological alteration due to application of the process will continue to be required as a condition of preclearance.

RECOMMENDATION

- 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 under natural conditions where competitor organisms would be present.

RESPONSE

The Departments of Agriculture and National Health and Welfare agree that more research in this area is desirable, particularly with respect to ascertaining the minimum dose required to kill spores of aflatoxin-producing fungi. This issue is not a concern with all foods but may be important to consider in the case of nuts and cereals produced under hot and humid growing conditions encountered in other parts of the world.

While an experiment by Schindler et al (1980) showed apparently higher aflatoxin production after irradiation of aflatoxin producing spores of A. flavus and A. parasiticus, this experiment has little relevance to practical irradiation situations inasmuch as the experiment was conducted on isolated spores in a liquid medium. It is well known that the support medium can have significant effects on both the growth of the microorganisms and aflatoxin production. Of greater relevance to practical irradiation situations is the study of Temcharoen and Thilly (1982) whereby peanut meal fortified with aflatoxin and irradiated at dose levels of 0.1 to 1.0 kGy resulted in 75-100% destruction of the aflatoxin present.

It must be stressed that the proposed regulations dealing with pre-clearance of new individual applications of the irradiation process will require petitioners to supply such data on this issue as a component of food irradiation submissions in those instances where aflatoxin could be a problem.

RECOMMENDATION

- 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.

RESPONSE

The effect of irradiation on the nutritional degradation of foods already listed has been examined and numerous papers have been published in the scientific literature concerning the effects of irradiation on nutrient degradation in these foods. In addition, evaluations were undertaken by the FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods on nutrient degradation prior to recommending individual clearances. The Department of National Health and Welfare will continue to evaluate new data as they become available and reassess the implications of irradiation in these foods based on current dietary intake patterns.

The Department of National Health and Welfare agrees with the recommendation to examine information on nutritional degradation and its impact on the diet in the case of foods not presently cleared for irradiation and points out that this is a requirement in the 1983 proposed preclearance regulations regarding food irradiation.

RECOMMENDATION

- 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.

RESPONSE

There are many chronic toxicity/carcinogenicity studies in mice, rats and dogs available supporting the contention that consumption of food irradiated up to a dose of 10 kGy would not result in any health risk or hazard to the human population. As indicated in the response to Recommendation (1), the Department of National Health and Welfare accepts in principle the lack of toxicological hazards for foods irradiated below 10 kGy but may require selected additional toxicological tests in some instances.

RECOMMENDATION

- 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.

RESPONSE

The Department of Consumer and Corporate Affairs has supported and will continue to support the position that Canadian consumers be given the choice of purchasing non-irradiated or irradiated foods, and this choice will be guaranteed through the provision of a labelling scheme under the Food and Drugs Act. It should be emphasized that any labelling requirement would not be influenced by the fact that food irradiation is regarded as a process or an additive.

The Department of Consumer and Corporate Affairs recognizes that food irradiation is a novel process and that some designation should be used to enable consumers to exercise a choice in purchasing their foods. The overwhelming number of consumer requests received by Consumer and Corporate Affairs Canada for the labelling of irradiated foods attests to the importance of such an information requirement.

The Department of Consumer and Corporate Affairs is committed to ensuring that the consumers' right to product choice is respected in the marketplace and, therefore, fully endorses the principle of this recommendation.

RECOMMENDATION

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



along with the word "irradiated".

RESPONSE

In July of 1983, Consumer and Corporate Affairs Canada issued Communiqué No. 39 requesting comments from food manufacturers, trade and consumer associations on a number of possible options to be considered for the labelling of irradiated foods. A second communiqué (No. 50) issued in November 1985 summarized the responses to the options provided in Communiqué No. 39 and offered for comment a proposed labelling scheme for irradiated foods. Responses to this communiqué indicated support from both the Consumers' Association of Canada and the major industry associations for the use of the international symbol only as a

means of identifying irradiated foods. On the other hand, other consumer groups and individual consumer responses indicated clear support for a labelling scheme using descriptives such as "irradiated" on the product label.

In April 1986, the U.S.A. announced a labelling regulation applicable to irradiated foods which requires both the disclosure of the international symbol and the use of the wording "treated with (by) radiation (irradiation)". It is now evident that since the Canadian proposal, as outlined in Communiqué No. 50 differs significantly from the U.S.A. position, its adoption could be viewed as creating a potential non-tariff trade barrier.

The Department of Consumer and Corporate Affairs agrees with the recommendation that a symbol be used to identify prepackaged irradiated foods and, in this regard, will propose the use of the international symbol currently applied in other countries such as the U.S.A. and the Netherlands. The Department will also propose that, along with the symbol, prepackaged irradiated foods be further identified on the label by a written statement, the precise wording of which is yet to be determined.

RECOMMENDATION

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

RESPONSE

As a member of the Codex Alimentarius Commission, Canada has an obligation to consider the adoption of international recommendations dealing with food irradiation and the labelling of irradiated foods. The Codex Alimentarius Commission, operating under the aegis of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), prepares, through international consensus, model standards for foods. The Codex food standards are used by approximately 150 countries as reference standards when preparing national legislation in the interest of eliminating non-tariff trade barriers, protecting consumers' health and ensuring fair practices in the food trade.

The Codex Alimentarius Commission has adopted a General Standard for Irradiated Foods. In essence, the Commission recommends that irradiated foods and foods containing irradiated ingredients be identified on the product label. However, the form and manner of the identification is not specifically prescribed. This issue

will be addressed further at the next meeting of the Codex Committee on Food Labelling in approximately two years.

The Department of Consumer and Corporate Affairs will continue to fulfill its commitment to working towards establishing a uniform method of labelling irradiated foods on an international level. It recognizes that, under GATT, labelling requirements could pose a barrier to trade. Therefore, the labelling proposal under consideration for publication in Part 1 of the Canada Gazette will take into account the related developments in the U.S.A. and international regulation developments in Codex Alimentarius.

RECOMMENDATION

- 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 millimetres (3/16 inches), but otherwise in accordance with the size prescribed by the Consumer Packaging and Labelling Regulations (section 14).

RESPONSE

The Department of Consumer and Corporate Affairs supports the principle that both the symbol and associated wording be subject to a minimum size requirement and be positioned on the principal display surface of the label applied to prepackaged irradiated foods.

The proposed labelling requirements will take into consideration the related provisions of the Consumer Packaging and Labelling Act, international regulation developments in Codex Alimentarius, as well as their practicality in light of domestic industry operations.

RECOMMENDATION

- 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.

RESPONSE

Responses received to Communiqué No. 50 have clearly indicated that the proposed use of a green coloured symbol would impose unjustifiable technical difficulties and incur additional labelling costs to food manufacturers, importers and retailers.

Furthermore, those consumers who commented on the proposed symbol and colour scheme reacted negatively to the use of the colour green.

The Department of Consumer and Corporate Affairs recognizes that there are no economic or informational advantages to require the use of a green coloured symbol. Accordingly, it fully endorses this recommendation and will propose that both the symbol and associated wording be shown on the label in a manner easily legible to the consumer under normal conditions of sale or use.

RECOMMENDATION

- 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.

RESPONSE

The Department of Consumer and Corporate Affairs does not agree entirely with the recommendation pertaining to the format and colour scheme suggested for the identification of irradiated ingredients. Specifically, there is no justification to indicate, on the principal display panel of labels, that a food contains an irradiated ingredient.

The Department of Consumer and Corporate Affairs agrees that major ingredients which have been irradiated should be identified and will ensure that labelling requirements meet that commitment.

RECOMMENDATION

- 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 a 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.

RESPONSE

The Department of Consumer and Corporate Affairs supports the principle that any food which is not prepackaged and which has been subjected to treatment with ionizing radiation shall be offered for sale in a manner which clearly and prominently displays the symbol and the wording.

The proposed labelling requirements will take into consideration the related provisions of the Consumer Packaging and Labelling Act, the international regulation developments in Codex Alimentarius as well as their practicality in light of domestic industry operations.

RECOMMENDATION

- 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".

RESPONSE

The Department of National Health and Welfare agrees that a food already irradiated up to the maximum absorbed dose should not be reirradiated and that a mechanism be developed to achieve this end. However, it is possible that a petitioner may, for technological reasons, wish to apply a maximum total overall average absorbed dose on an incremental basis. The Department of National Health and Welfare will consider this situation if it occurs as part of the evaluation of individual submissions and will formulate regulatory provisions accordingly.

The Department of Consumer and Corporate Affairs endorses the recommendation that shipping containers carry a statement to the effect that the food has been subjected to treatment with ionizing radiation and that it should not be irradiated again. However, the Department believes there is no justification to incur additional costs to manufacturers by requiring the use of the international symbol to appear on the label of shipping containers, invoices and bills of lading of such foods.

RECOMMENDATION

- 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.

RESPONSE

Consumer interest in food facts is growing, and it is becoming increasingly evident that consumer acceptance of food irradiation will require the development of a comprehensive information programme. Such information should be prepared by the food industry in cooperation with the various departments that have responsibilities in this regard. Consumer and Corporate Affairs Canada, in conjunction with other involved federal departments and industry, will cooperate in the development and distribution of information material.

The Department of National Health and Welfare is supportive of educational initiatives and has incorporated information on food irradiation into its own publication 'Health Protection and Food Laws'. In addition, in responding to comments received in the first Information Letter, detailed information on various aspects of this process will be provided. Further endeavours are also under consideration.

The Department of Agriculture also agrees that greater emphasis must be placed on consumer education and will cooperate with other federal departments in providing information on the application and advantages of food irradiation as an alternate complementary process.

The Department of Energy, Mines and Resources strongly supports the recommendation of the Standing Committee as it relates to consumer education initiatives. Atomic Energy of Canada Limited will continue to provide information on food irradiation to the public within its own areas of responsibility.

RECOMMENDATION

- 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.

RESPONSE

Department of National Health and Welfare officers have discussed this matter with nuclear scientists who have advised that with regard to the use of Cobalt-60 and Cesium 137 as sources, the energy of their gamma-radiation is too low to cause X-ray production in atoms of foil-lined packaging material.

In the case of electron beam sources, considering the fact that aluminum (the most likely material to be used in manufacturing a foil-lined packaging material) has a very low atomic number and the foil is very thin, any resultant production of X-rays or concomitant induced radioactivity in the food will be insignificant.

Notwithstanding the above, the Department of National Health and Welfare agrees that actual data on this aspect should be provided with any submission involving irradiation through foil-lined packaging materials. Indeed, the regulatory proposals outlined in Information Letter No. 651 would require these data.

RECOMMENDATION

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

RESPONSE

Methodology for the detection of irradiated foods has been extensively reviewed by Jeffries (1983). The conclusion of this author is that no one method presently available is suitable for wide and routine application in order to identify irradiated foods. Chemists within the Health Protection Branch of the Department of National Health and Welfare have also investigated this situation and have reached the same conclusion.

The general lack of simple and suitable methods for routine detection of irradiated foods is the reason why the Health Protection Branch has developed record-keeping requirements as a means to promote compliance. The Department of National Health and Welfare concurs with the desirability to undertake further research to develop methods for the detection of irradiated foods.

RECOMMENDATION

- 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.

RESPONSE

The Department of Agriculture recognizes the need for a reliable test to detect whether or not a food product has been irradiated. While efforts in this regard will continue, the prospects of developing a test to detect irradiation of foods are considered very remote.

Several attempts have been made to develop methods to identify irradiated foods. The suggested methods fall into 3 categories as follows:

1. Chemical/Biochemical methods. These include quantitative determinations of malonaldehyde, D-glucosone, SH groups, hydrocarbons, o-hydroxytyrosine and lysosomal enzymes. All such so called radiolytic products are the same as those occurring naturally in foods or those formed during conventional processing such as canning, cooking, roasting and frying.
2. Physical: Free radicals formed as a result of ionizing radiation can be detected by physical methods such as electron spin resonance, chemiluminescence, thermoluminescence, and electrical conductivity. However, free radicals are short lived. Free radicals occur universally and are not specific nor unique to food irradiation.
3. Microbiological: Methods based on knowledge of microflora of a specific food, and their sensitivity to gamma irradiation could provide indirect methods for the detection of irradiation.

While it is recognized that this recommendation is directed to Agriculture Canada, it should be pointed out that since the Health Protection Branch of the Department of National Health and Welfare is responsible for undertaking inspection and ensuring compliance with the Food and Drug Regulations, any method used for regulatory enforcement purposes will have to be evaluated by Health Protection Branch analysts and be deemed to be an acceptable method of analysis.

RECOMMENDATION

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

RESPONSE

The Codex Alimentarius Commission Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods is evidence of international activity to establish uniform standards in food irradiation practices. The Manual of Food Irradiation Dosimetry (1977) published by the International Atomic Energy Agency, is referenced in the above-mentioned Code of Practice and this manual provides detailed data on the subject of dosimeters and dosimeter placement in food. The Department of National Health and Welfare supports such international initiatives.

RECOMMENDATION

- 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.

RESPONSE

As a member country of the Codex Alimentarius Commission, Canada is faced with rejection or adoption in whole or in part (i.e. adoption with specified deviations) of the Recommended International Standard for Irradiated Foods and consideration of the Recommended International Code of Practice for the Operation of Irradiation Facilities. There is an international acceptance procedure and other countries will be advised of Canada's acceptance of this Standard and Code of Practice. Any obligations on Canada's part resulting from such acceptance would be discretionary, rather than obligatory, such as that implied by existence of a treaty. Inspection of imported and domestic foods would be undertaken by Health Protection Branch inspection officers in the usual manner to ensure compliance with the Food and Drug Regulations. The requirement for record-keeping should assist in executing this mandate.

The Department of Agriculture advises that other international agencies, such as the International Consultative Group on Food Irradiation, are already active in the area of uniform international standards and their acceptance worldwide. Uniformity of international standards and systems of inspection worldwide is important particularly because of the lack of reliable methods of detection.

RECOMMENDATION

- 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.

RESPONSE

Atomic Energy of Canada Limited - Radiochemical Company (AECL-RCC) guarantees to its customers that spent Cobalt-60 will be recovered by AECL-RCC for resale, regeneration or disposal as economics and regulations dictate. The regeneration of "used" Cobalt-60 is technically feasible, but the decision to do so must be based on ongoing comparative evaluations of the economics of disposal and resale. Since waste volumes are small, volume reduction will not be a major factor in the feasibility of disposal systems.

RECOMMENDATION

- 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.

RESPONSE

Irradiation, like all physical processes including cooking, canning, and freezing, can cause some nutrient losses and chemical alteration. The extent of such changes depends on the composition of the food, absorbed dose, temperature during irradiation, and the presence or absence of air during irradiation and storage. Whether or not a nutrient loss is of importance depends on the contribution of that food to the total dietary intake of the nutrient in question, and the magnitude of the loss of that nutrient in the food under the irradiation conditions used.

Data on the effect of irradiation on the nutritive value of food is a requirement of the 1983 proposed regulations and such data will be taken into account in the assessment of any irradiation submissions.

RECOMMENDATION

- 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.

RESPONSE

While the Department of National Health and Welfare accepts in principle the lack of toxicological hazards for foods irradiated below 10 kGy, additional toxicological tests may be required in some instances, irrespective of whether food irradiation is considered an additive or a process as indicated in the response to Recommendation (1). Insofar as the 1 kGy upper limit is concerned, as outlined in the response to Recommendation (9), adoption of such a limit would not reduce the health threat of pathogenic and toxin producing bacteria.

RECOMMENDATION

- 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.

RESPONSE

The response to this recommendation is dealt with under the responses to Recommendations (1), (9), and (30). The proposed regulations do, in fact, strengthen regulatory control over this process.

RECOMMENDATION

- 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 Health Protection Branch for a further period of twenty years.

RESPONSE

The retention of records respecting the irradiation of foods is intended to provide the Health Protection Branch with a mechanism of regulatory control. Based on the fact that there is no one analytical method suitable for wide and routine application to identify irradiated foods, the Health Protection

Branch considers it necessary for purposes of regulatory control and inspection audit to have a requirement for record-keeping by the manufacturer who sells the food or, in cases involving imported foods, the importer. The section in the new Regulatory Proposals dealing with these aspects (Section B.27.005) sets out the information requirements considered necessary for the Health Protection Branch to carry out its compliance mandate in the area of food irradiation. For this purpose two years is considered adequate.

Retention of such records for twenty years as proposed by the Committee would reflect what foods were irradiated, the quantity irradiated and the dose applied, but would not reflect what was actually sold at the retail level or indeed consumed in the home by individuals. Thus, data from these records would not provide reliable information on consumption of irradiated foods by target populations of interest such as youngsters, women of child-bearing age, etc. Therefore, such a further imposition on the industry is not considered useful or warranted at this time.

RECOMMENDATION

- 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.

RESPONSE

With regard to the first of these two recommendations, the Department of National Health and Welfare does not intend to specify locations for placement of dosimeters. The view of the Department of Energy, Mines and Resources is that it is not usual, necessary or advantageous to regulate dosimeter placement, since process efficacy or safety would not necessarily be improved and not all contingencies would be covered as processors integrate irradiation with other systems and as technological advances are implemented.

As indicated in the response to Recommendation (26), the Manual of Food Irradiation Dosimetry (1977), which is referenced in the Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods, gives

great detail on the practice of dosimetry. The concepts of dose uniformity and dose uniformity ratios are well-known to the Health Protection Branch of the Department of National Health and Welfare and are similarly mentioned in the above two documents. Designs for multi-purpose irradiation plants should (and do) attempt to optimize the dose uniformity ratio. Food irradiation facilities would be subject to routine inspection.

With regard to the second recommendation, the recommended conditions of irradiation will implicitly be required as part of the data requested under B.27.004(d). The Department of National Health and Welfare also intends to require details of any other processes to be applied prior to or after the irradiation process and modify the wording of the existing B.27.004(d) to require "data which would indicate the effects, if any, on the nutritional quality of the food, raw and ready-to-serve under the proposed conditions of irradiation or combination processes."

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