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PETITION POR

SPROUT INHIBITION OF

WHITE POTATOES

WITH COBALT-60

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IRRADIATION OF WHITE POTATOES

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FOR SPROUT INHIBITION

WITH COBALT-60

The Army Petition for Clearance and Approval to the Food and Drug Administration

Quartermaster Research and Engineering Command, U. S. Army Quartermaster Research and Engineering Center Natick, Massachusetts

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IRRADIATION OF WHITE POTATOES,

FOR SPROUT INHIBITION,

WITH COBALT-60

- SECTION A "Name, and all pertinent information concerning the food additives."
- SECTION B "The amount of the food additives proposed for use, and the purpose for which it is proposed, together with directions and suggestions regarding the proposed use."
- SECTION C "All relevant data bearing on the physical or other technical effects such additive is intended to produce, and the quantity of such additive required to produce such effect."
- SECTION D "Description of practical methods to determine the amount of food additive in or on the food because of its use."
- SECTION E "Wholesomeness."

SECTION A

"Name, and all pertinent information concerning the food additive."

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SECTION A

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"Name, and all pertinent information concerning the food additives."

NAME: IONIZING RADIATION

General Effects of Radiation

Ionization is the process wherein one or more electrons are removed from an atom. The end result is two or more separate entities; an electron, or some electrons, bearing negative electrical. charges, and the remainder of the atom bearing, consequently, a positive electrical charge since it was in fact electrically neutral before ionization occurred. This phenomenon of ionization accounted for much of the biological effect of radiation on living things and its components.

Based on data set forth in the U. S. Army Quartermaster Corps Monograph on Radiation Preservation of Food⁽¹⁾ when converted to the assumed sprout inhibition dose of 7,500 rad, the energy requirements appear to be in the order of 7.5 x 10^{-2} joules per gram or 7.5 x 10^5 ergs per gram. This represents equivalent energy absorbed of about 4.68×10^{17} electron-volts per gram. At the rate of 25 ev as a requirement for breaking a C-H bond, dose of 7,500 rad (7.5 x 10^{-2} joules per gram) could result in the breakage of 1.87 x 10^{16} bonds per gram. Assuming that potatoes contain 1.3 x 10^{23} bonds per gram, this would represent only 0.0002 percent of the bonds present.

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The absolute changes brought about by the ionizing treatment are therefore minutely small. Even our most modern physical and chemical techniques are not, for the most part, sensitive enough to detect changes of such small orders of magnitude.

Type of Radiation to be Employed

The source of energy referred to in this petition is to be the gamma photons emitted from the isotope Cobalt-60. Cobalt-60 emits two gamma photons of 1.17 and 1.33 Mev and an electron of .31 Mev per atomic disintegration⁽²⁾. The electron of energy .31 Mev is of such low energy that it is absorbed in the encapsulation material of the Cobalt-60, and is, therefore, not further considered in this request for clearance.

The two gamma photons emitted per disintegration have the characteristic property of being able to energize individual atoms or molecules of a food to such an extent that an orbital electron is ejected from the molecule and a positively charged ion remains. This process is the basic mechanism of inactivation of the germination center in potatoes processed by ionizing radiation.

The use of the gamma photons from Cobalt-60 does not produce any reaction by-product or other impurities in white potatoes. This petition pertains only to the irradiation of white potatoes for sprout inhibition by gamma photons from Cobalt-60. All other regulations pertaining to processing and packing of potatoes as specified by the U.S.D.A. are also applicable.

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The use of this process in no way impairs the stability of the potatoes since the intent of the additive is only to inhibit the growth of sprouts.

Electromagnetic Radiation

Electromagnetic radiation consists of a wave motion in free or occupied space in which an electric field oscillates at right angles to a magnetic field, both of which are at right angles to the direction of propagation of the wave motion.

One property of this type of radiation is that all of it travels at the same speed in any one medium, but at different speeds in different media. Although its speed is constant, its wave length and frequency are not. These two must vary with each other for the speed to remain constant, since frequency times wave length equals speed.

References

- (1) Food Additive Petition No. 890 for the Radiation Preservation of Canned Bacon, Reference A-1.
- (2) Food Additive Petition No. 890 for the Radiation Preservation of Canned Bacon, Reference A-2.

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SECTION B

"The amount of the food additives proposed for use, and the purpose for which it is proposed, together with directions and suggestions regarding the proposed use."

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SECTION B

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"The amount of the food additives proposed for use, and the purpose for which it is proposed, together with directions and suggestions regarding the proposed use."

Background Information

The use of radiation to suppress sprouting in potatoes is one of the most promising applications of Cobalt-60 and has been studied extensively in most countries doing research on radiation preservation. Gamma irradiation is a very potent sprout inhibitor irrespective of storage temperature, thus permitting at high storage temperature $(50^{\circ}-68^{\circ}F.)$ an excellent control of weight losses due to the absence of any sprout growth.

In the Canadian study, a dose of 8,500 rad completely inhibited sprouting of Katahdin and Netted Gem (Russet Burbank) potatoes for 11 months at storage temperature of $68^{\circ}F$.⁽¹⁾ Work at Brookhaven and University of Michigan indicates that the storage life can be increased following exposure to gamma radiation for up to 18 months with little or no loss of quality⁽²⁾.

The principal problems in storing nonirradiated white potatoes for later consumption are sprouting and dehydration. To combat these conditions, controlled temperature and humidities have been used. Low temperature (40°F.) controls rot and sprouting, but results in reducing sugar accumulation. However, storage at 50°F. and above does not result in excessive reducing sugar content, although sprouting and rot increase⁽³⁾.

Under normal storage conditions, sprouting and softening will occur in about 4 months with a maximum of 8 months if temperature and humidity are controlled⁽²⁾.

Furthermore, gamma irradiation of white potatoes is more affective than maleic hydrazide, naphthalene acetic acid and isopropyl-Nphenylcarbamate chemical sprout inhibitors, which have been used for this purpose. The disadvantage of many chemical methods is that under the conditions prevailing in temperate climates they are only partly efficient during the spring season when losses due to sprouting become most severe. And of more serious consequences is the residue formed on the tubers treated with isopropyl-N-phenylcarbamate. This compound is carcinogenic to rats and mice in the presence of a co-carcinogen⁽⁴⁾.

The variations observed in reducing sugars, sucrose, starch, and ascorbic acid content of white potatoes are mainly influenced by storage time, temperature, and varietal difference and not necessarily by Cobalt-60 irradiation treatment⁽¹⁾.

On a weight basis, the potato remains the most important single vegetable in the domestic diet; annual production is about 415 million bushels valued at more than 1/2 billion dollars⁽²⁾.

About 70-75% of the U.S. potato crop is harvested in the fall and cannot be held in unrefrigerated storage later than early $spring^{(2)}$, (5).

Therefore, the demand for an improved sprout inhibition process is related to the losses incurred through sprouting and internal softening or because of the inefficiency of current storage and chemical methods. Losses due to sprouting fluctuate annually.

The effective sprout control provided by radiation results in considerable savings in both weight losses and peeling losses which occur when sprouting is not adequately controlled. Furthermore, refrigeration would not be required. The market season would be extended, and improvement of overseas shipment would result.

The Amount of Food Additives Proposed

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The process of irradiating white potatoes involves exposing the tubers to an average dose of 7,500 rad of gamma radiation emitted by a sealed source of Cobalt-60. The allowable tolerance range will be a maximum of 10,000 rad and a minimum of 5,000 rad.

The rad is defined as the unit of radiation dose equal to the absorption of 100 ergs by each gram of irradiated material. The dose of radiation required to inhibit sprouting effectively is very small in comparison with the dose required to produce sterilization of foods. The potatoes do not come in contact with the radioactive material itself, but are conveyed through the radiation field emitted by the source. The gamma rays penetrate the tubers and instantly interact with the germination cells. Sprouting is inhibited because the cells can then no longer divide.

Conditions for Use of Ionizing Radiation

The processing of potatoes for sprout inhibition would be a continuous flow assembly line as the cured potatoes are brought in from the field or warehouse. The loose (bulk) potatoes or pre-packaged potatoes shall be unloaded on a moving trough.

The feed-trough would carry the potatoes to a bucket conveyor system within the radiation chamber, around the Cobalt-60 plaques. The irradiated potatoes, after exit from the gamma cell, and unless irradiated in commercial packing materials, can be dumped into a packaging feeder trough and either packed in plastic bags, sacks, or placed in barrels. The potatoes could then be stored for a year or more without sprouting or rotting.

Description of Process

Material:

The potatoes procured for irradiation for sprout inhibition shall be of good quality, long type, which includes such varieties as Russet Burbank, White Rose, and Early Gem; round type includes such varieties as Bliss Triumph, Sebago, Pontiac, Katahdin, Chippewa, Cobbler, and Kennebec, and shall be Federal Specification HHH-P-622a, <u>Potatoes;</u> <u>White, Fresh</u>⁽⁶⁾.

Packaging:

The potatoes shall be packed in commercial sacks, boxes, crates, cartons, film bags, or other commercial containers which shall be clean, sound, and secured⁽⁶⁾.

Labeling:

Any commercial labeling or additional labeling, as specified, that complies with the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder is $acceptable^{(6)}$.

Suggested label:

White Potatoes <u>(Variety)</u> Weight <u>Pounds</u> Sprout inhibited by emanations from Cobalt-60

Processed by (Company Name)

Radiation Processing

The product shall be processed in a conveyor type bucket or other suitable container packaged as described above, and shall be exposed to a field of Cobalt-60 gamma rays in such a manner that the dose absorbed by the surface of each potato shall not exceed more than 10,000 rad. Since Cobalt-60 gamma rays to not induce radioactivity in food products, induced activity measurements are not necessary. See Section D for dosimetry methods and Section E, <u>Induced Activity</u>.

Health Physics

Health physics procedures will comply with AEC License standards in or near the radiation processing facility.

Referencea

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- (2) <u>Radiation Sterilisation of Foods</u>, Journal of Agricultural and Food Chemistry, Vol. 2, No. 25, American Chemical Society, Dec 8, 1954, p. 1260.
- U. S. Army Quartermaster Corps, <u>Radiation Preservation of</u> <u>Food</u>, U. S. Army Research and Development Series, Number 1, U. S. Government Printing Office, 1 August 1957, p. 283.
- (4) Kraybill, H. F., <u>Carcinogenesis Associated with Foods, Food</u> <u>Additives, Food Degradation Products, and Related Dietary</u> <u>Factors, Clinical Pharmacology and Therapeutics, Vol. 4,</u> No. 1, 1963, p. 80.
- (5) <u>Fruits, Vegetables, and Tree Nuts 1960</u>; Table 358, <u>Potatoes</u> <u>Production</u>; U. S. Department of Agriculture, Agricultural Statistics, 1960, U. S. Government Printing Office, Washington 25, D. C., 1961, p. 248.
- (6) <u>Potatoes, White, Fresh;</u> Federal Specification HHH-P-622a, October 26, 1959.

SECTION C

"All relevant data bearing on the physical or other technical effects such additive is intended to produce, and the quantity of such additive required to produce such effect."

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SECTION C

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"All relevant data bearing on the physical or other technical effects such additive is intended to produce, and the quantity of such additive required to produce such effect."

Background Information

The data on the nature and effects of gamma radiation set forth in Food Additive Petition No. 890, Section C, pages 1-7, are hereby incorporated by reference.

Effects of Gamma Irradiation on Sprouting

The inhibition of sprouting by gamma irradiation influences the physiology, biochemistry, organoleptic and other characteristics of the stored tubers; and the extent of change is a function of the irradiation dose and other factors such as variations in varieties, and pre- and post-irradiation handling methods. Among the observable changes produced by irradiation are:

- (a) breakage of chromosomes,
- (b) biochemical alteration,
- (c) changes in characteristics of cell division,
- (d) metabolic changes, and
- (e) cellular death.

The effects of radiation have been thought to be due either to direct action or indirect action.

A comprehensive study conducted at Purdue University involved the gamma irradiation of several tons of potatoes. The potatoes were irradiated at five levels ranging from 5,000 to 15,000 rad and were atored after irradiation at 41°, 47°, and 55°F. (R. H. 85%). Included in this study were some experiments, particularly on Sebago variety, concerning the influence of curing on sprouting in relation to gamma irradiation and other storage factors. Some of the potatoes were irradiated without curing, a second lot was cured for seven days at 70°F. and high relative humidity prior to irradiation, a third lot was similarly cured after irradiation, and a fourth lot was cured both before and after irradiation. The results of this study showed that 7,500 rad would inhibit sprouting for all practical purposes⁽¹⁾.

The Canadian study involving many tons of several varieties of potatoes stored under different conditions has also shown that sprouting can be effectively controlled with gamma irradiation. From the data, it was concluded "a dose of 8,000 rad of gamma irradiation from Cobalt-60 was completely effective in controlling sprouting in all 26 storage studies regardless of variety, storage temperature, date of irradiation, method of storage, or length of storage". This report also states that "no single condition or combination of conditions was observed which limited the effective-ness of the treatment"⁽²⁾.

Effects of Gamma Irradiation on Weight Loss of Potatoes During Storage

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Experimentation at the Brookhaven National Laboratory indicated that loss in weight of potatoes during storage could be markedly reduced by the prevention of sprouting with gamma irradiation. In these experiments, in which Katahdin potatoes, irradiated at 20,000 rep* and 5,000 rep and then stored for 18 months at $41^{\circ}-45^{\circ}$ F., were compared with nonirradiated controls, the irradiated tubers lost only 20.3% and 24.7%, respectively, of their initial weight, whereas the nonirradiated control lost $55.5\%^{(3)}$.

In another study, seven different varieties of potatoes were irradiated at 15,000 rad and stored for 7 months at 50°F. (R. H. 85%). The weight loss of the irradiated tubers ranged from 5.10% to 18.93% as compared to 15.14% to 30.9% in the nonirradiated controls⁽⁴⁾.

It has been clearly demonstrated that gamma irradiation is very effective in reducing storage weight losses through sprout inhibition. While, on the other hand, there is no striking difference in the rate of weight loss between the gamma irradiated lots and the nonirradiated control lots until sprouting occurs. Temperature at which nonirradiated potatoes are stored influences the time of sprouting. For example, at 41°F, sprouting occurred in control lots at 200, 300, and 350 days after harvest, depending, of course, on the variety of potato tested.

*One rep is equivalent to 0.93 rad.

At 55°F. the rate of weight loss was similar in both the gamma irradiated lot and the nonirradiated controls up to 25 to 50 days storage, at which time sprouting in the controls commenced⁽⁵⁾.

It is concluded that when sprouting is t controlled, potatoes quickly lose commercial value and become 100% loss⁽⁶⁾.

Effects of Gamma Irradiation on Decay

At a dose of 5,000 to 10,000 rad, the amount of decay in irradiated tubers is of little significance when compared to control lots, and because sprouting had been inhibited in the gamma irradiated lots, the amount of usable portion in the treated lots was markedly increased when compared to the usable portion in the nonirradiated lots. Without irradiation, some of the lots were completely unusable because of softening and shriveling due primarily to the growth of sprouts⁽⁷⁾. Other data show that irradiation at 7,500 rad does not materially influence decay (5, 8). Decay in the tubers stored at 41°F. was generally light, up to 430 to 550 days storage depending on variety, and differences in decay rate between the irradiated lots and nonirradiated lots were minor. At 55°F. storage decay occurred later and to a lesser extent in the lots irradiated at 7,500 and 10,000 rad than in the nonirradiated controls or the lots treated with higher doses of gamma irradiation. Decay was

also less in the lots treated with 5,000 rad, where sprouting was not excessive, than in the nonirradiated controls or the lots treated with more than 10,000 rad⁽⁹⁾.

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The extent of storage rot or decay is materially reduced in nonirradiated potatoes if freshly harvested potatoes are cured prior to storage. Because irradiation has an influence on periderm formation and suberization⁽¹⁰⁾, the practice of curing will allow the tubers a chance to heal their harvest wounds before being processed for sprout inhibition. Although irradiated, cured potatoes are generally more susceptible to soft and dry rot at high levels of radiation⁽¹¹⁾, the extent of storage rot is of little significance in cured and properly handled tubers irradiated at 7,500 rad.

Effects of Gamma Irradiation on the Organoleptic Characteristics of Potatoes

In taste panel evaluations comparing irradiated and nonirradiated potatoes stored for four months at 41°F. to 45°F., it was found that there was no significant difference between irradiated and nonirradiated potatoes. After eight months storage, the tasters expressed a preference for the irradiated tubers. And after 18 months storage, the only samples considered accemtable were the potatoes treated with 5,000 and 20,000 rad⁽¹²⁾.

Results of preference testing on two varieties of potatoes stored at 55°F. and 72°F. showed that the panelists liked the irradiated and nonirradiated potatoes equally. An analysis of the data also showed that there were no interactions among the variables studied: storage time, temperature of storage, and irradiation dose⁽¹³⁾.

Studies conducted on the utilization of stored irradiated tubers show that irradiation treatments at minimum sprout inhibition levels had no detrimental effects and irradiated potatoes were successfully processed into chips, instant mashed potato flakes, freezer French fries, and fresh pre-peeled boilers⁽¹⁴⁾.

In a study on commercial-like storage of irradiated potatoes, the tubers were processed into dehydrated potato flakes, and after reconstitution, evaluation of the irradiated product revealed that it is similar to the nonirradiated controls for flavor, reconstitution capacity and texture but inferior in $color^{(15)}$.

Under home kitchen type conditions, there were no differences observed in preparation or taste as determined by taste panels between irradiated (7,500 to 10,000 rad) and nonirradiated potatoes, when baked, boiled, fried, or prepared as in a recipe, e.g., mashed, scalloped, Au Gratin, or O'Brien potatoes⁽¹⁶⁾.

The organoleptic characteristics of cooked and processed potatoes made from storage potatoes is closely related to the

carbohydrates in the potatoes; therefore, many investigations have been conducted concerning the influence of gamma irradiation on the carbohydrates, respiration and the ability of the potatoes to "recondition" after storage so they can be used in the manufacture of potato products.

Temperature, length of storage, and varietal difference have a more pronounced effect on total sugar and reducing sugar content of three varieties of tubers tested than any irradiation treatment. The only significant effect of irradiation is an increase in reducing sugars which disappeared with storage time. Therefore, the effect of irradiation should be of no commercial importance except possibly in Katahdin variety held for over 6 months in storage(17).

Effects of Gamma Irradiation on Specific Gravity

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Specific gravity measurements of three varieties of irradiated potatoes stored under a simulated commercial environment for 13 months in which the temperature varied from 31°F. to 66°F. did not reveal any apparent differences of commercial importance between the irradiated and nonirradiated lots⁽¹⁸⁾.

Effects of Gamma Irradiation on Ascorbic Acid

The vitamin C content of both irradiated and nonirradiated potatoes decreased during 7 months of storage at 41°F. However, with continued storage at this temperature, ascorbic acid levels were restored with those of the irradiated tubers assaying higher than those of the controls. (19)

Summary

Research conducted in the United States, and elsewhere, on the influence of gamma irradiation on potato tubers has amply demonstrated that the treatment is an efficient sprout inhibitor. Gamma irradiation at doses of 7,500 rad $^+30\%$ effectively inhibits sprouting for all practical purposes irrespective of variety, storage environment, or handling techniques. For most varieties, and particularly those most commonly used in commercial storage, irradiation within the range of 5,000 to 7,500 rad is adequate particularly if storage is at 41°F. to 55°F.

Irradiation at the above described level will increase the utilization of stored tubers. The treatment will, in effect, reduce losses that occur during storage through inhibition of sprouting.

Treatment with minimum sprout inhibition levels of gamma irradiation does not materially influence the organoleptic characteristics of either cooked potatoes or processed potato products made from irradiated tubers handled under normal commercial practices.

The influence of gamma irradiation at minimum sprout inhibition doses on the amount and rate of decay that normally occurs in potatoes during storage is of no practical 'mportance. Gamma irradiation at these levels does not alter the immunity of potatoes to storage diseases, or make them more susceptible to storage rot.

Gamma irradiation of potatoes at minimum sprout inhibition levels does not materially alter the physiology of the potato or the biochemistry of the potato constituents. The accumulation of reducing sugar and sucrose that occurs shortly after treatment disappears, and after relatively short storage periods the sugars in the irradiated tubers are equal to comparable nonirradiated controls. Irradiation does not influence the ability of stored tubers to "recondition" so they can be used for processed potato products, or does not affect the changes in specific gravity of potatoes that normally occur during storage. Irradiation does not influence the change in rate of ascorbic acid disappearance in potatoes that normally occurs during storage.

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- 2. <u>Report on the Results of the Canadian Pilot Plant Scale Potato Irradiation</u> <u>Program</u>, 1961-1962 Season. Atomic Energy of Canada Limited, Ottawa, Canada, pp. 8.
- 3. Sparrow, A. H., and Christenson, E., <u>Improved Storage Quality of Potato</u> <u>Tubers after Exposure to Cobalt-60 Gammas</u>. Nucleonics, 12 (8), 16, (1954).
- 4. Heiligman, F., <u>Effects of Ionizing Radiation on the Sprouting Characteristics</u> of Various Varieties of White Potatoes. Report 1 (Final), 1 May 1956 to 30 June 1957. Internal (020-4A3) Quartermaster Food and Container Institute for the Armed Forces, Chicago, Illinois, pp. 3,4,5.
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- 13. Heiligman, F., <u>Effects of Ionizing Radiation on White Potatoes</u>. Reprint from American Potato Journal 34, (6), 156, (1957).

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- 18. <u>Ibid</u>, pp 470.
- 19. <u>Ibid</u>, pp. 469, 470.

SECTION D

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"Description of practical methods to determine the amount of food additive in or on the food because of its use."

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SECTION D.

"Description of practical methods to determine the amount of the food additive in or on the food because of its use."

Background Information

Ideally, it would be desirable to specify dose or radiation energy delivered to an irradiated food, in terms of some measurable chemical or physical characteristic (or change therein) of the food itself. Owing to the large natural variation in the chemical and physical make-up of foods⁽¹⁾, however, attempts to develop dosimetric methods along such lines have not generally been successful. As reliable methods for direct measurements are unknown in today's state of knowledge, we must resort to indirect determination of dose through measurement of effect on, or change in, uniform systems under accurately defined conditions, and extrapolation of such information to foods and their packages irradiated under similar conditions. In cluer to achieve the highest degree of accuracy, dosimeters are placed in specially prepared potatoes, which are referred to as "phantoms", and irradiated under the same conditions as the processed potatoes. The dose measurements obtained with these phantoms are applied to determination of the dose in potatoes.

Although many instruments and methods for measuring ionizing radiations have been proposed and used(2), (3), (4), no single one has proved to be adequate for all measurements of radiation. In general, the instrument used or the technique employed is determined by the type of ionizing radiation being measured, the energy of the particle, the

dose to be measured, and the accuracy desired. As scientific developments in this field are progressing rapidly, the methods proposed herein should be considered only as the best presently available; it is reasonable to assume that with the advance of scientific progress in this field, simpler and more accurate systems will be developed.

In measurement of irradiation, the outstanding accuracy and reproducibility of calorimetry makes it highly satisfactory as a p.imary standard for calibrating other methods. Radiation calorimetry involves measurement of the increase in thermal energy in a known material or chemical substance exposed to a radiation energy flux⁽⁵⁾. The thermal rise may be accurately measured and the absorbed energy calculated in terms of ergs, electron volts, or calories. The dose absorbed in the calorimeter depends on the gamma ray spectrum at the place of measurement and on the atomic number of the material used in making the calorimeter. In the gamma ray of Cobalt-60, the dose absorbed in potatoes is practically equivalent to that of water. Therefore, the calorimeter should be made of water or water equivalent material. Once a calorimetric measurement has been made with a water equivalent calorimeter in a stable radiation flux, other dosimetry systems can be calibrated against it by exposing them to the same flux field under identical conditions. Changes are then measured by accepted procedures and the degree of molecular change related to energy absorbed. In chemical

dosimetry systems, the number of molecules changed per 100 electron volts of energy absorbed is defined as the "G value"⁽⁶⁾.

The radiation field used to treat the food is usually described in terms of rad per hour, the rate at which ionizing energy is being absorbed in an irradiated material. The rad is defined as the quantity of ionizing radiation which results in the absorption of 100 ergs of energy per gram of irradiated material at the point of interest⁽⁷⁾.

Proposed System of Measuring Dose in Irradiated Potatoes

Briefly, the proposed system consists of:

1. Fabricating phantoms using potatoes as a vehicle for carrying the dosimeter.

2. Establishing a radiation exposure geometry so that all potatoes will pass through the irradiation field in a uniform manner.

3. Exposing the phantoms in order to determine the maximum dose received and making exposure geometry adjustment as necessary.

Dosimeter Phantoms

The phantoms will consist of potatoes which have been prepared by coring a hole the size of the chemical dosimeter with a cork borer or other hole-cutting device. This phantom shall not be limited to potatoes, but made be made of any other material with nearly the same average atomic number and density and hence similar energy absorption characteristics⁽⁸⁾, (9). There appears, however, little necessity in selecting any material other than potatoes, for they are easy to fabricate into phantoms, inexpensive, and therefore may be discarded

after use. These phantoms can be placed at the points of maximum dose in the irradiation package which according to the basic exponential process of gamma ray absorption are at the surface of the package. It is reasonable to assume that the point of maximum dose on the surface will vary with the geometry of the source. Therefore, if no previous dose distribution data is available, one should determine the dose along the surfaces of the irradiation container in order to establish the points of maximum absorbed dose.

Dosimetry Systems

The chemical dosimetry system which is most suitable for this dose range is the Fricke dosimeter (ferrous sulfate)⁽²⁾, (3). It has been proven highly reliable and accurate during extensive use over a period of years. Its chemical change is a result of the radiation induced oxidation of the ferrous ions to ferric ion; this change is accurate to approximately $\pm 1\%$ up to a total dose of 40,000 rad ⁽¹⁰⁾.

The speed at which a conveyor enters and leaves the source is the only variable which can affect the maximum dose rate, presuming a constant load of potatoes, therefore a calibration curve of dose vs. conveyor speed should be made.

Over a sufficiently long period of time, the decay of the source (1.06% per month) also changes the dose rate. Therefore, the only variables which can all or the dose rate over a period of time are the conveyor speed and the decay of the source.

Measurement of total dose shall be made by use of one phantom per 24-hour period of operation. A record of the total dose absorbed shall be obtained by the use of phantoms having the same geometry as the tubers being irradiated for sprout inhibition and containing dosimeters suitable for the maintenance of a permanent record of $exposure^{(11)}$.

Ferrous Dosimetry

The ferrous sulfate dosimetry solution is a 0.001M ferrous sulfate solution made in 0.8N sulfuric acid and containing 1 ml of 1.0N sodium chloride solution per liter. By using the sodium chloride in the solution, the necessity of using triply distilled water and recrystallized ferrous sulfate is eliminated. This solution is irradiated in either polystyrene or glass cells of greater than 8 mm ID as suggested by Weiss⁽¹²⁾. After irradiation, the amount of absorbed radiation is determined spectrophotometrically, at a wave length of 304 Å, by the change in optical density of the solution (due to conversion of ferrous to ferric ion). The change in optical density is directly proportional to dose absorbed, at a dose varying to 50 40,000 rad. The absorbed dose is calculated from the formula:

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Dose (rads) =
$$\frac{\Delta 0.D. \times \frac{44 \text{ M}(\text{Fe}^{+3})}{\text{ml x OD unit}} \times \frac{\text{\# molecules}}{44 \text{ M}} \times \frac{\text{\# ergs}}{\text{ev}}}{\frac{44 \text{ M}}{\text{ev}}}$$

$$\frac{100 \text{ ergs}}{\text{gm rad}}$$

 ΔOD = difference in optical density between irradiated and unirradiated sample.

$$\mu$$
 M(Fe⁺³) 25°C/ml x 0.D. unit = number of micromoles
of ferric ion per milliliter of solution.

C sol = density of the dosimeter solution, (1.023).

$$G_{Fe}$$
 = G value of the ferrous dosimeter, (15.6).

Substituting the appropriate physical constants, the molarity of the solution utilized, in this example (0.001M), and the values given above results in:

Dose (rads) =
$$\frac{(\Delta 0.D.) \times (\frac{1}{2.23}) \times (6.023 \times 10^{17}) \times (1.602 \times 10^{-12})}{(1.023) \times (\frac{15.6}{100}) \times (100)}$$

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Dose (rads) =
$$\triangle$$
 7.D. x 2.71 x 10⁴

Reference

(1)	Food Additive Petition No. 890, Radiation Preservation of Canned Bacon, Section D, pp. 1
(2)	Ibid.
(3)	Ibid.
(4)	Ibid.
(5)	Food Additive Petition, No. 890, Radiation Preservation of Canned Bacon, Section D, pp. 2
(6)	Ibid.
(7)	Ibid.
(8)	Food Additive Petition, No. 890, Radiation Preservation of Canned Bacon, Section D, pp. 3
(9)	Ibid.
(10)	Food Additive Petition No. 890, Radiation Preservation of Canned Bacon, Section D, pp. 4
(11)	Food Additive Regulation on Canned Bacon; Title 2] CFR; Part 121; Section 121.3002; February 8, 1963
(12)	Food Additive Petition, No. 890, Radiation Preservation of Canned Bacon, Section D, pp. 5



SECTION E

1

"Full reports of investigations made with respect to the safety of the food additive"

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<u>SECTION E</u>

"Full reports of investigations made with respect to the safety of the food additive"

1. <u>Background Information</u>

The safety of white potatoes irradiated by Cobalt-60 is considered under four general areas: bacteriologic safety, induced activity, carcinogenicity, wholesomeness, and other information.

The concept of wholesomeness used in this report is that wholesomeness is measured by major biologic end-points. Thus, a food is considered wholesome if long-term feeding to animals <u>does not</u>:

a. Lead to the development of previously unreported disease entities, or to increased incidence of known diseases such as carcinoma, leukemia, malnutrition, pneumonia, etc.,

- b. Cause shortening of life-span,
- c. Cause reduction in growth or in growth rate,
- d. Cause reduction in fertility of animals of either sex, and,

'e. Cause reduction or cessation of lactation in the post-partum female.

To be considered toxic or unwholesome, an irradiated food must produce a direct adverse effect on animals when fed as part or all of a diet. Effects secondary to alterations in vitamin content or other nutrient qualities of the food, such as occur with other types of food processing, are not peculiar to irradiation and are correctable.

2. Bacteriological Data

In as much as the purpose of the Cobalt-60 irradiation of white potatoes is for sprout inhibition and not pasteurization or sterilization no data on bacteriology are presented.

3. Induced Activity

3.1 Cobalt-60 Irradiated White Potatoes

It is generally agreed that energies in excess of 2.2 Mev (threshold energy to produce the radioactive nuclide from deuterium) are required to induce radioactivity of the neutron production and interaction or particle emission type (4. p. 4, 10., 11. pp. 19-20)

However, when Cobalt-60 gamma rays (1.17 and 1.33 Mev) are employed, a theoretical possibility exists for the isomer activation reaction to occur since only 0.1 to 3 Mev energies are required. The isomers $\mathrm{Sr}^{87\mathrm{m}}$, $\mathrm{In}^{115\mathrm{m}}$, $\mathrm{Co}^{11\mathrm{m}}$, $\mathrm{Hr}^{180\mathrm{m}}$, $\mathrm{Sn}^{119\mathrm{m}}$, and others are possible. The possibilities were specifically studied and it has been concluded that no definite induced isomer radioactivity was found in samples of whole food or food $\mathrm{ash}^{(5.\mathrm{p.}3)}$. 4. <u>Carcinogenicity</u>

4.1 General

Carcinogenicity studies have been conducted using rats, dogs, and mice.

Inbred strains of mice with previously demonstrated susceptibility for developing tumors were used. All tissues have been examined by the principal investigators using methods recommended by the Armed Forces Institute of Pathology. In most instances, the tissues have been reviewed directly at the AFIP.

4.2 Wisconsin Alumni Research Foundation Study

Fresh pork brain and egg, commercial sterol concentrates high in cholesterol and ergosterol, a mixture of vegetable oils, a mixture of ground meat - fish cheese - milk powder, and lard were subjected to beta or gamma irradiation and tested in rate and mice for the presence of a cancer producing substance. The irradiation levels ranged from approximately 10^5 to approximately 10^7 rad. The lard was injected, the sterols and vegetable oils were fed, "painted" and injected, the brain and erg were fed and an alcohol, ether soluble extract of the brain and egg and of the meat - fish - cheese - milk were "painted" and injected into mice using a total of nearly 3700 mice. The mice included random bred (Swiss), inbred (C3H) and hybrid (CAF1, BDF1) strains. No carcinogen could be demonstrated in the irradiated food preparations^(6.).

In the long term feeding of irradiated potatoes, which had been irradiated by 15,000 rad of Cobalt-60 irradiation, among 104 rats there were no unusual findings and there were no significant differences between control and irradiated diet rats. Approximately 35 per cent of the females developed mammary tumors, which is within the expected range for Sprague-Dawley rats on a moderately high (about 12%) fat diet. Other pathology was minor and consistent with the aging process(7.).

4.3 Histologic Review by AFIP for Wisconsin Alumni Research Foundation.

It was concluded that the ingestion of irradiated potatoes by rats under the conditions of the experiment produced little data suggesting that irradiated potatoes were of etiologic significance (18 pp. i-ii)

4.4 Histologic Review by AFIP for University of Michigan.

A review of the tissues from rats fed potatoes exposed to 13.5 - 20 and 27-40 kilorads of Cobalt-60 irradiation revealed that although no definite patterns emerged on an overall basis it appeared that in some organs (spleen, kidney, testis, and mesenteric vessels) there was an increased prevalence of some conditions that could possibly be ascribed to sex, and/or level of irradiation^(17, p.1). There was no evidence to indicate that tumor incidence or type was influenced by the feeding of irradiated potatoes^(17, p. 3).

4.5 Histologic Review by AFIP for Cornell University.

After reviewing the tissues from dogs fed irradiated potatoes there was no conclusive evidence noted of any histopathologic change that could be attributed to the foods or level of irradiation $\begin{pmatrix} 16. & p.2 \end{pmatrix}$

5. Wholesomeness

5.1 General

Included in this paragraph are data on toxicity and nutritional adequacy on animals fed gamma irradiated white potatoes using Cobalt-60 as the energy source. Included also are data on some other foods irradiated with gamma irradiation where findings are felt to be pertinent to feeding of irradiated white potatoes.

5.2 Toxicity Studies, Dogs.

White potatoes irradiated at levels of 7,500 and 15,000 rep and non-irradiated white potatoes were mixed with commercial meal to provide 35 per cent of the dry matter content of three individual diets and fed to purebred Beagles over a two year period. Data included hematology, X-ray photographs of the bones, and growth and reproduction studies. Potato when included as 35%of the dry matter did not constitute a nutritionally adequate diet for the dog. This fact was evidenced by poor reproduction and growth of all dogs on the potato diet. Normal sdult weights were never attained by these dogs. Also, the general over-all condition of those dogs was described as poor when compared with well fed animals. It must be realized that the poor records of reproduction and growth were evident in all three diets. It would appear the irradiation did not affect the nutritive value of potatoes as similar results were recorded on the control diet (9. p.4).

After reviewing the tissues from dogs fed irradiated potatoes there was no conclusive evidence noted of any histopathologic change that could be attributed to the foods or level of irradiation (16. p.2)

5.3 Toxicity Studies, Rats.

For two years a colony of albino rats was fed a diet which contained potatoes at 35% of the total diet solids. One third of the animals received unirradiated potatoes, one third received potatoes irradiated with 13.5-20 kilorads and one third received potatoes irradiated with 27-40 kilorads. Growth, food consumption, reproductive performance, hematologic changes, mortality, and pathologic changes in these rats were compared with the same in animals fed a nonirradiated potato diet. The growth, reproductive performance, and pathologic changes up to 30 weeks of second- and third-generation anima's were also compared with corresponding controls.

Three results emerged from this study. (1) There were no consistent effects due to irradiation of potatoes which could be established by these criteria. (2) There was a slightly greater mortality rate among males of the first generation fed th irradiated potato diets which was of questionable statistical significance and may be related to the poor condition of the irradiated potatoes relative to the nonirradiated controls. Second-generation males and females fed irradiated potato diets also experienced a higher mortality rate but this was attributed to genetic factors. (3) An unusually high incidence of a necrotizing arteritis resembling "peri-arteritis nodosa" occurred in the first- and second-generation animals in this experiment. The combination of a genetic and a dietary factor was implicated in causing the disease, but irradiation of the potatoes was not a factor^{(2.} p.v.)</sup>.

Subsequent studies confirmed the conclusion that irradiation of the potatoes was not the causative factor in the necrotizing arteritis in rats^(3, p.16).

In the long term feeding study in rats at Wisconsin Alumni Research Foundation, referred to in Carcinogenicity Studies, there were no unusual findings among the rats. There were no significant differences between the control rats and the irradiated diet rats(7.1).

5.4 Toxicity Studies, Mice.

In a study originally designed to test for the carcinogenicity of irradiated white potatoes, among other foods, Dr. Harry Monsen of the University of Illinois reported a peculiar heart lesion in mice. This finding generated considerable interest and partially because of variation in results on some subsequent studies a large experiment was initiated at the Army Medical Research and Nutrition Laboratory under Lt. Col. Thompson with the intention of running a study parallel with Dr. Monsen's in an attempt to determine the etiology of the lesion. The studies by Dr. Monsen and Lt. Col. Thompson have not been finally analyzed but since the lesion has been found in both control and test groups, has been reported as spontaneous in certain strains, and can be produced by feeding unirradiated evaporated milk to mice and in rats by a 40%butter ration, Dr. Monsen and others have concluded that irradiation of the food was not the cause of the lesion^(14. p.35).

5.5 Human Feeding Studies

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Human feeding studies have been performed under the supervision of the U.S. Army Medical Research and Nutrition Laboratory, Denver, Colorado. Several feeding protocols were used in which potatoes irradiated at either 10,000 rep or 3 million rep gamma rays were fed for 15 days. From March 1957 to March 1958, seven short-term studies were done on human volunteers, testing 19 food items. No clinical or laboratory abnormalities were evident in any of these short-term studies (1. p.i., 8. pp.3-5)

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6. Other Information

6.1 Studies on Enzyme Systems.

Studies on the influence of irradiated foods on enzyme systems concerned with digestion indicated that irradiation of starch at 3×10^6 or 6×10^6 megarad reduced its digestibility and irradiation of fat had a similar effect. However, after being fed for eight months it was the conclusion of the investigator that although "statistically significant" variations in digestibility due to irradiation of macronutrients could be demonstrated, it was doubtful whether the gain or loss of digested nutrients could be of biological significance (12. p.1, 13. p.9).

6.2 Vitamins.

Destruction of some of the contained vitamins of food by gamma irradiation has been reported but reports also indicate that similar destruction is found with cooking, heating and with dehydration (15., 19.)

6.3 Other.

General reference is made to the Irradiated Bacon Petition which was accepted by the Food and Drug Administration in February 1963 and to the Irradiated Potato Petition which has been accepted by the Canadian Government as an indication of the safety and acceptability of irradiated food. Many of the references of the Canadian petition are to work performed under contract with the U.S. Army Surgeon General.

7. <u>Summary</u>

Evaluations of the safety of gamma irradiated white potatoes using a Cobalt-60 source have been performed; including short and long term animal feeding, short term human feeding and laboratory analyses.

Bacteriologic datawere not considered to be pertinent since the purpose of the irradiation concerns sprout inhibition and not pasteurization or sterilization.

induced activity No induced activity in whole foods or food ash was detectable and is not considered a problem in Cobalt-60 irradiated food.

The wholesomeness of gamma irradiated potatoes was studied in terms of biologic end-points of a) new disease and incidence of known disease, b) life span, c) growth and growth-rate, d) fertility and e) lactation. In no longterm animal feeding study was there evidence of cancer induction or any effect on the other parameters of wholesomeness due directly to the feeding of gamma irradiated potatoes. When vitamins which are known to be destroyed by irradiation were replaced, the foods proved to be wholesome.

Thus, there appears to be no evident effect of gamma irradiation on potatoes that is not related to destruction of nutrients ordinarily seen in other food processing methods.

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